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 'medical events' which were reported to the NRC."

The following table lists the number of NMED event records that are designated as reportable medical events. These events are medical events per 10CFR 35.3045. 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 Reportable Medical Events

Year	Events
2005	38
2006	38
2007	42
2008	34
2009	36
2010*	34
Total	**222**

*Note that calendar year 2010 is not yet complete.

The following section contains the NMED event record for each of the 222 events. The manufacturer and model number information for IAEA Category 1-3 sources and devices was redacted.

Full Report

10/28/2010

Item Number: 100510 **Last Updated:** 10/19/2010

Narrative:

Riverside Methodist Hospital reported that a patient prescribed a dose of 10,000 cGy (rad), from a prostate seed implant procedure performed on 4/6/2010, only received a D90 dose of 6,250 cGy (rad). The 37.5% underdose was identified during post plan dosimetry performed by a radiation therapist on 5/12/2010. Those results were reviewed by a medical physicist on 5/18/2010. The patient received I-125 brachytherapy seeds (Theragenics model 125.S06) with a total activity of 710.03 GBq (19.19 mCi). The Ohio Department of Health identified the incident during a special inspection performed on 7/28 and 7/29/2010. However, the NRC was not notified until 10/14/2010.

Event Date: 04/06/2010 **Discovery Date:** 05/12/2010 **Report Date:** 10/14/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120250070	Name:	RIVERSIDE METHODIST HOSPITAL
NRC Docket Number:	NA	City:	COLUMBUS
NRC Program Code:	NA	State: OH	Zip Code: 43124
Respons ble NRC Region:	3		

Site of Event:

Site Name: COLUMBUS
State: OH

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:	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:	Y

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: 19.19 mCi 710.03 MBq Dose: 6250 rad 62.5 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 19.19 mCi 710.03 MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 37.5
Effect on Patient:

Source of Radiation:
MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: THERAGENICS CORP. Activity: 0.01919 Ci 0.71003 GBq
Model Number: 125.S06
Serial Number: NA

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46333	10/19/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100025	10/19/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100507

Last Updated: 10/25/2010

Narrative:

Liberty Hospital reported that a patient received 11% of the prescribed dose of 12,500 cGy (rad) during a prostate brachytherapy treatment on 10/6/2010. The treatment involved 79 Pd-103 seeds, each with an activity of 0.05694 GBq (1.539 mCi), for a total activity of 4.4985 GBq (121.581 mCi). The physician notified the patient and his guardian.

Event Date: 10/06/2010 **Discovery Date:** 10/07/2010 **Report Date:** 10/07/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	24-16178-01	Name:	LIBERTY HOSPITAL
NRC Docket Number:	03010532	City:	LIBERTY
NRC Program Code:	02120	State: MO	Zip Code: 64068
Respons ble NRC Region:	3		

Site of Event:

Site Name: LIBERTY
State: MO

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	N	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: Y Date Informed: 10/07/2010

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: PD-103 Activity: 121.581 mCi 4498.497 MBq Dose: 1375 rad 13.75 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: PD-103 Activity: 121.581 mCi 4498.497 MBq Dose: 12500 rad 125 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 89
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY
Radionuclide or Voltage (kVp/MeV): PD-103
Manufacturer: NR
Activity: 0.121581 Ci 4.498497 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

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46320	10/14/2010		DCH	EVENT NOTIFICATION
ML102930102	10/25/2010		RLS	LICENSEE REPORT

Item Number: 100506

Last Updated: 10/27/2010

Narrative:

Community Hospital reported that a patient received 680 cGy (rad) at one cm from the breast tumor cavity instead of the prescribed dose of 340 cGy (rad). The incident occurred during brachytherapy treatment to the patient's breast on 10/6/2010. The error was due to an incorrect entry of the catheter position from the treatment planning system, which was caused by a missed change of a program default in the software program of the radiation treatment planning system. A new check step has been added to the procedure in order to correct the issue. The physician notified the patient of the event.

Event Date: 10/06/2010 **Discovery Date:** 10/08/2010 **Report Date:** 10/08/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-06009-01	Name:	COMMUNITY HOSPITALS OF INDIANA
NRC Docket Number:	03001625	City:	INDIANAPOLIS
NRC Program Code:	02230	State: IN	Zip Code: 46219
Respons ble NRC Region:	3		

Site of Event:

Site Name: INDIANAPOLIS
State: IN

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	N	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: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 10/08/2010

Given:

Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 680 rad 6.8 Gy

Intended:

Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 340 rad 3.4 Gy

% Dose Exceeds Prescribed: 100
% 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):	NR	
Manufacturer:	NR	Activity:	NR Ci	NR GBq
Model Number:	NR			
Serial Number:	NR			

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	REMOTE AFTERLOADER HDR	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46319	10/14/2010		DCH	EVENT NOTIFICATION
EN46319A	10/27/2010		DCH	EVENT NOTIFICATION

Item Number: 100501

Last Updated: 10/12/2010

Narrative:

The Ohio Department of Health (ODH) received information on 9/10/2010 of an unreported medical event that occurred at the Clinton Memorial Hospital (CMH) on 5/20/2009. CMH implanted a patient with I-125 brachytherapy seeds (Core Oncology model 125SL, lot #092731) for treatment of the prostate. The total seed activity was 1.44 GBq (38.8 mCi). The patient was prescribed a dose of 14,400 cGy (rad) to the prostate, but only received a dose of 10,750 cGy (rad). Post implant dosimetry showed that the prostate only received 74.66% of the prescribed dose.

Event Date: 05/20/2009 **Discovery Date:** 09/10/2010 **Report Date:** 09/10/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120140000	Name:	CLINTON MEMORIAL HOSPITAL
NRC Docket Number:	NA	City:	WILMINGTON
NRC Program Code:	NA	State: OH	Zip Code: 45177
Respons ble NRC Region:	3		

Site of Event:

Site Name: WILMINGTON
State: OH

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:	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	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: 38.8 mCi 1435.6 MBq Dose: 10750 rad 107.5 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 38.8 mCi 1435.6 MBq Dose: 14400 rad 144 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 25.34
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125	
Manufacturer:	CORE ONCOLOGY	Activity:	0.0388 Ci	1.4356 GBq
Model Number:	125SL			
Serial Number:	AGGREGATE			

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46306	10/12/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100024	10/12/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100500

Last Updated: 10/12/2010

Narrative:

The Ohio Department of Health (ODH) received information on 9/10/2010 of an unreported medical event that occurred at the Clinton Memorial Hospital (CMH) on 3/21/2008. CMH implanted a patient with I-125 brachytherapy seeds (Core Oncology model 125SL, lot #080481) for treatment of the prostate. The total seed activity was 1.114 GBq (30.107 mCi). The patient was prescribed a dose of 14,500 cGy (rad) to the prostate, but only received a dose of 10,250 cGy (rad). Post implant dosimetry showed that the prostate only received 70.69% of the prescribed dose.

Event Date: 03/21/2008 **Discovery Date:** 09/10/2010 **Report Date:** 09/10/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120140000	Name:	CLINTON MEMORIAL HOSPITAL
NRC Docket Number:	NA	City:	WILMINGTON
NRC Program Code:	NA	State: OH	Zip Code: 45177
Respons ble NRC Region:	3		

Site of Event:

Site Name: WILMINGTON
State: OH

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:	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	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: 30.107 mCi 1113.959 MBq Dose: 10250 rad 102.5 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 30.107 mCi 1113.959 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 29.31
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125	
Manufacturer:	CORE ONCOLOGY	Activity:	0.030107 Ci	1.113959 GBq
Model Number:	125SL			
Serial Number:	AGGREGATE			

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46306	10/12/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100023	10/12/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100499

Last Updated: 10/12/2010

Narrative:

The Ohio Department of Health (ODH) received information on 9/10/2010 of an unreported medical event that occurred at the Clinton Memorial Hospital (CMH) on 2/6/2008. CMH implanted a patient with I-125 brachytherapy seeds (Core Oncology model 125SL, lot #080480) for treatment of the prostate. The total seed activity was 1.259 GBq (34.017 mCi). The patient was prescribed a dose of 14,400 cGy (rad) to the prostate, but only received a dose of 9,750 cGy (rad). Post implant dosimetry showed that the prostate only received 67.71% of the prescribed dose.

Event Date: 02/06/2008 **Discovery Date:** 09/10/2010 **Report Date:** 09/10/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120140000	Name:	CLINTON MEMORIAL HOSPITAL
NRC Docket Number:	NA	City:	WILMINGTON
NRC Program Code:	NA	State: OH	Zip Code: 45177
Respons ble NRC Region:	3		

Site of Event:

Site Name: WILMINGTON
State: OH

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:	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	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: 34.017 mCi 1258.629 MBq Dose: 9750 rad 97.5 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 34.017 mCi 1258.629 MBq Dose: 14400 rad 144 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 32.29
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125	
Manufacturer:	CORE ONCOLOGY	Activity:	0.034017 Ci	1.258629 GBq
Model Number:	125SL			
Serial Number:	AGGREGATE			

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46306	10/12/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100022	10/12/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100492

Last Updated: 10/07/2010

Narrative:

Baylor Radiosurgery Center reported that a patient only received 5% of the prescribed dose during a gamma knife procedure performed on 9/30/2010. The RSO stated that while conducting a single fraction exposure to the patient, the computer screen froze. The patient was immediately removed from the gamma knife unit [redacted], which contained Co-60 sources [redacted]). The patient was prescribed to receive 2,000 cGy (rad) to one location and 1,500 cGy (rad) to a second location, both to be delivered simultaneously. The referring physician and patient have been notified of the event.

Event Date: 09/30/2010 **Discovery Date:** 09/30/2010 **Report Date:** 10/01/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TX-L05842	Name:	BAYLOR RADIOSURGERY CENTER
NRC Docket Number:	NA	City:	DALLAS
NRC Program Code:	NA	State: TX	Zip Code: 75246
Respons ble NRC Region:	4		

Site of Event:

Site Name: DALLAS
State: TX

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:	Y	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:

EQP - EQUIPMENT
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: NOT REPORTED

MD2
Cause: NOT REPORTED

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	NOT REPORTED
MD2	
1	NOT REPORTED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 10/01/2010

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 100 rad 1 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 2000 rad 20 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 95
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 10/01/2010

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 75 rad 0.75 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 1500 rad 15 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 95
Effect on Patient:

Source of Radiation:
EQP
Source Number: 1
Source/Radioactive Material: SEALED SOURCE GAMMA KNIFE Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: [redacted] Activity: NR Ci NR GBq
Model Number: [redacted]
Serial Number: AGGREGATE

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE GAMMA KNIFE Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: [redacted] Activity: NR Ci NR GBq
Model Number: [redacted]
Serial Number: AGGREGATE

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

MD2
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:

EQP

Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46300	10/07/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
TX-I-8790	10/07/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100483

Last Updated: 10/01/2010

Narrative:

Cleveland Clinic Foundation (CCF) reported that a gamma knife [redacted] serial #MV010) gave a fatal error and terminated treatment to a patient on 9/27/2010. The gamma knife contained 511.49 TBq (13,824 Ci) of Co-60 sources [redacted] . The error appeared to be a failed computer disc drive. The gamma knife safety system functioned as designed, moving the patient out of the unit and closing the shielding doors. The patient was safely removed from the treatment room. The patient was prescribed to receive 1,400 cGy (rad) to the brain, but only received 71.5 cGy (rad). The patient was informed of the error on the same day. A service representative was contacted and repairs are in progress. CCF intends to give the remaining prescribed dose to the patient once the unit is repaired.

Event Date: 09/27/2010 **Discovery Date:** 09/27/2010 **Report Date:** 09/28/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02110180013	Name:	CLEVELAND CLINIC FOUNDATION
NRC Docket Number:	NA	City:	CLEVELAND
NRC Program Code:	NA	State: OH	Zip Code: 44195
Respons ble NRC Region:	3		

Site of Event:

Site Name: CLEVELAND
State: OH

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

Event Type:

EQP - EQUIPMENT
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: DEFECTIVE OR FAILED PART

MD2
Cause: DEFECTIVE OR FAILED PART

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	REPAIRS MADE WITHOUT ENGINEERING CHANGE TO SYSTEM
MD2	
1	REPAIRS MADE WITHOUT ENGINEERING CHANGE TO SYSTEM

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 09/27/2010

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 13800000 mCi 510600000 MBq Dose: 71.5 rad 0.715 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 13800000 mCi 510600000 MBq Dose: 1400 rad 14 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 95
Effect on Patient:

Source of Radiation:
EQP
Source Number: 1
Source/Radioactive Material: SEALED SOURCE GAMMA KNIFE Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: [redacted] Activity: 13824 Ci 511488 GBq
Model Number: [redacted]
Serial Number: AGGREGATE

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE GAMMA KNIFE Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: [redacted] Activity: 13824 Ci 511488 GBq
Model Number: [redacted]
Serial Number: AGGREGATE

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: MV010

MD2
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: MV010

Reporting Requirements:
EQP
Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46286	10/01/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100021	10/01/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100482

Last Updated: 10/21/2010

Narrative:

Saint John Medical Center (SJMC) reported that a patient prescribed to receive 3.7 GBq (100 mCi) of I-131 on 1/10/2008 was only administered 0.925 GBq (25 mCi). It was determined that the 3.7 GBq (100 mCi) dose provided by the nuclear pharmacy (Nuclear RX, PC) was divided among three capsules. Two capsules each contained 0.925 GBq (25 mCi), while the third contained 1.85 GBq (50 mCi). The bottle received by SJMC was opaque and stated that it contained one capsule of 11.43 GBq (309 mCi). That label was due to a software error at the pharmacy. SJMC administered one capsule to the patient, while the other two stuck to the bottom of the bottle. The presumed empty bottle was then repackaged and shipped back to the pharmacy, where it was discovered that two capsules remained in the bottle. It was determined that those two capsules contained 2.78 GBq (75 mCi). The capsules were not discovered before shipment back to the pharmacy because the SJMC technician errantly surveyed the package before placing the bottle inside. Corrective actions taken by SJMC included providing additional personnel training. Corrective actions taken by the pharmacy included contacting the software developer for an update that would ensure that shipments are accurately labeled. The pharmacy also agreed to write the number of capsules contained in each bottle on the lid of the bottle.

Event Date: 01/10/2008 **Discovery Date:** 01/16/2008 **Report Date:** 01/16/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OK-00376-02	Name:	SAINT JOHN MEDICAL CENTER
NRC Docket Number:	NA	City:	TULSA
NRC Program Code:	NA	State: OK	Zip Code: NR
Respons ble NRC Region:	4		

Site of Event:

Site Name: TULSA
State: OK

Additional Involved Party:

License Number:	OK-31035-01MD	Name:	NUCLEAR RX
NRC Docket Number:	NA	City:	TULSA
NRC Program Code:	NA	State: OK	Zip Code: 74104
Respons ble NRC Region:	4		

Other Information:

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

Event Type:

LAS - LOST/ABANDONED/STOLEN
MD2 - MEDICAL EVENT

Event Cause:

LAS
Cause: HUMAN ERROR

MD2
Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
LAS	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING
2	PROCEDURE MODIFIED
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 25 mCi 925 MBq Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 100 mCi 3700 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 75
Effect on Patient:

Source of Radiation:
LAS
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NUCLEAR RX, PC Activity: 0.075 Ci 2.775 GBq
Model Number: NA
Serial Number: NA

MD2
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NUCLEAR RX, PC Activity: 0.025 Ci 0.925 GBq
Model Number: NA
Serial Number: NA

Device/Associated Equipment:
LAS
Device Number: 1
Device Name: CONTAINER, SHIPPING Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:
LAS
Reporting Requirement: 20.2201(a)(1)(i) - Lost, stolen, or missing licensed material in a quantity greater than or equal to 1,000 times the Appendix C quantities.

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.

Keywords:
LAS
MATERIAL LOST AND FOUND

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46277	09/30/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR101011	10/14/2010		DCH	NRC LETTER
LTR101015	10/21/2010		DCH	AGREEMENT STATE LETTER

Item Number: 100480

Last Updated: 09/29/2010

Narrative:

The Ohio Department of Health (ODH) received information on 5/4/2010 of an unreported medical event that occurred at the Tiffin Mercy Hospital (TMH) on 12/10/2008. TMH implanted a patient with 54 I-125 brachytherapy seeds (North American Scientific model MED3631) for treatment of the prostate. The total seed activity was 835.39 MBq (22.58 mCi). The patient was prescribed a dose of 14,500 cGy (rad) to the prostate, but only received a dose of 10,476 cGy (rad). During the procedure, six seeds became stuck in one needle and were inadvertently placed inferior to the prostate. The post implant dosimetry calculation performed on 2/12/2009 revealed a D90 dose of 72.25 percent. The patient was notified of the incident on 2/12/2009. Corrective actions included training of the RSO, medical physicist, clinical director, and radiation oncologists. New procedures were also developed for brachytherapy seed implant procedures. This incident was discovered during a self audit of all brachytherapy cases performed since March 2007. ODH required the audit after the discovery of an unreported medical event at an affiliated facility (Mercy Saint Vincent Medical Center, see NMED Item 100113).

Event Date: 12/10/2008 **Discovery Date:** 05/04/2010 **Report Date:** 05/04/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120750001	Name:	TIFFIN MERCY HOSPITAL
NRC Docket Number:	NA	City:	TIFFIN
NRC Program Code:	NA	State: OH	Zip Code: 44883
Respons ble NRC Region:	3		

Site of Event:

Site Name: TIFFIN
State: OH

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	INCREASED MONITORING BY OUTSIDE AGENCIES TO ENSURE COMPLIANCE

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 02/12/2009

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 22.578 mCi 835.386 MBq Dose: 10476 rad 104.76 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 22.578 mCi 835.386 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 27.8

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: NORTH AMERICAN SCIEN Activity: 0.022578 Ci 0.835386 GBq

Model Number: MED3631

Serial Number: AGGREGATE

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: APPLICATOR Model Number: NA

Manufacturer: NR Serial Number: NA

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46273	09/29/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR100916	09/29/2010		DCH	AGREEMENT STATE LETTER
OH100003A	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100003B	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100019	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100479

Last Updated: 09/29/2010

Narrative:

The Ohio Department of Health (ODH) received information on 4/27/2010 of an unreported medical event that occurred at Mercy Saint Vincent Medical Center (MSVMC) on 9/23/2005. MSVMC implanted a patient with I-125 brachytherapy seeds for treatment of the prostate. The patient was prescribed a dose of 10,800 cGy (rad) to the prostate, but only received a dose of 7,940 cGy (rad). The patient had received external beam radiation therapy (4,500 cGy or rad) and seed implant was used as a boost to the prostate following IMRT. Post implant dosimetry indicated a clinically satisfactory dose distribution. No further therapy was planned. The patient was not notified of the incident. Corrective actions included training of the RSO, medical physicist, clinical director, and radiation oncologists. New procedures were also developed for brachytherapy seed implant procedures. This incident was discovered during a self audit of all brachytherapy cases performed since 11/1/2004, which ODH required MSVMC to perform (see NMED Item 100113). An adjudication order was issued to MSVMC on 6/25/2010. That order increased the inspection frequency of MSVMC activities, removed the authorization for MSVMC to perform brachytherapy procedures, and required MSVMC to submit a quarterly report to ODH on all brachytherapy procedures performed if authorization is restored.

Event Date: 09/23/2005 **Discovery Date:** 04/27/2010 **Report Date:** 04/27/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120490000	Name:	MERCY SAINT VINCENT MEDICAL CENTER
NRC Docket Number:	NA	City:	TOLEDO
NRC Program Code:	NA	State: OH	Zip Code: 43608
Respons ble NRC Region:	3		

Site of Event:

Site Name: TOLEDO
State: OH

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:	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:	Y

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	INCREASED MONITORING BY OUTSIDE AGENCIES TO ENSURE COMPLIANCE

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 7940 rad 79.4 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10800 rad 108 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 26.5
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: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: APPLICATOR Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46272	09/29/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100003A	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100003B	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100018	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100478

Last Updated: 09/29/2010

Narrative:

The Ohio Department of Health (ODH) received information on 4/27/2010 of an unreported medical event that occurred at Mercy Saint Vincent Medical Center (MSVMC) on 4/17/2007. MSVMC implanted a patient with I-125 brachytherapy seeds for treatment of the prostate. The patient was prescribed a dose of 10,800 cGy (rad) to the prostate, but only received a dose of 5,860 cGy (rad). Seed implant was used as a boost to the prostate following IMRT. Post implant dosimetry showed a suboptimal dose distribution at the base of the gland. However, satisfactory dose was observed about the mid gland, where biopsy proven adenocarcinoma was present. No further therapy was planned. The patient was notified of the incident. Corrective actions included training of the RSO, medical physicist, clinical director, and radiation oncologists. New procedures were also developed for brachytherapy seed implant procedures. This incident was discovered during a self audit of all brachytherapy cases performed since 11/1/2004, which ODH required MSVMC to perform (see NMED Item 100113). An adjudication order was issued to MSVMC on 6/25/2010. That order increased the inspection frequency of MSVMC activities, removed the authorization for MSVMC to perform brachytherapy procedures, and required MSVMC to submit a quarterly report to ODH on all brachytherapy procedures performed if authorization is restored.

Event Date: 04/17/2007 **Discovery Date:** 04/27/2010 **Report Date:** 04/27/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120490000	Name:	MERCY SAINT VINCENT MEDICAL CENTER
NRC Docket Number:	NA	City:	TOLEDO
NRC Program Code:	NA	State: OH	Zip Code: 43608
Respons ble NRC Region:	3		

Site of Event:

Site Name: TOLEDO
State: OH

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:	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:	Y

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	INCREASED MONITORING BY OUTSIDE AGENCIES TO ENSURE COMPLIANCE

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 5860 rad 58.6 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10800 rad 108 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 45.7
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: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: APPLICATOR Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46272	09/29/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100003A	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100003B	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100017	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100477

Last Updated: 09/29/2010

Narrative:

The Ohio Department of Health (ODH) received information on 4/27/2010 of an unreported medical event that occurred at Mercy Saint Vincent Medical Center (MSVMC) on 7/14/2005. MSVMC implanted a patient with I-125 brachytherapy seeds for treatment of the prostate. The patient was prescribed a dose of 16,000 cGy (rad) to the prostate, but only received a dose of 5,740 cGy (rad). The patient and referring urologist were notified of the incident on 4/27/2010. A post implant dose calculation revealed a suboptimal dose distribution to the base of the prostate gland. The prostate volume, on which the dosimetry was calculated, was 40 percent greater than the intra-operative prostate volume. Therefore, dosimetry was inaccurate due to gland edema. The patient and referring urologist opted for close monitoring of the prostate and PSA levels without additional therapy. Corrective actions included training of the RSO, medical physicist, clinical director, and radiation oncologists. New procedures were also developed for brachytherapy seed implant procedures. This incident was discovered during a self audit of all brachytherapy cases performed since 11/1/2004, which ODH required MSVMC to perform (see NMED Item 100113). An adjudication order was issued to MSVMC on 6/25/2010. That order increased the inspection frequency of MSVMC activities, removed the authorization for MSVMC to perform brachytherapy procedures, and required MSVMC to submit a quarterly report to ODH on all brachytherapy procedures performed if authorization is restored.

Event Date: 07/14/2005 **Discovery Date:** 04/27/2010 **Report Date:** 04/27/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120490000	Name:	MERCY SAINT VINCENT MEDICAL CENTER
NRC Docket Number:	NA	City:	TOLEDO
NRC Program Code:	NA	State: OH	Zip Code: 43608
Respons ble NRC Region:	3		

Site of Event:

Site Name: TOLEDO
State: OH

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:	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:	Y

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	INCREASED MONITORING BY OUTSIDE AGENCIES TO ENSURE COMPLIANCE

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 04/27/2010

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 5740 rad 57.4 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 64.1

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: NR Ci NR GBq

Model Number: NR

Serial Number: AGGREGATE

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: APPLICATOR Model Number: NA

Manufacturer: NR Serial Number: NA

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46272	09/29/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100003A	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100003B	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100016	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100476

Last Updated: 09/29/2010

Narrative:

The Ohio Department of Health (ODH) received information on 4/27/2010 of an unreported medical event that occurred at Mercy Saint Vincent Medical Center (MSVMC) on 1/11/2005. MSVMC implanted a patient with I-125 brachytherapy seeds for treatment of the prostate. The patient was prescribed a dose of 16,000 cGy (rad) to the prostate, but only received a dose of 10,170 cGy (rad). The patient was notified of the incident on 4/27/2010. A post implant dose calculation revealed a suboptimal dose distr bution to the base of the prostate gland. No further therapy was planned. Corrective actions included training of the RSO, medical physicist, clinical director, and radiation oncologists. New procedures were also developed for brachytherapy seed implant procedures. This incident was discovered during a self audit of all brachytherapy cases performed since 11/1/2004, which ODH required MSVMC to perform (see NMED Item 100113). An adjudication order was issued to MSVMC on 6/25/2010. That order increased the inspection frequency of MSVMC activities, removed the authorization for MSVMC to perform brachytherapy procedures, and required MSVMC to submit a quarterly report to ODH on all brachytherapy procedures performed if authorization is restored.

Event Date: 11/11/2005 **Discovery Date:** 04/27/2010 **Report Date:** 04/27/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120490000	Name:	MERCY SAINT VINCENT MEDICAL CENTER
NRC Docket Number:	NA	City:	TOLEDO
NRC Program Code:	NA	State: OH	Zip Code: 43608
Respons ble NRC Region:	3		

Site of Event:

Site Name: TOLEDO
State: OH

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:	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:	Y

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	INCREASED MONITORING BY OUTSIDE AGENCIES TO ENSURE COMPLIANCE

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 04/27/2010

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10170 rad 101.7 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 36.4
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: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: APPLICATOR Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46272	09/29/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100003A	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100003B	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100015	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100475

Last Updated: 09/29/2010

Narrative:

The Ohio Department of Health (ODH) received information on 4/27/2010 of an unreported medical event that occurred at Mercy Saint Vincent Medical Center (MSVMC) on 7/3/2007. MSVMC implanted a patient with I-125 brachytherapy seeds for treatment of the prostate. The patient was prescribed a dose of 16,000 cGy (rad) to the prostate, but only received a dose of 10,182 cGy (rad). The patient was not notified of the incident. MSVMC determined that the dose was clinically adequate and that no further therapy was needed. There was limited dose distribution at the gland base. Corrective actions included training of the RSO, medical physicist, clinical director, and radiation oncologists. New procedures were also developed for brachytherapy seed implant procedures. This incident was discovered during a self audit of all brachytherapy cases performed since 11/1/2004, which ODH required MSVMC to perform (see NMED Item 100113). An adjudication order was issued to MSVMC on 6/25/2010. That order increased the inspection frequency of MSVMC activities, removed the authorization for MSVMC to perform brachytherapy procedures, and required MSVMC to submit a quarterly report to ODH on all brachytherapy procedures performed if authorization is restored.

Event Date: 07/03/2007 **Discovery Date:** 04/27/2010 **Report Date:** 04/27/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120490000	Name:	MERCY SAINT VINCENT MEDICAL CENTER
NRC Docket Number:	NA	City:	TOLEDO
NRC Program Code:	NA	State: OH	Zip Code: 43608
Respons ble NRC Region:	3		

Site of Event:

Site Name: TOLEDO
State: OH

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:	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:	Y

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	INCREASED MONITORING BY OUTSIDE AGENCIES TO ENSURE COMPLIANCE

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10182 rad 101.82 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 36.4
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: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: APPLICATOR Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46272	09/29/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100003A	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100003B	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100014	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100461

Last Updated: 10/05/2010

Narrative:

Marshfield Clinic reported that a patient received a dose of 8,000 cGy (rad) during a permanent implant of I-125 brachytherapy seeds to the prostate on 9/9/2010, instead of the prescribed dose of 14,500 cGy (rad). Marshfield Clinic calculated that the patient received 55% of the intended D80 dose. The underdose was identified during post-implant planning for the procedure. Marshfield stated that the medical event occurred because the maximum insertion depth was 0.6 cm below the base of the prostate gland and all needles were implanted distal to the base, resulting in the area being "cold." The patient and referring urologist have been notified of the incident. Possible corrective actions are under review by the Clinic's staff and a one month post-implant CT is planned to determine the impact on the patient. The Wisconsin Department of Health Services investigated the incident on 9/16/2010.

Event Date: 09/09/2010 **Discovery Date:** 09/09/2010 **Report Date:** 09/14/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-141-1162-01	Name:	MARSHFIELD CLINIC
NRC Docket Number:	NA	City:	MARSHFIELD
NRC Program Code:	NA	State: WI	Zip Code: 54449
Respons ble NRC Region:	3		

Site of Event:

Site Name: MARSHFIELD
State: WI

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:	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	NOT REPORTED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 09/15/2010

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 8000 rad 80 Gy

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

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 44.83
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: NR Ci NR 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

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46249	09/20/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI100016	10/05/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100457

Last Updated: 10/05/2010

Narrative:

The Department of Veteran Affairs (VA) reported that 11 medical events occurred at G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi. The medical events involved I-125 permanent prostate seed implant brachytherapy and occurred between 2/16/2005 and 8/4/2008. The medical events were identified during follow-up of 10 previously discovered events (see NMED Item 080606). Following up on those 10 medical event reports, the Veterans Health Administration initiated a comprehensive external review and reanalysis of post-treatment dose parameters for all prostate seed implants performed at the medical center. Upon evaluation of update dose information generated by external review, medical center staff, working with the National Health Physics Program, discovered the 11 additional events on 9/8/2010. Ten of the 11 events were based on updated D90 final values for the planned treatment site being 80% or less than the prescribed dose. One of the 11 events was based on absorbed dose to tissue other than the treatment site exceeding the expected dose by 50% or more. VA notified the referring physicians and patients. This event was caused by suboptimal seed placement due to inadequate procedures. No significant deterministic effect to the patients is expected. The brachytherapy program at the medical center was suspended in September 2008 and terminated in August 2009.

Event Date: 09/08/2010 **Discovery Date:** 09/08/2010 **Report Date:** 09/09/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: JACKSON
State: MS

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 23.87 mCi 883.19 MBq Dose: 10590 rad 105.9 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 32.49 mCi 1202.13 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 27
Effect on Patient:

Patient Number: 10
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 36.288 mCi 1342.656 MBq Dose: 9720 rad 97.2 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 34.776 mCi 1286.712 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 33
Effect on Patient:

Patient Number: 11
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 39.27 mCi 1452.99 MBq Dose: 23320 rad 233.2 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 35.494 mCi 1313.278 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: 61
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 2
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 24.78 mCi 916.86 MBq Dose: 10010 rad 100.1 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 28.025 mCi 1036.925 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 31
Effect on Patient:

Patient Number: 3
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 30.432 mCi 1125.984 MBq Dose: 9570 rad 95.7 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 28.53 mCi 1055.61 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 34
Effect on Patient:

Patient Number: 4
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 21.186 mCi 783.882 MBq Dose: 8990 rad 89.9 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 21.507 mCi 795.759 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 38
Effect on Patient:

Patient Number: 5
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 33.584 mCi 1242.608 MBq Dose: 11170 rad 111.7 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 32.103 mCi 1187.811 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 23
Effect on Patient:

Patient Number: 6
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 23.52 mCi 870.24 MBq Dose: 9140 rad 91.4 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 24.86 mCi 919.82 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 37
Effect on Patient:

Patient Number: 7
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 23.689 mCi 876.493 MBq Dose: 6530 rad 65.3 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 25.456 mCi 941.872 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 55
Effect on Patient:

Patient Number: 8
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 27.565 mCi 1019.905 MBq Dose: 9570 rad 95.7 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 27.216 mCi 1006.992 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 34
Effect on Patient:

Patient Number: 9
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 32.113 mCi 1188.181 MBq Dose: 9280 rad 92.8 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 35.12 mCi 1299.44 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 36
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: 0.02387 Ci 0.88319 GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 10
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: NR Activity: 0.036288 Ci 1.342656 GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 11
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: NR Activity: 0.03927 Ci 1.45299 GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 2
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: NR Activity: 0.02478 Ci 0.91686 GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 3

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125		
Manufacturer:	NR	Activity:	0.030432 Ci	1.125984	GBq
Model Number:	NR				
Serial Number:	AGGREGATE				

Source Number: 4

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125		
Manufacturer:	NR	Activity:	0.021186 Ci	0.783882	GBq
Model Number:	NR				
Serial Number:	AGGREGATE				

Source Number: 5

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125		
Manufacturer:	NR	Activity:	0.033584 Ci	1.242608	GBq
Model Number:	NR				
Serial Number:	AGGREGATE				

Source Number: 6

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125		
Manufacturer:	NR	Activity:	0.02352 Ci	0.87024	GBq
Model Number:	NR				
Serial Number:	AGGREGATE				

Source Number: 7

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125		
Manufacturer:	NR	Activity:	0.023689 Ci	0.876493	GBq
Model Number:	NR				
Serial Number:	AGGREGATE				

Source Number: 8

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125		
Manufacturer:	NR	Activity:	0.027565 Ci	1.019905	GBq
Model Number:	NR				
Serial Number:	AGGREGATE				

Source Number: 9

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125		
Manufacturer:	NR	Activity:	0.032133 Ci	1.188921	GBq
Model Number:	NR				
Serial Number:	AGGREGATE				

Reporting Requirements:

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 prescr bed 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:
EN46236	09/15/2010		DCH	EVENT NOTIFICATION
ML102660637	10/05/2010		RLS	LICENSEE REPORT

Item Number: 100448

Last Updated: 09/15/2010

Narrative:

Providence Hospital reported that a patient was implanted with I-125 brachytherapy seeds in the anus for a palliative procedure on 8/30/2010. Two days later (9/1/2010), a follow-up CT scan revealed that the implants had been inserted 4 cm superior to the intended location, which would lead to less dose at the target location. The intended dose was 9,000 cGy (rad) to the anus. The patient was schedule to be implanted again after completion of the imaging study. The reason for the error is believed to be twofold; the tumor had progressed markedly since the original planning and the decision was made to correct the plan for the additional growth based on palpation indications, and the 10-cm mark on the needle may have been mistaken for the 5-cm mark. Both the patient and physician were informed. Doses to normal tissue from the implants at the end of the treatment plan were 375 cGy (rad) to the bladder instead of the prescribed dose of 7 cGy (rad), 2,517 cGy (rad) to the seminal vesicles instead of the prescribed 538 cGy (rad), 420 cGy (rad) to the prostate instead of the prescribed 624 cGy (rad), and 316 cGy (rad) to the rectum instead of the prescr bed 4,518 cGy (rad).

Event Date: 08/30/2010 **Discovery Date:** 09/01/2010 **Report Date:** 09/02/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-02802-03	Name:	PROVIDENCE HOSPITAL
NRC Docket Number:	03002022	City:	SOUTHFIELD
NRC Program Code:	02120	State: MI	Zip Code: 48037
Respons ble NRC Region:	3		

Site of Event:

Site Name: NOVI
State: MI

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:	Y	Abnormal Occurrence:	P
Agreement State Reportable Event:	N	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: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NOT REPORTED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

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

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: ANUS
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 9000 rad 90 Gy

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

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: SEMINAL VESICLE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 2517 rad 25.17 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: SEMINAL VESICLE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 538 rad 5.38 Gy

% Dose Exceeds Prescribed: 368
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1B
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: BLADDER
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 375 rad 3.75 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: BLADDER
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 70 rad 0.7 Gy

% Dose Exceeds Prescribed: 436
% 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):	I-125	
Manufacturer:	NR	Activity:	NR Ci	NR GBq
Model Number:	NR			
Serial Number:	AGGREGATE			

Reporting Requirements:

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 prescr bed 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:
EN46224	09/08/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN46224A	09/15/2010		DCH	EVENT NOTIFICATION

Item Number: 100427

Last Updated: 10/21/2010

Narrative:

Rush-Presbyterian-Saint Lukes Medical Center reported that a patient prescribed to receive 0.57 GBq (15.4 mCi) of colloidal Y-90 SIR-Spheres (Sirtex Medical) on 8/18/2010, only received an estimated 0.41 GBq (11.1 mCi). The entire volume of material appeared to have been delivered without complication, including a complete repeated flushing of the delivery line. However, measurements of the associated tubing, vial, and other contaminated items showed that a notable quantity of Y-90 remained. The Medical Center notified the attending physician and the patient on 8/18/2010. The patient will undergo PET and CT scans in six and 12 weeks to determine if any additional actions are warranted. Preliminary indications are that no changes in procedures or processes are necessary and that general delivery system design, coupled with characteristics of material to be administered, resulted in the unintended coagulation and accumulation of microspheres either within the three way stopcock or the microcatheter, despite routine agitation of the suspension delivery vial.

Event Date: 08/18/2010 **Discovery Date:** 08/18/2010 **Report Date:** 08/18/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	IL-01766-01	Name:	RUSH-PRESBYTERIAN-SAINT LUKES
NRC Docket Number:	NA	City:	CHICAGO
NRC Program Code:	NA	State: IL	Zip Code: 60612
Respons ble NRC Region:	3		

Site of Event:

Site Name: CHICAGO
State: IL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DESIGN, MANUFACTURING, OR INSTALLATION ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NO CORRECTIVE ACTION TAKEN

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 08/18/2010

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: LIVER

Radiopharmaceutical: NA

Radionuclide: Y-90 Activity: 11.1 mCi 410.7 MBq Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: LIVER

Radiopharmaceutical: NA

Radionuclide: Y-90 Activity: 15.4 mCi 569.8 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 27.9

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90

Manufacturer: SIRTEX MEDICAL Activity: 0.0154 Ci 0.5698 GBq

Model Number: SIR-SPHERES

Serial Number: NA

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: APPLICATOR Model Number: NR

Manufacturer: MDS NORDION, INC. Serial Number: NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46189	08/25/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IL10055	10/19/2010		DCH	AGREEMENT STATE EVENT REPORT
LTR101019	10/21/2010		DCH	AGREEMENT STATE LETTER

Item Number: 100397

Last Updated: 08/25/2010

Narrative:

Greater Baltimore Medical Center (GBMC) reported that a patient received radiation exposure to an unintended area during a cervical cancer brachytherapy treatment on 7/9/2010. The patient was prescribed 3,500 cGy (rad) to the uterus. The treatment was being performed using two 1.64 GBq (44.2 mCi) Cs-137 sources. The physician failed to correctly place the sources in the afterloader and one source fell onto the patient's buttocks. The second source was missing from the patient and later recovered from the trash before it left the facility, when it set off their radiation monitor alarms. GBMC estimated that the maximum dose received by the unintended site (buttocks) was 1,050 cGy (rad). No reddening of the skin has been noticed. GBMC stated that 89% of the medical directive was administered to the intended site and no medical impact to the patient is anticipated. The patient's physician and the patient were notified of the event. The State investigation is ongoing. The INL has requested additional information for this event.

Event Date: 07/09/2010 **Discovery Date:** 07/09/2010 **Report Date:** 07/12/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	MD-05-002-03	Name:	GREATER BALTIMORE MEDICAL CENTER
NRC Docket Number:	NA	City:	BALTIMORE
NRC Program Code:	NA	State: MD	Zip Code: 21204
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:	Y	Abnormal Occurrence:	P
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Y	NMED Record Complete:	R
Consultant Hired:	N	Event Closed by Region/State:	N

Event Type:

LAS - LOST/ABANDONED/STOLEN
MD2 - MEDICAL EVENT

Event Cause:

LAS
Cause: HUMAN ERROR

MD2
Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
LAS	
1	NOT REPORTED
MD2	
1	NOT REPORTED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 07/09/2010

Given:
Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: BUTTOCKS
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 44.2 mCi 1635.4 MBq Dose: 1050 rad 10.5 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Source of Radiation:
LAS
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: NR Activity: 0.0442 Ci 1.6354 GBq
Model Number: NR
Serial Number: NR

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: NR Activity: 0.0442 Ci 1.6354 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: MANUAL AFTERLOADER Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
LAS
Reporting Requirement: 20.2201(a)(1)(i) - Lost, stolen, or missing licensed material in a quantity greater than or equal to 1,000 times the Appendix C quantities.

MD2
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).

Keywords:
LAS
MATERIAL LOST AND FOUND

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46143	08/11/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MD100009	08/25/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100388

Last Updated: 07/29/2010

Narrative:

Rhode Island Hospital (dba Miriam Hospital) reported that a patient prescribed to receive 7.4 MBq (200 uCi) of I-123 for a diagnostic uptake scan, was administered 148 MBq (4 mCi) of I-131 for a whole body scan on 4/21/2010. The administration resulted in a dose of approximately 3,108 cGy (rad) to the patient's intact thyroid tissue, rather than an estimated 7 cGy (rad) from the I-123 administration. The patient's physician gave her a written prescription slip for the I-123 scan. However, the physician's office faxed an order to the hospital for an I-131 scan. The patient allegedly presented the correct written prescription slip to admitting. The receptionist allegedly refused the written prescription, because she thought the hospital already had the correct procedure in their records. On 4/23/2010, the whole body scan was performed. At that time, the nuclear medicine technologist noticed there was something wrong when the scan indicated the thyroid was intact. The referring physician and patient were notified. The cause of the incident was a result of human error and failure to follow procedures. Training and written procedures were in place, but the nuclear medicine technologist failed to follow the written procedures. Corrective actions included modifying procedures and re-educating the nuclear medicine technologists. Additionally, a pathology report is now required for all thyroid cancer patients before an I-131 dose is administered. Thyroid interview and patient assessment and history sheets were developed for use. The nuclear medicine technologists received training on 6/8/2010. The physicians were also re-educated on 6/9/2010.

Event Date: 04/21/2010 **Discovery Date:** 04/23/2010 **Report Date:** 04/23/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	RI-7D-051-01	Name:	RHODE ISLAND HOSPITAL
NRC Docket Number:	NA	City:	PROVIDENCE
NRC Program Code:	NA	State: RI	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: PROVIDENCE
State: RI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 04/23/2010

Given:

Diagnostic Study: WHOLE BODY I-131/THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 4 mCi 148 MBq

Intended:

Diagnostic Study: THYROID UPTAKE MEASUREMENT

Radiopharmaceutical: SODIUM IODIDE

% Dose Exceeds Prescribed: NA

% 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): I-131

Manufacturer: NR Activity: 0.004 Ci 0.148 GBq

Model Number: NA

Serial Number: NA

Reporting Requirements:

MD2

Reporting Requirement: 35.3045(a)(2)(i) - Administration of a wrong radioactive drug containing byproduct material that results in a dose that exceeds 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:
RI100001	07/29/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100386

Last Updated: 08/20/2010

Narrative:

The University of New Mexico Hospital (UNMH) reported that a patient prescribed to receive 7.4 GBq (200 mCi) of I-131 for therapy for post thyroidectomy ablation only received 2.96 GBq (80 mCi) on 7/21/2010. Cardinal Health contacted UNMH on 7/22/2010 and informed them that a capsule had been returned. The returned capsule was the second of two capsules in the same shipping vial, meant to be administered to the patient. However, only one capsule was indicated on various paperwork. Cardinal Health estimated that the returned capsule contained 4.44 GBq (120 mCi) and that the capsule administered to the patient contained 2.96 GBq (80 mCi). Corrective actions included modifying Standard Operating Procedures at UNMH and Cardinal Health, providing additional training on shipping protocols, and improving radioactive material labeling and handling.

Event Date: 07/21/2010 **Discovery Date:** 07/21/2010 **Report Date:** 07/23/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NM-BM-233-79	Name:	UNIVERSITY OF NEW MEXICO HOSPITAL
NRC Docket Number:	NA	City:	ALBUQUERQUE
NRC Program Code:	NA	State: NM	Zip Code: 87131
Respons ble NRC Region:	4		

Site of Event:

Site Name: ALBUQUERQUE
State: NM

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

Event Type:

LAS - LOST/ABANDONED/STOLEN
MD2 - MEDICAL EVENT

Event Cause:

LAS
Cause: MANAGEMENT DEFICIENCY

MD2
Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
LAS	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	IMPROVE RADIOACTIVE MATERIAL LABELING AND HANDLING
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	IMPROVE RADIOACTIVE MATERIAL LABELING AND HANDLING

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 80 mCi 2960 MBq Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 200 mCi 7400 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 60
Effect on Patient:

Source of Radiation:
LAS
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: CARDINAL HEALTH Activity: 0.12 Ci 4.44 GBq
Model Number: NA
Serial Number: NA

MD2
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: CARDINAL HEALTH Activity: 0.08 Ci 2.96 GBq
Model Number: NA
Serial Number: NA

Device/Associated Equipment:
LAS
Device Number: 1
Device Name: CONTAINER, SHIPPING Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:
LAS
Reporting Requirement: 20.2201(a)(1)(i) - Lost, stolen, or missing licensed material in a quantity greater than or equal to 1,000 times the Appendix C quantities.

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.

Keywords:
LAS
MATERIAL LOST AND FOUND

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46119	07/29/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NM100002	08/20/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100371

Last Updated: 08/26/2010

Narrative:

The University of Pennsylvania reported that a patient received less dose than prescr bed and dose to an unintended site during the first of three vaginal treatment fractions using a high dose rate afterloader with Ir-192. The first fraction of 700 cGy (rad) was delivered on 7/7/2010. When the patient returned for the second fraction on 7/14/2010, imaging revealed that the end of the treatment tube was 3.5 cm short of its intended position. Preliminary dose estimates for the first fraction indicate that the intended treatment volume received only about 10% of the intended dose for that fraction. It was determined that the applicator was correctly placed in the patient by medical staff as confirmed by MRI, but moved 3.5 cm short of its intended location prior to treatment. A fourth treatment fraction may be added in order for the patient to receive the intended total dose. There is no anticipated adverse effect to the patient. The patient and the referring physician were notified. To prevent recurrence, the procedure for the treatments was changed to require review of the entire pelvis field in the x-ray image to detect any shift or misplacement of the applicator, in addition to the review of the immediate area that is done to check cylinder diameter. The INL has requested additional information for this event.

Event Date: 07/07/2010 **Discovery Date:** 07/14/2010 **Report Date:** 07/15/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	PA-0131	Name:	UNIVERSITY OF PENNSYLVANIA
NRC Docket Number:	NA	City:	PHILADELPHIA
NRC Program Code:	NA	State: PA	Zip Code: 19104
Respons ble NRC Region:	1		

Site of Event:

Site Name: PHILADELPHIA
State: PA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: MANAGEMENT DEFICIENCY

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 07/14/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 70 rad 0.7 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 700 rad 7 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 07/14/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 700 rad 7 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): IR-192
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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:

EN46101	07/22/2010	RLS	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN46101A	07/26/2010	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PA100015	08/26/2010	DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100357

Last Updated: 10/26/2010

Narrative:

Marshfield Clinic (MC) reported the preliminary identification of nine medical events involving permanent implants of I-125 seeds (Bard Brachytherapy) for prostate brachytherapy where the total dose delivered differed from the prescribed dose by 20% or more, or an unintended organ received more than intended. During a recent inspection, the Wisconsin Department of Health Services (DHS) determined that MC was not reviewing prostate brachytherapy cases against the medical event criteria. MC evaluated 275 prostate implants performed since August 2003. The review included an assessment of whether implants involved doses to an organ or tissue above 50 cGy (rad) and 50% more than the expected dose. MC notified the affected patients and referring physicians. The reported medical events involved two locations of use. One facility identified three under doses of 25.2, 24.8, and 23.5%, and one overdose of 21.4%. The other facility identified one under dose of 22.8% and one overdose of 21%. Three additional medical events involved overdoses to the urethra of 59.7, 61.3, and 51.6%. DHS investigated the medical events. The underdoses were generally caused by needle and seed placements that did not match the locations specified in the treatment plans. One prostate overdose was caused by an entry error in the planning process, when the dosimetrist used the standard isodose lines for a 16,000 cGy (rad) therapy for a patient prescribed a boost treatment of 12,000 cGy (rad). The implants that resulted in overdoses to the urethra were caused by needles that deviated from their intended tracks after insertion into the prostate, causing the seeds to be deposited closer to the urethra than planned. Corrective actions included generating a new procedure to increase ultrasound visualization during prostate implants and providing new training to personnel. In addition, MC determined that they were not always able to evaluate doses to unintended organs because the post implant CT scan did not extend to a patient's rectum or urethra.

Event Date: 07/08/2010 **Discovery Date:** 07/08/2010 **Report Date:** 07/08/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-141-1162-01	Name:	MARSHFIELD CLINIC
NRC Docket Number:	NA	City:	MARSHFIELD
NRC Program Code:	NA	State: WI	Zip Code: 54449
Respons ble NRC Region:	3		

Site of Event:

Site Name: MARSHFIELD
State: WI

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:	Y	Abnormal Occurrence:	P
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	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVE NEW TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 07/13/2010

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 11970 rad 119.7 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 25.2
Effect on Patient:

Patient Number: 2
Patient Informed: Y Date Informed: 07/09/2010

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 9024 rad 90.24 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 12000 rad 120 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 24.8
Effect on Patient:

Patient Number: 3
Patient Informed: Y Date Informed: 07/15/2010

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 9180 rad 91.8 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 12000 rad 120 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 23.5
Effect on Patient:

Patient Number: 4
Patient Informed: Y Date Informed: 07/12/2010

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 14570 rad 145.7 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 12000 rad 120 Gy

% Dose Exceeds Prescribed: 21.4
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 5
Patient Informed: Y Date Informed: 07/12/2010

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

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

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 22.8
Effect on Patient:

Patient Number: 6
Patient Informed: Y Date Informed: 07/12/2010

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

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

% Dose Exceeds Prescribed: 21
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 7
Patient Informed: Y Date Informed: 07/26/2010

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

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

% Dose Exceeds Prescribed: 59.7
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 8
Patient Informed: Y Date Informed: 07/21/2010

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

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

% Dose Exceeds Prescribed: 61.3
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 9
Patient Informed: Y Date Informed: 07/26/2010

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

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

% Dose Exceeds Prescribed: 51.6
% 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): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 2
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 3
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 4
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 5
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 6
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 7
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 8
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Source Number: 9
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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:
EN46082	07/15/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN46082A	07/21/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI100012	08/18/2010		DCH	AGREEMENT STATE EVENT REPORT
WI100012A	10/05/2010		DCH	AGREEMENT STATE EVENT REPORT
LTR101019	10/26/2010		DCH	AGREEMENT STATE LETTER

Item Number: 100347

Last Updated: 07/13/2010

Narrative:

West Virginia University Hospital reported that a patient only received 0.81 GBq (21.9 mCi) of Y-90 SIR-Spheres, instead of the prescribed 1.14 GBq (30.7 mCi). During the administration on 1/20/2010, the physician believed that there was leakage around the stopper and halted the procedure. The manufacturer was notified of the event and the apparatus was sent back to the manufacturer on 4/5/2010. A report was received from the manufacturer on 6/21/2010. The manufacturer noted that there was leakage, but could not conclude that it was an equipment defect or if the physician applied too much pressure to the V-vial during the procedure. The patient was notified of the incident. The INL has requested additional information for this event.

Event Date: 01/20/2010 **Discovery Date:** 01/20/2010 **Report Date:** 07/07/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	47-23066-02	Name:	WEST VIRGINIA UNIVERSITY HOSPITAL
NRC Docket Number:	03020233	City:	MORGANTOWN
NRC Program Code:	02230	State: WV	Zip Code: 26506
Respons ble NRC Region:	1		

Site of Event:

Site Name: MORGANTOWN
State: WV

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	N	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: Y Date Informed:

Given:

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

Radionuclide:	Y-90	Activity:	21.9	mCi	810.3	MBq	Dose:	NR rad	NR Gy

Intended:

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

Radionuclide:	Y-90	Activity:	30.7	mCi	1135.9	MBq	Dose:	NR rad	NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 28.66
Effect on Patient:

Source of Radiation:

MD2

Source Number: **1**

Source/Radioactive Material:	MICROSPHERES	Radionuclide or Voltage (kVp/MeV):	Y-90		
Manufacturer:	MDS NORDION, INC.	Activity:	0.0219 Ci	0.8103	GBq
Model Number:	SIR-SPHERES				
Serial Number:	NA				

Device/Associated Equipment:

MD2

Device Number: **1**

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	MDS NORDION, INC.	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46074	07/13/2010		DCH	EVENT NOTIFICATION

Item Number: 100346

Last Updated: 08/31/2010

Narrative:

Iredell Memorial Hospital reported that a patient only received 77% of the prescribed dose from a prostate seed implant procedure on 5/5/2010. The prescribed dose was 1,440 cGy (rad) and the seeds contained I-125. A scan was performed following the implant procedure and a seed was discovered in the urethra. When the patient returned to the facility for a follow-up on 5/19/2010 it was discovered that an additional strand of three seeds had come out of the patient during urination approximately a week before. The patient received a post implant CT scan and the underdose was determined. The patient received approximately 1,110 cGy (rad). The INL has requested additional information for this event.

Event Date: 05/05/2010 **Discovery Date:** 05/19/2010 **Report Date:** 07/02/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NC-049-0412-2	Name:	IREDELL MEMORIAL HOSPITAL
NRC Docket Number:	NA	City:	STATESVILLE
NRC Program Code:	NA	State: NC	Zip Code: 28687
Respons ble NRC Region:	1		

Site of Event:

Site Name: STATESVILLE
State: NC

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	Y	Investigation:	Y
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: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 1110 rad 11.1 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 1440 rad 14.4 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 22.92
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:	NR Ci	NR GBq
Model Number:	NR			
Serial Number:	AGGREGATE			

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46071	07/13/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC100032	07/13/2010		DCH	AGREEMENT STATE EVENT REPORT
NC100032A	08/31/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100320

Last Updated: 06/24/2010

Narrative:

Sutter Health Medical Physics Center (SHMPC) reported that a patient only received 12 cGy (rad) on 6/17/2010 during a gamma knife treatment, but was prescribed to receive 162 cGy (rad). The treatment was stopped approximately 15 seconds into the planned 3.5 minute procedure because the patient was complaining of pain. Upon investigation, it was determined that the head immobilization bracket was not fully secured. The incident occurred during the final treatment of eight fractions. SHMPC stated that they will l kely not administer the remaining 150 cGy (rad) to the patient. The patient received 1,150 cGy (rad) of the prescribed 1,300 cGy (rad) from the eight fractions. The State of California is tracking the incident as number 061810. The INL has requested additional information for this event.

Event Date: 06/17/2010 **Discovery Date:** 06/17/2010 **Report Date:** 06/18/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CA-2964-34	Name:	SUTTER HEALTH MEDICAL PHYSICS CENTER
NRC Docket Number:	NA	City:	SACRAMENTO
NRC Program Code:	NA	State: CA	Zip Code: NR
Respons ble NRC Region:	4		

Site of Event:

Site Name: SACRAMENTO
State: CA

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	Y	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: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NOT REPORTED

Patient Information:

Patient Number: 1

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 12 rad 0.12 Gy

Intended:

Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 162 rad 1.62 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 92.6
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:	NR Ci NR GBq
Model Number:	NR		
Serial Number:	AGGREGATE		

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	GAMMA KNIFE UNIT	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN46031	06/24/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

Item Number: 100314

Last Updated: 07/21/2010

Narrative:

Lancaster General Hospital reported that a patient undergoing high dose rate (HDR) treatment for ovarian cancer received a dose to an unintended area on 6/3/2010. The intended area also received less than 80% of the prescribed dose. The brachytherapy source [redacted]) involved contained Ir-192. The area to be treated was incorrectly entered into the HDR afterloader [redacted] computer. The error was discovered during the second fraction of treatment on 6/15/2010. The cause of the event was human error. The patient and attending physician were notified of the error on 6/16/2010. Corrective actions included procedure modifications. The State of Pennsylvania investigated the incident on 6/21/2010. The INL has requested additional information for this event.

Event Date: 06/03/2010 **Discovery Date:** 06/15/2010 **Report Date:** 06/16/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	PA-0233	Name:	LANCASTER GENERAL HOSPITAL
NRC Docket Number:	NA	City:	LANCASTER
NRC Program Code:	NA	State: PA	Zip Code: 17604
Respons ble NRC Region:	1		

Site of Event:

Site Name: LANCASTER
State: PA

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

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: 06/16/2010

Given:

Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: NR rad NR 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: Y Date Informed: 06/16/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: OVARIES
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: OVARIES
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: NR rad NR 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): IR-192
Manufacturer: [redacted] Activity: NR Ci NR GBq
Model Number: [redacted]
Serial Number: NR

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: NR
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
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 prescr bed 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:
EN46022	06/23/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PA100012	07/21/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100313

Last Updated: 07/28/2010

Narrative:

The University of Minnesota reported a medical event involving a gamma knife treatment administered to the wrong location on 6/15/2010. The total treatment consisted of 10 exposures to the intended site with an [redacted] gamma knife unit [redacted] containing Co-60 sources [redacted] serial #MX 1 through MX 201). The sources contained a total activity of 114.7 TBq (3,100 Ci). Five automatic positioning system shots were completed successfully. The treatment also called for five additional trunnion exposures. The first trunnion exposure called for a setting of 76.3, 86.5, and 148.1 in the X, Y, and Z directions, respectfully. Instead, the settings of 76.3, 86.5, and 76.3 were used. In effect, the X setting was inadvertently used for the Z setting. The error was noticed when the coordinates for the second trunnion exposure were being set. An unintended volume of 0.62 cm3 was given a dose of 320 cGy (rad). The originally prescr bed dose for the treatment region was later given. The patient was notified of the error. Corrective actions included procedure modifications.

Event Date: 06/15/2010 **Discovery Date:** 06/15/2010 **Report Date:** 06/15/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	MN-1049-206-27	Name:	UNIVERSITY OF MINNESOTA
NRC Docket Number:	NA	City:	MINNEAPOLIS
NRC Program Code:	NA	State: MN	Zip Code: 55455
Respons ble NRC Region:	3		

Site of Event:

Site Name: MINNEAPOLIS
State: MN

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

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: 06/15/2010

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 3100000 mCi 114700000 MBq Dose: 320 rad 3.2 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 06/15/2010

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 3100000 mCi 114700000 MBq Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 3100000 mCi 114700000 MBq Dose: 320 rad 3.2 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
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: [redacted] Activity: 3100 Ci 114700 GBq
Model Number: [redacted]
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
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 prescr bed 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:

EN46015	06/23/2010	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MN100002	07/28/2010	DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100305

Last Updated: 09/30/2010

Narrative:

Froedtert & Medical College of Wisconsin reported that a patient undergoing an intravascular brachytherapy procedure on 6/9/2010 was administered 2,300 cGy (rad) to the coronary artery instead of the prescribed 1,840 cGy (rad). The patient was treated using an intravascular brachytherapy device (Novoste Beta-Cath model A1767, serial #92591) containing a 1.76 GBq (47.6 mCi) Sr-90 source (AEA Technologies model SICW.2, serial #ZB571). The error was identified during post-planning for the procedure. It was determined that the wrong treatment time was selected for the procedure. The RSO stated that the treatment time was supposed to have been independently reviewed and approved on the written directive, and signed by the authorized user. The written directive was not signed by the authorized user prior to administration. The patient was notified of the incident on 6/9/2010. The Wisconsin Department of Health Services investigated the incident on 6/11/2010. Corrective actions included implementing new policies and procedures, and providing new training to personnel.

Event Date: 06/09/2010 **Discovery Date:** 06/09/2010 **Report Date:** 06/09/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-079-1104-01	Name:	FROEDTERT & MEDICAL COLLEGE OF WISCONSIN
NRC Docket Number:	NA	City:	MILWAUKEE
NRC Program Code:	NA	State: WI	Zip Code: 53226
Respons ble NRC Region:	3		

Site of Event:

Site Name: MILWAUKEE
State: WI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVE NEW TRAINING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 06/09/2010

Given:

Therapeutic Procedure: BRACHY, INTRAVASCULAR

Organ: HEART

Radiopharmaceutical: NA

Radionuclide: SR-90 Activity: 47.6 mCi 1761.2 MBq Dose: 2300 rad 23 Gy

Intended:

Therapeutic Procedure: BRACHY, INTRAVASCULAR

Organ: HEART

Radiopharmaceutical: NA

Radionuclide: SR-90 Activity: 47.6 mCi 1761.2 MBq Dose: 1840 rad 18.4 Gy

% Dose Exceeds Prescribed: 25

% 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): SR-90

Manufacturer: AEA TECHNOLOGIES Activity: 0.0476 Ci 1.7612 GBq

Model Number: SICW.2

Serial Number: ZB571

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: INTRAVASCULAR BRACHY UNIT Model Number: A1767

Manufacturer: NOVOSTE Serial Number: 92591

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45999	06/16/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI100008	08/18/2010		DCH	AGREEMENT STATE EVENT REPORT
WI100008A	09/30/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100298

Last Updated: 10/15/2010

Narrative:

Oncology Hematology Consultants (aka Centers for Cancer and Blood Disorders) reported that over a six-month period from September 2009 to March 2010, five patients received 50 to 66% less dose than prescribed using a High Dose Rate brachytherapy unit [redacted], which contained an Ir-192 source [redacted] with an activity of up to 555 GBq (15 Ci). The errors were discovered when a new group of medical physicists were hired and conducted a routine chart review of patients. It was discovered that the treatment planning system had been set up to calculate the time in seconds for a single treatment fraction, instead of the time for the complete patient treatment. A medical physicist had mistakenly taken that time displayed on the screen as the total treatment time for all fractions and divided that number by the number of fractions prescribed to each patient. Four of the patients were prescribed doses of 1,400 cGy (rad) and one patient was prescr bed 2,100 cGy (rad). Three patients that were prescribed 1,400 cGy and the patient that was prescribed 2,100 cGy (rad) only received 33% of their prescribed doses. One patient that was prescribed 1,400 cGy (rad) only received 50% of that dose. The patient that was prescr bed 2,100 cGy (rad) will receive additional treatment to make up for the 1,400 cGy (rad) needed. None of the other patients with receive make-up doses. The only patient informed of the error was the patient requiring make-up treatment. Corrective actions included a second check by another physicist for each plan and increased training and oversight of new staff to more clearly establish competency in operating the HDR unit.

Event Date: 06/08/2010 **Discovery Date:** 06/08/2010 **Report Date:** 06/08/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TX-L05919	Name:	ONCOLOGY HEMATOLOGY CONSULTANTS
NRC Docket Number:	NA	City:	FORT WORTH
NRC Program Code:	NA	State: TX	Zip Code: 76104
Respons ble NRC Region:	4		

Site of Event:

Site Name: FORT WORTH
State: TX

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:	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:	Y

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 15000 mCi 555000 MBq Dose: 700 rad 7 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 15000 mCi 555000 MBq Dose: 2100 rad 21 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 67
Effect on Patient:

Patient Number: 2
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 15000 mCi 555000 MBq Dose: 462 rad 4.62 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 15000 mCi 555000 MBq Dose: 1400 rad 14 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 67
Effect on Patient:

Patient Number: 3
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 15000 mCi 555000 MBq Dose: 462 rad 4.62 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 15000 mCi 555000 MBq Dose: 1400 rad 14 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 67
Effect on Patient:

Patient Number: 4
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 15000 mCi 555000 MBq Dose: 462 rad 4.62 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 15000 mCi 555000 MBq Dose: 1400 rad 14 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 67
Effect on Patient:

Patient Number: 5
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 15000 mCi 555000 MBq Dose: 700 rad 7 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 15000 mCi 555000 MBq Dose: 1400 rad 14 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 50
Effect on Patient:

Source of Radiation:
MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 15 Ci 555 GBq
Model Number: [redacted]
Serial Number: NR

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45988	06/14/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
TX-I-8751	06/14/2010		DCH	AGREEMENT STATE EVENT REPORT
LTR101012	10/15/2010		DCH	AGREEMENT STATE LETTER

Item Number: 100294

Last Updated: 09/15/2010

Narrative:

Lovelace Medical Center reported that a patient being treated for endometrial carcinoma of the vaginal cuff received skin burns on her thighs. The patient was prescribed to receive three fractions of 700 cGy (rad) each at a distance of 0.5 cm from the surface of the applicator. The dose to the skin of the thighs occurred during the third fraction performed on 5/4/2010. The treatment involved an HDR remote afterloader [redacted], serial #VS220) and a 129.735 GBq (3.50634 Ci) Ir-192 source [redacted] serial #02-01-0053-001-010810-10419-81). The patient started noticing two dark spots on each thigh on 5/11/2010. She notified Lovelace Medical Center on 5/18/2010 of the two spots that were somewhat painful. She returned to the facility on 5/19/2010. The prescribing physician did not diagnose the spots as radiation erythema. The patient was asked to return again on 5/24/2010. At that time, the physician identified two circular areas with a diameter of approximately 1 cm. The spots were determined to be radiation erythema on 5/26/2010. The cause was believed to be that the patient moved in such a way that the catheter moved and/or workers may have moved the catheter while trying to better align the stretcher with the treatment device. The estimated exposure received by the patient during the treatment is 3,025 cGy (rad) shallow dose to the thigh, 409 cGy (rad) deep dose at 2.5 cm to the thigh, and 6.2 cGy (rad) to the prescribed region. Corrective actions included procedure modifications to assure that the catheter is correctly positioned prior to the start of treatment. In addition, a special in-service will be held to address the procedure updates. The New Mexico Department of Health continues to investigate the incident.

Event Date: 05/04/2010 **Discovery Date:** 05/26/2010 **Report Date:** 05/26/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NM-MI-210-94	Name:	LOVELACE MEDICAL CENTER
NRC Docket Number:	NA	City:	ALBUQUERQUE
NRC Program Code:	NA	State: NM	Zip Code: 87102
Respons ble NRC Region:	4		

Site of Event:

Site Name: ALBUQUERQUE
State: NM

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:	Y	Abnormal Occurrence:	P
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: PROCEDURE PROBLEM

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 05/26/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 3506.34 mCi 129734.58 MBq Dose: 3025 rad 30.25 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 05/26/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 3506.34 mCi 129734.58 MBq Dose: 6.2 rad 0.062 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 3506.34 mCi 129734.58 MBq Dose: 700 rad 7 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 99.1
Effect on Patient:

Patient Number: 1B
Patient Informed: Y Date Informed: 05/26/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LEG
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 3506.34 mCi 129734.58 MBq Dose: 409 rad 4.09 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): IR-192

Manufacturer: [redacted]

Activity: 3.50634 Ci 129.73458 GBq

Model Number: [redacted]

Serial Number: 02-01-0053-001-01081

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: REMOTE AFTERLOADER HDR

Model Number: [redacted]

Manufacturer: [redacted]

Serial Number: VS220

Reporting Requirements:

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 prescr bed 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:
EN45978	06/10/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR100607	06/10/2010		DCH	LICENSEE REPORT
LTR100609	06/10/2010		DCH	AGREEMENT STATE LETTER
NM100001	06/10/2010		DCH	AGREEMENT STATE EVENT REPORT
NM100001A	06/10/2010		DCH	AGREEMENT STATE EVENT REPORT
LTR100901	09/15/2010		DCH	AGREEMENT STATE LETTER
NM100001B	09/15/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100290

Last Updated: 08/19/2010

Narrative:

Bristol Hospital reported that two patients received less dose than prescribed during prostate brachytherapy treatments. The first patient, with localized prostate cancer, had an ultrasound directed transperineal implant with 60 I-125 seeds (IsoAid model IAI-125A) on 1/12/2010. The total activity implanted was 754.8 MBq (20.4 mCi). The prescribed dose was 14,500 cGy (rad). The final D90 dose to the prostate gland was determined to be 8,400 cGy (rad). Final dosimetry was based on a CT scan performed on 2/16/2010. The patient and referring physician were notified and the patient then received supplemental external beam radiation with 3,000 cGy (rad) delivered between 3/11 and 4/8/2010. The second patient, also with localized prostate cancer, had an ultrasound directed transperineal implant with 66 Cs-131 seeds (IsoRay model CS-1) on 1/12/2010. The total activity implanted was 6.88 GBq (186 mCi). The prescribed dose was 11,000 cGy (rad). The final D90 dose to the prostate gland was determined to be 6,500 cGy (rad). Final dosimetry was based on a CT scan performed on 2/16/2010. The patient and referring physician were notified and the prescribing physician indicated that additional treatment was not necessary. Preliminary examination seems to indicate that the penile bulb was implanted with some seeds in both cases. Further evaluation is needed to determine the unintended dose to organs surrounding the prostate gland. Both events occurred due to unexpected displacement of the seeds in an inferior (caudal) direction, which was caused by human error as the surgeon incorrectly identified the location of the prostate glands. Bristol Hospital continues to use preplanning for all prostate brachytherapy patients with careful direct supervision of needle and seed placement.

Event Date: 01/12/2010 **Discovery Date:** 02/16/2010 **Report Date:** 06/02/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	06-02057-01	Name:	BRISTOL HOSPITAL, INC.
NRC Docket Number:	03001249	City:	BRISTOL
NRC Program Code:	02120	State: CT	Zip Code: 06010
Respons ble NRC Region:	1		

Site of Event:

Site Name: BRISTOL
State: CT

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	N	Investigation:	Y
Atomic Energy Act Material:	Y	NMED Record Complete:	N
Consultant Hired:	Y	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	NOT REPORTED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 20.4 mCi 754.8 MBq Dose: 8400 rad 84 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 20.4 mCi 754.8 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 42.07
Effect on Patient:

Patient Number: 2
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: CS-131 Activity: 186 mCi 6882 MBq Dose: 6500 rad 65 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: CS-131 Activity: 186 mCi 6882 MBq Dose: 11000 rad 110 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 40.91
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: ISOAID, L.L.C. Activity: 0.0204 Ci 0.7548 GBq
Model Number: IAI-125A
Serial Number: AGGREGATE

Source Number: 2
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-131
Manufacturer: ISORAY, INC. Activity: 186 Ci 6882 GBq
Model Number: CS-1
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Device Number: 2
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45973	06/08/2010		DCH	EVENT NOTIFICATION
LTR100812	08/19/2010		DCH	NRC LETTER

Item Number: 100263

Last Updated: 06/01/2010

Narrative:

Saint Mary's Regional Medical Center reported that a patient only received 11,400 cGy (rad) instead of the intended 14,500 cGy (rad) during a prostate brachytherapy procedure performed on 3/16/2010. The patient received 112 I-125 seeds (Core Oncology model I125SL) that contained 12.65 MBq (0.342 mCi) each, or a total activity of 1.42 GBq (38.3 mCi). When the patient returned for follow-up approximately two months after the implant, CT images were imported into the treatment planning system to determine the actual dose to the prostate and to review the overall quality of the implant. It was determined that the dose to the prostate was only 79% of the prescribed dose. The physician was notified and the dosimetry reviewed. The lower dose was in the middle of the prostate gland, close to the urethra where there was a desire for dose sparing. The higher doses were on the periphery of where the dose was intended. A contributing factor to the incident may be due to the urethra-gram performed during surgery. Additional care will be taken to ensure that the sources are evenly distributed throughout the prostate in the future. It was the physician's desire to spare the urethra. It will be under the discretion of the physician as to how to implant the prostate and still deliver the desired dose. The incident is being tracked by Nevada as number NV100010.

Event Date: 03/16/2010 **Discovery Date:** 05/13/2010 **Report Date:** 05/14/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NV-16-12024402	Name:	SAINT MARY'S REGIONAL MEDICAL CENTER
NRC Docket Number:	NA	City:	RENO
NRC Program Code:	NA	State: NV	Zip Code: 89503
Respons ble NRC Region:	4		

Site of Event:

Site Name: RENO
State: NV

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

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: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 38.3 mCi 1417.1 MBq Dose: 11400 rad 114 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 38.3 mCi 1417.1 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 21
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY Activity: 0.0383 Ci 1.4171 GBq
Model Number: I125SL
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45933	05/24/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NV100010	06/01/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100219

Last Updated: 08/16/2010

Narrative:

Mary Bird Perkins Cancer Center reported that a patient being treated for adenocarcinoma of the prostate gland received less than 50% of the prescribed V100 dose during a brachytherapy implant performed on 3/12/2010. The patient also received dose to an unintended site. The patient was implanted with 95 I-125 brachytherapy seeds (Bard Brachytherapy model STM-1251) that contained an activity of 11.91 MBq/seed (322 uCi/seed). The prescribed dose was 14,500 cGy (rad). The radiation oncologist (RO), with the assistance of the urologist, inserted the needles through the appropriate holes in the needle template. During the procedure, the radiation oncologist used ultrasound to guide the needle placement. However, the RO and ultrasound technologist had difficulty visualizing the balloon location (indicating the prostate base) clearly on the sagittal view of the ultrasound while the seeds were being dispensed from the needles. It is believed that the patient may have moved during the procedure, which may have caused the balloon and ultimately the base plane to shift. A variance was suspected by the RO after reviewing the post implant seed count x-ray. The patient was asked to return for an early post-implant CT on 3/22/2010 to confirm the implanted seed locations. Using those images, a treatment plan was constructed using the treatment planning system's post-plan software. Based on that plan, it was estimated that the entire implanted volume was shifted approximately 3 cm inferiorly, resulting in a D90 dose of 1,288 cGy (rad). The patient was informed and supplemental treatment was recommended. Corrective actions included a change in procedures such that the Morganstern needles will be inserted into the prostate prior to acquiring the planning images. The Louisiana Department of Environmental Quality is tracking the incident as number LA100003.

Event Date: 03/12/2010 **Discovery Date:** 03/22/2010 **Report Date:** 04/27/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	LA-2651-L01	Name:	MARY BIRD PERKINS CANCER CENTER
NRC Docket Number:	NA	City:	BATON ROUGE
NRC Program Code:	NA	State: LA	Zip Code: 70809
Respons ble NRC Region:	4		

Site of Event:

Site Name: BATON ROUGE
State: LA

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

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:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 30.59 mCi 1131.83 MBq Dose: 1288 rad 12.88 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 30.59 mCi 1131.83 MBq Dose: 14500 rad 145 Gy

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

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: NR
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 30.59 mCi 1131.83 MBq Dose: NR rad NR 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): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: 0.03059 Ci 1.13183 GBq
Model Number: STM 1251
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
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 prescr bed 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:

EN45876	05/03/2010	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR100806	08/16/2010	DCH	AGREEMENT STATE LETTER

Item Number: 100148

Last Updated: 04/26/2010

Narrative:

The Mayo Clinic reported that a patient received two fractions of a high dose rate (HDR) afterloader treatment to the wrong location. The patient was prescribed four fractions of 400 cGy (rad) for a biliary HDR treatment. The HDR unit [redacted] serial #VS 437) contained a 329.49 GBq (8.905 Ci) Ir-192 source [redacted] serial #02-01-0219-001-03101). The catheter had been placed and imaged. A dummy source was pushed into the catheter until it met resistance, which was assumed to be the end of the catheter. In fact, the resistance was actually a tight bend approximately 17 cm short of the end of the catheter. This incorrect distance was used for the treatment distance and the patient was subsequently treated. Prior to treatment the following day, a dummy source was again inserted. That dummy source extended beyond the programmed distance. An x-ray revealed that the end of the catheter was beyond the initial treatment location. For the first two fractions, the HDR source was 17 cm from its intended location. This resulted in the tumor receiving only 30% of the prescribed fractional dose and an unintended location (duodenum) receiving 1,000 cGy (rad). The patient was informed of the incident on 3/24/2010. Corrective actions included implementing a new procedure that requires that prior to administering the first fraction on each biliary HDR patient, an image be taken with the measurement cable in place. An additional fraction was completed to provide a total tumor dose that was within 90% of the prescribed dose.

Event Date: 03/23/2010 **Discovery Date:** 03/24/2010 **Report Date:** 03/25/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	MN-1047-205-55	Name:	MAYO CLINIC
NRC Docket Number:	NA	City:	OLMSTED
NRC Program Code:	NA	State: MN	Zip Code: NR
Respons ble NRC Region:	3		

Site of Event:

Site Name: OLMSTED
State: MN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 03/24/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BILIARY TRACT
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8905 mCi 329485 MBq Dose: 240 rad 2.4 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BILIARY TRACT
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8905 mCi 329485 MBq Dose: 800 rad 8 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 70
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 03/24/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: INTESTINE
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8905 mCi 329485 MBq Dose: 1000 rad 10 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): IR-192
Manufacturer: [redacted] Activity: 8.905 Ci 329.485 GBq
Model Number: [redacted]
Serial Number: 02-01-0219-001-03101

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: VS 437

Reporting Requirements:
MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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:

EN45788	03/31/2010	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MN100001	04/26/2010	DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100118

Last Updated: 06/02/2010

Narrative:

The Coral Springs Clinic reported that a patient received more dose than prescribed during the second of 14 high dose rate (HDR) fraction treatments to the ear on 3/11/2010. The patient was prescr bed 250 cGy (rad) to the ear for each fraction using an HDR surface applicator [redacted] and 210.9 GBq (5.7 Ci) Ir-192 source. However, the therapist accidently pushed the "auto radiography" button rather than the "treatment" button, which delivered approximately nine times the intended dose or 2,250 cGy (rad). The patient and doctor were notified of the incident. Corrective actions taken by the Clinic included deactivating the autoradiograph function and providing training to technicians concerning the incident.

Event Date: 03/11/2010 **Discovery Date:** 03/11/2010 **Report Date:** 03/11/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-3109-2	Name:	CORAL SPRINGS CLINIC
NRC Docket Number:	NA	City:	CORAL SPRINGS
NRC Program Code:	NA	State: FL	Zip Code: 33071
Respons ble NRC Region:	1		

Site of Event:

Site Name: CORAL SPRINGS
State: FL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 03/11/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: EAR
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 5700 mCi 210900 MBq Dose: 2250 rad 22.5 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: EAR
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 5700 mCi 210900 MBq Dose: 250 rad 2.5 Gy

% Dose Exceeds Prescribed: 800
% 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): IR-192
Manufacturer: NR Activity: 5.7 Ci 210.9 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
MD2
Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45759	03/17/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL10-035	05/11/2010		DCH	AGREEMENT STATE EVENT REPORT
LTR100524	06/02/2010		DCH	AGREEMENT STATE LETTER

Item Number: 100113

Last Updated: 09/29/2010

Narrative:

The Ohio Department of Health (ODH) received information on 3/3/2010 of an unreported medical event that occurred at Mercy Saint Vincent Medical Center (MSVMC) on 11/8/2005. ODH performed an on-site investigation on 3/5/2010 and confirmed the unreported medical event. MSVMC implanted a patient with 67 I-125 brachytherapy seeds (North American Scientific model MED3631) for treatment of the prostate on 11/8/2005. The 67 seeds contained an aggregate activity of 1.14 GBq (30.686 mCi). The patient was prescribed a dose of 16,000 cGy (rad) to the prostate. Thirteen seeds were removed from the patient's bladder immediately after the procedure, leaving 54 seeds in the patient for a total activity of 0.915 GBq (24.732 mCi). A post implant dose calculation showed that the prostate only received a dose of 1,543 cGy (rad), or 9.6% of the prescribed dose. The patient was notified of the incident on 11/8/2005. MSVMC performed an external beam treatment with a linear accelerator to treat the tumor. An independent medical expert evaluation ordered by ODH was completed on 8/11/2010. That evaluation concluded that a circumferential portion of the sigmoid colon received at least 16,000 cGy (rad). Also, a significant portion of the bladder base, including the region of the ureteral orifices, received at least 10,800 cGy (rad). Corrective actions included training of the RSO, medical physicist, clinical director, and radiation oncologists. New procedures were also developed for brachytherapy seed implant procedures. ODH required MSVMC to perform a self audit of all brachytherapy cases performed since 11/1/2004. That audit revealed eight additional medical events that were not reported. An adjudication order was issued to MSVMC on 6/25/2010. That order increased the inspection frequency of MSVMC activities, removed the authorization for MSVMC to perform brachytherapy procedures, and required MSVMC to submit a quarterly report to ODH on all brachytherapy procedures performed if authorization is restored.

Event Date: 11/08/2005 **Discovery Date:** 11/08/2005 **Report Date:** 03/03/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120490000	Name:	MERCY SAINT VINCENT MEDICAL CENTER
NRC Docket Number:	NA	City:	TOLEDO
NRC Program Code:	NA	State: OH	Zip Code: 43608
Respons ble NRC Region:	3		

Site of Event:

Site Name: TOLEDO
State: OH

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	INCREASED MONITORING BY OUTSIDE AGENCIES TO ENSURE COMPLIANCE

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 11/08/2005

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 24.732 mCi 915.084 MBq Dose: 1543 rad 15.43 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 30.686 mCi 1135.382 MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90.4
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 11/08/2005

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: COLON
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 16000 rad 160 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: 1B
Patient Informed: Y Date Informed: 11/08/2005

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: BLADDER
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10800 rad 108 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): I-125
Manufacturer: NORTH AMERICAN SCIEN
Activity: 0.030686 Ci 1.135382 GBq
Model Number: MED3631
Serial Number: AGGREGATE

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: APPLICATOR
Model Number: NA
Manufacturer: NR
Serial Number: NA

Reporting Requirements:

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 prescr bed 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:
EN45750	03/15/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR100315	03/15/2010		DCH	AGREEMENT STATE LETTER
OH100003	03/15/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100003A	09/13/2010		DCH	AGREEMENT STATE EVENT REPORT
LTR100914	09/14/2010		DCH	AGREEMENT STATE LETTER
EN46272	09/29/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN46273	09/29/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100003B	09/29/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100085

Last Updated: 06/09/2010

Narrative:

The University of Pennsylvania reported a medical event involving a patient treated for prostate cancer. The treatment included implanting 65 I-125 brachytherapy seeds (Bard Brachytherapy model STM 1251), containing a total activity of 0.814 GBq (22 mCi), in the patient's prostate for a prescribed therapeutic radiation dose of 14,500 cGy (rad). The prostate gland only received approximately 500 cGy (rad). The seeds were implanted on 1/21/2010 using real time dosimetry under ultrasonic guidance. On 2/23/2010, the patient returned to the facility for a 30-day post implant CT scan. The scan showed that the implanted seeds, although in an appropriate pattern, were placed outside the intended target. The University's Radiation Oncology group determined that an additional quality assurance review was warranted. The Pennsylvania Bureau of Radiation Protection performed a reactive inspection during the week of 3/1/2010. Initially, a malfunction of the ultrasound unit was suspected. That unit was re-evaluated and was determined to be working properly. The cause was determined to be human error. An unintended dose to the penile bulb of approximately 16,100 cGy (rad) was received, where no dose was anticipated. The Radiation Oncology Department suspended prostate brachytherapy treatments. Corrective actions included changes to the prostate brachytherapy protocol to incorporate an additional step to ensure the urologist and radiation oncologist clearly identifies the prostate gland and the surrounding anatomy. The treatment will be cancelled if the prostate gland and surrounding anatomy cannot be visualized adequately.

Event Date: 01/21/2010 **Discovery Date:** 02/23/2010 **Report Date:** 02/25/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	PA-0131	Name:	UNIVERSITY OF PENNSYLVANIA
NRC Docket Number:	NA	City:	PHILADELPHIA
NRC Program Code:	NA	State: PA	Zip Code: 19104
Respons ble NRC Region:	1		

Site of Event:

Site Name: PHILADELPHIA
State: PA

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

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: 02/23/2010

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 500 rad 5 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 22 mCi 814 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 96.5
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 02/23/2010

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PENILE BULB
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 22 mCi 814 MBq Dose: 16100 rad 161 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: 0.022 Ci 0.814 GBq
Model Number: STM 1251
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
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 prescr bed 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:

EN45727	03/03/2010	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PA100002	03/29/2010	DCH	AGREEMENT STATE EVENT REPORT
PA100002A	03/29/2010	DCH	AGREEMENT STATE EVENT REPORT
PA100002B	03/29/2010	DCH	AGREEMENT STATE EVENT REPORT
PA100002C	04/05/2010	DCH	AGREEMENT STATE EVENT REPORT
LTR100603	06/09/2010	DCH	AGREEMENT STATE LETTER
PA100002D	06/09/2010	DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100082

Last Updated: 09/02/2010

Narrative:

Christiana Care Health System reported a measurement error that resulted in a medical event during an HDR brachytherapy treatment to a patient's left breast. The procedure involved an HDR unit [redacted] serial #31503) and a 247.49 GBq (6.689 Ci) Ir-192 source. The procedure utilized a multi-lumen [redacted] catheter device and involved 10 treatments between 1/18/2010 and 1/22/2010. The intent was to deliver 3,400 cGy (rad) to the left breast. On 2/22/2010, the patient complained of skin reddening and tenderness on the external left breast, distal to [redacted] catheter insertion site. It was determined that an incorrect measurement resulted in placement of the radioactive source 10 cm proximal to the intended position, delivering the prescribed dose to an unintended site. During pre-treatment simulation, the physicist used a dummy source wire to measure the distance to the tips of the catheters at 115.2 cm. There were two representatives from the manufacturer present at that time. The measured distance was entered into the plan as the position of the first dwell position of the source for each catheter. The physicist was informed of the patient's skin reaction and immediately began an investigation. The physicist determined that the actual distance to the tips of the catheters was 125.2 cm. The patient received an average dose of 1,700 cGy (rad) to approximately 100 cc of the unintended breast tissue. About 7.5 cc of the skin and underlying tissue received a maximum dose of 6,800 cGy (rad). Approximately 35 cc of the intended site received an average dose of 340 cGy (rad), or 10% of the total prescribed dose. The patient was notified on 2/25/2010. This event was caused by the use of a damaged source positioning simulator (SPS) tool. Corrective actions included removing the damaged SPS tool from service, obtaining a new SPS tool, developing and posting a reference table of source to catheter tip distances, procedure revisions to require a double-check of all patient measurements, and personnel training. The NRC contacted a medical consultant to review this event, who stated that the patient experienced acute/sub-acute radiodermatitus. He concluded that the patient could experience fat necrosis, the dose to the unintended breast tissue is probably unlikely to result in any significant or unusual adverse effect, the affected skin may not heal and could ulcerate, and that local tumor recurrence cold occur if additional intervention is not performed.

Event Date: 01/18/2010 **Discovery Date:** 02/22/2010 **Report Date:** 02/24/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	07-12153-02	Name:	CHRISTIANA CARE HEALTH SYSTEM
NRC Docket Number:	03001303	City:	WILMINGTON
NRC Program Code:	02120	State: DE	Zip Code: 19899
Respons ble NRC Region:	1		

Site of Event:

Site Name: WILMINGTON
State: DE

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: MANAGEMENT DEFICIENCY

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	NEW QUALITY MANAGEMENT PLAN
3	NEW EQUIPMENT OBTAINED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 02/25/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6689 mCi 247493 MBq Dose: 6800 rad 68 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 02/25/2010

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6689 mCi 247493 MBq Dose: 340 rad 3.4 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6689 mCi 247493 MBq Dose: 3400 rad 34 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 6.689 Ci 247.493 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31503

Device Number: 2
Device Name: CATHETER Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:

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 prescr bed 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:
EN45721	03/02/2010		DCH	EVENT NOTIFICATION
LTR100526	06/03/2010		DCH	NRC LETTER
ML100700085	07/23/2010		RLS	ADAMS DOCUMENT PACKAGE
ML101950203	07/23/2010		RLS	NRC LETTER
ML102150517	08/26/2010		RLS	LICENSEE REPORT
ML102370150	08/26/2010		RLS	NOTICE OF VIOLATION
ML102370150	08/26/2010		RLS	NRC LETTER
ML101950062	09/02/2010		RLS	INSPECTION REPORT

Item Number: 100079

Last Updated: 05/27/2010

Narrative:

The University of Kentucky reported a gamma knife treatment that was administered to the wrong location on 2/23/2010. The procedure was performed using a gamma knife unit [redacted] serial #6035) that contained 220.15 TBq (5,950 Ci) of Co-60 sources [redacted] serial #PA-001 through PA-192). The treatment was prescr bed to the left side of the patient's brain, but was administered to the right side. The scheduled 30 minute, 9,000 cGy (rad) procedure, was terminated after 1.4 minutes, when the administering physician identified the error. Human error occurred when the person entering the information into the positioning system entered incorrect information. It was estimated that 4% or 360 cGy (rad) was administered to the wrong site. Corrective actions included introducing an additional stop check by the oncologist and the addition of a form to verify the information. That form requires the signatures of the oncologist, physicist, and doctor. The Kentucky Department of Health visited the site and assured that the corrective actions were in place.

Event Date: 02/23/2010 **Discovery Date:** 02/23/2010 **Report Date:** 02/23/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	KY-202-024-31	Name:	UNIVERSITY OF KENTUCKY
NRC Docket Number:	NA	City:	LEXINGTON
NRC Program Code:	NA	State: KY	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: LEXINGTON
State: KY

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Y	NMED Record Complete:	Y
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: U Date Informed:

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 5950000 mCi 220150000 MBq Dose: 360 rad 3.6 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 5950000 mCi 220150000 MBq Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 5950000 mCi 220150000 MBq Dose: 9000 rad 90 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
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: [redacted] Activity: 5950 Ci 220150 GBq
Model Number: [redacted]
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 6035

Reporting Requirements:
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 prescr bed 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:

EN45716	03/01/2010	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR100521	05/27/2010	DCH	AGREEMENT STATE LETTER

Item Number: 100074

Last Updated: 06/02/2010

Narrative:

University Community Hospital reported that two patients received doses to the wrong sites during [redacted] treatments. The procedure involved an HDR unit [redacted] that contained an Ir-192 source [redacted] serial #D36C-0609). The Ir-192 source contained 361.1 GBq (9.76 Ci) during the first patient's treatment and 320.4 GBq (8.66 Ci) during the second patient's treatment. It was determined on 2/14/2010 that the source was positioned approximately 2 to 2.5 cm proximal to the correct patient treatment sites. Both patients were prescribed to receive 340 cGy/fraction for 10 fractions. The first patient's treatments had been completed in January 2010 before the error was identified. It was determined that approximately 25% of the planned volume received the prescribed dose. It was also determined that another 25% of the planned volume received 25% or less than the prescribed dose. Also, a large volume outside the prescribed treatment volume exceeded the prescribed dose. The maximum proximal skin dose was approximately 220% greater than the prescribed dose. The second patient received eight of 10 fractions prior to the discovery of the error. That patient's last two fractions were delivered correctly. The second patient received at least 50% of the prescribed dose to about 50% of the correct treatment volume. Some areas of the planned volume received greater than 700%. There was also several areas not prescr bed treatment that received 300 to 400% greater than anticipated. The proximal skin received about 125% more dose than prescr bed. Both patients and their doctors were notified of the event. The Florida Bureau of Radiation Control investigated the incident. The mistakes were believed to be caused by inputting the wrong parameters into the program (human error). Corrective actions included improving the review of paperwork and data prior to the start of patient treatment.

Event Date: 02/14/2010 **Discovery Date:** 02/14/2010 **Report Date:** 02/16/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-0549-3	Name:	UNIVERSITY COMMUNITY HOSPITAL
NRC Docket Number:	NA	City:	TAMPA
NRC Program Code:	NA	State: FL	Zip Code: 33613
Respons ble NRC Region:	1		

Site of Event:

Site Name: TAMPA
State: FL

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

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:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 9760 mCi 361120 MBq Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 9760 mCi 361120 MBq Dose: NR rad NR Gy

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

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 9760 mCi 361120 MBq Dose: NR rad NR Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 2
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8660 mCi 320420 MBq Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8660 mCi 320420 MBq Dose: NR rad NR Gy

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

Patient Number: 2A

Patient Informed: Y Date Informed:

Given:

Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR

Organ: BREAST

Radiopharmaceutical: NA

Radionuclide: IR-192 Activity: 8660 mCi 320420 MBq Dose: NR rad NR Gy

Intended:

A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100

% 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): IR-192

Manufacturer: [redacted] Activity: 9.76 Ci 361.12 GBq

Model Number: [redacted]

Serial Number: D36C-0609

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]

Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:

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 prescr bed 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:
EN45702	02/22/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL10-027	04/29/2010		DCH	AGREEMENT STATE EVENT REPORT
LTR100525	06/02/2010		DCH	AGREEMENT STATE LETTER

Item Number: 100071

Last Updated: 04/16/2010

Narrative:

Massachusetts General Hospital (MGH) reported a medical event that resulted in an underdose of 90% during an HDR afterloader [redacted], serial #31668) patient treatment on 2/10/2010. The HDR contained a 407 GBq (11 Ci) Ir-192 source. The incident was described as two treatment fraction underdoses delivered on the same day to the same patient that differed from the prescribed dose by more than 50% per fraction. The event was caused by equipment software [redacted] failure. The prescription was for two treatments of 400 cGy (rad) per fraction per day for two days and one final 400 cGy (rad) fraction on the third day. Two fractions of 40 cGy (rad) were delivered on the first day of treatment. The prescr bing physician and equipment manufacturer were notified. The equipment manufacturer found that the software issue was reproducible and may be classified as a potential patient safety issue. The suspect portion of software will not be used again until the program is debugged and documented to be correct. The suspect portion of the software had not been used in the past by MGH, so no previous patients were affected. The equipment manufacturer published a customer information bulletin describing the problem. MGH stated that since the underdose could be made up, there will be no effect on the treatment outcome.

Event Date: 02/10/2010 **Discovery Date:** 02/11/2010 **Report Date:** 02/12/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	MA-60-0055	Name:	MASSACHUSETTS GENERAL HOSPITAL
NRC Docket Number:	NA	City:	BOSTON
NRC Program Code:	NA	State: MA	Zip Code: 02114
Respons ble NRC Region:	1		

Site of Event:

Site Name: BOSTON
State: MA

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

Event Type:

EQP - EQUIPMENT
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: DESIGN, MANUFACTURING, OR INSTALLATION ERROR

MD2
Cause: DESIGN, MANUFACTURING, OR INSTALLATION ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	MANUFACTURER WILL NOTIFY CUSTOMERS OF DEFECT
MD2	
1	MANUFACTURER WILL NOTIFY CUSTOMERS OF DEFECT

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 40 rad 0.4 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 400 rad 4 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90
Effect on Patient:

Patient Number: 1A
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 40 rad 0.4 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 400 rad 4 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90
Effect on Patient:

Source of Radiation:
EQP
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 11 Ci 407 GBq
Model Number: NR
Serial Number: NR

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 11 Ci 407 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31668

Device Number: 2
Device Name: COMPUTER SOFTWARE Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

MD2

Device Number: **1**

Device Name:	REMOTE AFTERLOADER HDR	Model Number:	[redacted]
Manufacturer:	[redacted]	Serial Number:	31668

Device Number: **2**

Device Name:	COMPUTER SOFTWARE	Model Number:	[redacted]
Manufacturer:	[redacted]	Serial Number:	NR

Reporting Requirements:

EQP

Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45695	02/18/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MA-02-8893	02/18/2010		DCH	AGREEMENT STATE EVENT REPORT
MA-02-8893A	02/18/2010		DCH	AGREEMENT STATE EVENT REPORT
EN45695A	03/24/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MA-02-8893B	03/24/2010		DCH	AGREEMENT STATE EVENT REPORT
LTR100325	03/29/2010		DCH	AGREEMENT STATE LETTER
LTR100325A	03/29/2010		DCH	AGREEMENT STATE LETTER
LTR100415	04/15/2010		DCH	AGREEMENT STATE LETTER
LTR100416	04/16/2010		DCH	AGREEMENT STATE LETTER

Item Number: 100053

Last Updated: 03/02/2010

Narrative:

The Jewish Hospital reported that a patient only received 10,800 cGy (rad) instead of the prescribed 14,400 cGy (rad) from a prostate seed implant procedure performed on 12/28/2009. Each I-125 brachytherapy seed (Core Oncology model 125SL) contained an activity of 11.84 MBq (0.32 mCi). Post implant CT showed no problems, but follow-up CT scans performed on 1/26/2010 revealed that the patient only received 75% of the prescr bed dose to the prostate gland. The physician notified the patient on 1/26/2010. The Ohio Bureau of Radiation Protection investigated the incident on 2/4/2010. A second implant was performed on 2/5/2010. Corrective actions included writing a new procedure.

Event Date: 12/28/2009 **Discovery Date:** 01/26/2010 **Report Date:** 01/26/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120310029	Name:	THE JEWISH HOSPITAL
NRC Docket Number:	NA	City:	CINCINNATI
NRC Program Code:	NA	State: OH	Zip Code: 45236
Respons ble NRC Region:	3		

Site of Event:

Site Name: CINCINNATI
State: OH

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 01/26/2010

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10800 rad 108 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 14400 rad 144 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 25
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

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

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45665	02/02/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100002	02/02/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100002A	03/02/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100049

Last Updated: 03/02/2010

Narrative:

The Jewish Hospital reported that a patient only received 67% of his prescribed dose to the prostate from an I-125 seed (Core Oncology model 125SL) implant procedure on 1/21/2010. The seeds contained a total activity of 1.84 GBq (49.7 mCi). The prescribed dose was 14,400 cGy (rad) and the actual dose delivered to the prostate was 9,648 cGy (rad). The physician notified the patient on 1/28/2010. The Ohio Bureau of Radiation Control investigated the incident on 2/4/2010. Corrective actions included writing a new procedure.

Event Date: 01/21/2010 **Discovery Date:** 01/22/2010 **Report Date:** 01/22/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120310029	Name:	THE JEWISH HOSPITAL
NRC Docket Number:	NA	City:	CINCINNATI
NRC Program Code:	NA	State: OH	Zip Code: 45236
Respons ble NRC Region:	3		

Site of Event:

Site Name: CINCINNATI
State: OH

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 01/28/2010

Given:

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

Radionuclide:	I-125	Activity:	NR	mCi	NR	MBq	Dose:	9648 rad	96.48 Gy

Intended:

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

Radionuclide:	I-125	Activity:	49.7	mCi	1838.9	MBq	Dose:	14400 rad	144 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 33
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125	
Manufacturer:	CORE ONCOLOGY	Activity:	0.0497 Ci	1.8389 GBq
Model Number:	125SL			
Serial Number:	AGGREGATE			

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45649	01/28/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH100001	01/28/2010		DCH	AGREEMENT STATE EVENT REPORT
OH100001A	03/02/2010		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 100031

Last Updated: 03/09/2010

Narrative:

QHG of Indiana reported that a patient receiving hyperthyroid therapy on 1/14/2010 received 1.16 GBq (31.4 mCi) of I-131 instead of the prescribed 0.93 GBq (25 mCi), a 25.6% increase. Two patients were to receive hyperthyroid therapy on the same day. One was prescribed 0.93 GBq (25 mCi) of I-131 and the other was prescribed 1.11 GBq (30 mCi). The shielded vials for both patients were shipped in the same container. The technologist preparing the dosage failed to notice two vials in the container and removed the wrong one. The error was noticed when the second patient arrived for treatment. The patient and prescribing physician were not informed of the incident. QHG does not expect any long-term medical consequence to the patient. Corrective actions included assigning one technologist the responsibility for all patient treatment parameters prior to administration by the authorized user, developing a dual verification protocol to verify that the treatment parameters are in agreement with the written directive, and training staff on the new requirements.

Event Date: 01/14/2010 **Discovery Date:** 01/14/2010 **Report Date:** 01/14/2010

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-01535-01	Name:	QHG OF INDIANA INC.
NRC Docket Number:	03001594	City:	FORT WAYNE
NRC Program Code:	02120	State: IN	Zip Code: 46804
Respons ble NRC Region:	3		

Site of Event:

Site Name: FORT WAYNE
State: IN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: N Date Informed:

Given:

Therapeutic Procedure: SODIUM IODIDE - T

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 31.4 mCi 1161.8 MBq Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - T

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 25 mCi 925 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 25.6

% 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): I-131

Manufacturer: NR Activity: 0.0314 Ci 1.1618 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:
EN45630	01/20/2010		DCH	EVENT NOTIFICATION
LTR100302	03/05/2010		DCH	NRC LETTER
LTR100305	03/09/2010		RLS	NRC LETTER
ML100390114	03/09/2010		RLS	INSPECTION REPORT
ML100390114	03/09/2010		RLS	NRC LETTER

Item Number: 100009

Last Updated: 07/28/2010

Narrative:

The Department of Veterans Affairs (VA) reported that a patient only received 74.4% of the prescr bed 2.34 GBq (63.2 mCi) of Y-90 during a Nordion TheraSphere treatment on 12/30/2009. The incident was discovered on the same day as the treatment when the waste container from the procedure was assayed. The waste material indicated a higher than expected residual activity equal to about 25% of the activity that was in the source vial prior to treatment. Examination of the waste material revealed that nearly all of the residual activity was distributed somewhat uniformly along the length of the 100 cm microcatheter tubing. Therefore, the patient received approximately 1.74 GBq (47.03 mCi) and 0.58 GBq (15.67 mCi) was identified in the waste. VA estimated that the absorbed dose to the target organ was approximately 10,900 cGy (rad) and was within the therapeutic target range of 10,000 to 15,000 cGy (rad). Initial visual examination showed no apparent kinks or obstructions in the catheter or tubing that would have cause a blockage of infused microspheres. After the Y-90 activity decayed in the source vial and delivery tubing, a more accurate assessment was made of where in the apparatus the held-up microspheres remained. An investigation was conducted in collaboration with the material's vendor. A possible cause involved the infusion of iodinated contrast media in the catheter. The contrast media has a higher viscosity than the saline solution microspheres, so residual contrast media might impede or trap an aggregation of microspheres along the microcatheter. In the future, the contrast media will be flushed from the catheter with saline before the microspheres are infused. Corrective actions also include additional monitoring of the flow of microspheres from the source vial through the delivery tubing. If a higher than expected exposure rate is detected at the exit point of the vial, the vial will be removed from the shield, shaken vigorously, and flushed one or two additional times into the patient's liver.

Event Date: 12/30/2009 **Discovery Date:** 12/30/2009 **Report Date:** 12/31/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: INDIANAPOLIS
State: IN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 47.03 mCi 1740.11 MBq Dose: 10900 rad 109 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 63.2 mCi 2338.4 MBq Dose: 15000 rad 150 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 25.6
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: NORDION Activity: 0.0632 Ci 2.3384 GBq
Model Number: THERASPHERE
Serial Number: NA

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NA
Manufacturer: NORDION Serial Number: NA

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45602	01/06/2010		DCH	EVENT NOTIFICATION
LTR100111	04/13/2010		DCH	LICENSEE REPORT
LTR100304	04/13/2010		DCH	LICENSEE REPORT
LTR100408	04/13/2010		DCH	NRC LETTER
LTR100423	07/27/2010		DCH	INSPECTION REPORT
LTR100713	07/27/2010		DCH	NRC LETTER

Item Number: 090868

Last Updated: 12/10/2009

Narrative:

Fox Chase Cancer Center (FCCC) reported that a patient received 57.6% of the prescribed dose of I-131 during a therapeutic treatment of thyroid cancer on 9/2/2009. The patient was prescribed 5.55 GBq (150 mCi) for the procedure. The nuclear medicine technologist made the appropriate tube connections to the delivery system. The connections were checked with water prior to administration of the I-131 and no leaks were identified. The dose was administered; however, during the flushing process, the technologist noted some leakage of liquid on the absorbent material that was placed under the tubing. The syringe, tubing, and absorbent material were immediately removed and assayed in a cal brator. It was determined that 3.2 GBq (86.42 mCi) was delivered to the patient. A second written directive was generated for additional dose to provide assurance that the patient received the appropriate amount of I-131 for treatment of the thyroid cancer. The cause of the incident was determined to be a procedure problem. Corrective actions included performing a thorough investigation of various stopcocks prior to future administrations of radioactive material. When the appropriate stopcock is determined, several will be ordered and kept in stock. Prior to any radioactive tracer administration, FCCC will test the functionality of the stopcock with water or saline solution.

Event Date: 09/02/2009 **Discovery Date:** 09/02/2009 **Report Date:** 09/03/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	PA-0293	Name:	FOX CHASE CANCER CENTER
NRC Docket Number:	NA	City:	PHILADELPHIA
NRC Program Code:	NA	State: PA	Zip Code: 19111
Respons ble NRC Region:	1		

Site of Event:

Site Name: PHILADELPHIA
State: PA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: PROCEDURE PROBLEM

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW EQUIPMENT OBTAINED
2	NEW QUALITY MANAGEMENT PLAN

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 09/02/2009

Given:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 86.42 mCi 3197.54 MBq Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 150 mCi 5550 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 42.39
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.15 Ci 5.55 GBq
Model Number: NA
Serial Number: NA

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: TUBING, INTRAVENOUS Model Number: NA
Manufacturer: 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:
EN45540	12/09/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PA090034	12/09/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR091210	12/10/2009		DCH	AGREEMENT STATE LETTER

Item Number: 090840

Last Updated: 06/02/2010

Narrative:

Boca Raton Community Hospital reported that a patient received an incorrect dose while being treated with TheraSpheres (MDS Nordion) for liver cancer. The first treatment of 1.27 GBq (34.32 mCi) of Y-90 was intended to be delivered to the left lobe of the liver, but was actually delivered to the right lobe on 10/26/2009. The second treatment was going to be to the right lobe. The right lobe was prescribed a dose of 12,500 cGy (rad), but actually received 7,600 cGy (rad). The error was discovered on 10/30/2009. The patient will be retreated to bring the dose up to the prescr bed level. The patient and doctor were notified. In the future, the radiologist will submit a written statement on the treatment to be performed before it is accomplished.

Event Date: 10/26/2009 **Discovery Date:** 10/30/2009 **Report Date:** 11/17/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-0550-1	Name:	BOCA RATON COMMUNITY HOSPITAL
NRC Docket Number:	NA	City:	BOCA RATON
NRC Program Code:	NA	State: FL	Zip Code: 33486
Respons ble NRC Region:	1		

Site of Event:

Site Name: BOCA RATON
State: FL

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

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:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 34.32 mCi 1269.84 MBq Dose: 7600 rad 76 Gy

Intended:

A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A

Patient Informed: Y Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: LIVER

Radiopharmaceutical: NA

Radionuclide: Y-90 Activity: 0 mCi 0 MBq Dose: 0 rad 0 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: LIVER

Radiopharmaceutical: NA

Radionuclide: Y-90 Activity: 34.32 mCi 1269.84 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 100

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90

Manufacturer: NR Activity: 0.03432 Ci 1.26984 GBq

Model Number: NR

Serial Number: NA

Reporting Requirements:

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 prescr bed 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:
EN45502	11/23/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL09-077	04/21/2010		DCH	AGREEMENT STATE EVENT REPORT
LTR100524	06/02/2010		DCH	AGREEMENT STATE LETTER

Item Number: 090786

Last Updated: 09/30/2010

Narrative:

The University of Michigan Medical Center reported that a three-year-old boy received 76% of a prescribed therapeutic treatment for resistant or recurrent neuroblastoma on 10/14/2009. The boy was prescribed to receive 6.68 GBq (180.5 mCi) of I-131 mIBG, but received 5.11 GBq (138 mCi). During the treatment, a technician noticed air bubbles in the intravenous tubing leading to the patient and stopped the treatment. The patient's physician and parents were notified on 10/15/2009. An investigation determined that the dosage volume was 40 ml instead of the recommended 50 ml because the pharmacist miscalculated the volume of saline solution needed. The dosage was administered through an infusion pump that was set to alarm when 45 ml of the dosage had been delivered so that the technologist could watch for air in the line. However, because of the reduced volume, air appeared in the line earlier than expected. The infusion pump alarmed and stopped the infusion when it detected air in the line. There was no means to remove the air from the line to allow the administration of the remaining dosage. Despite receiving less dosage than prescribed, it was determined that the patient received an adequate dose and no significant medical effect to the patient was expected. This event was caused by an inadequate procedure to purge air from the line, which would have allowed the treatment to continue to completion. Corrective actions included procedure revision to require verification of the dosage volume, setting the infusion pump to alarm at 40 ml instead of 45 ml, and designing a means of purging air bubbles back into the dosage vial.

Event Date: 10/14/2009 **Discovery Date:** 10/14/2009 **Report Date:** 10/15/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-00215-04	Name:	UNIVERSITY OF MICHIGAN
NRC Docket Number:	03001988	City:	ANN ARBOR
NRC Program Code:	02110	State: MI	Zip Code: 48109
Respons ble NRC Region:	3		

Site of Event:

Site Name: ANN ARBOR
State: MI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 10/15/2009

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: NR
Radiopharmaceutical: MIBG (METAIODOBENZYL GUANIDINE
Radionuclide: I-131 Activity: 138 mCi 5106 MBq Dose: rad Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: NR
Radiopharmaceutical: MIBG (METAIODOBENZYL GUANIDINE
Radionuclide: I-131 Activity: 180.5 mCi 6678.5 MBq Dose: rad Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 23.5
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.138 Ci 5.106 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:
EN45436	10/21/2009		DCH	EVENT NOTIFICATION
ML093200190	11/30/2009		RLS	INSPECTION REPORT
ML093200190	11/30/2009		RLS	NOTICE OF VIOLATION
ML093200190	11/30/2009		RLS	NRC LETTER
ML093210521	11/30/2009		RLS	LICENSEE REPORT
LTR100104	01/06/2010		DCH	NRC LETTER
LTR100112	01/12/2010		DCH	NRC LETTER
ML102650282	09/30/2010		RLS	INSPECTION REPORT

Item Number: 090754

Last Updated: 03/01/2010

Narrative:

Martha Jefferson Hospital reported that a patient was administered a therapeutic dose of 3.7 GBq (100 mCi) of I-131 on 9/30/2009, instead of the prescribed diagnostic dose of 0.15 GBq (4 mCi). The patient had received a therapeutic dose in August 2008 and was scheduled for the diagnostic follow up on 9/30/2009. During scheduling, the dose was incorrectly entered as therapeutic instead of diagnostic. The hospital notified the patient's physician and consulted with the patient on 9/30/2009. The hospital also notified their risk management group and began an investigation into the incident. Corrective actions included generating a new written procedure, improving the patient identification verification, and an engineering change to the system.

Event Date: 09/30/2009 **Discovery Date:** 09/30/2009 **Report Date:** 09/30/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	VA-540-137-1	Name:	MARTHA JEFFERSON HOSPITAL
NRC Docket Number:	NA	City:	CHARLOTTESVILLE
NRC Program Code:	NA	State: VA	Zip Code: 22902
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHARLOTTESVILLE
State: VA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	IMPROVED PATIENT IDENTIFICATION VERIFICATION
2	ENGINEERING CHANGE TO SYSTEM
3	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 09/30/2009

Given:

Therapeutic Procedure: SODIUM IODIDE - T

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 100 mCi 3700 MBq Dose: rad Gy

Intended:

Diagnostic Study: THYROID IMAGING

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 4 mCi 148 MBq

% Dose Exceeds Prescribed: 2400

% 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): I-131

Manufacturer: NR Activity: 0.1 Ci 3.7 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:
EN45396	10/06/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
VA090004	11/11/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR100301	03/01/2010		DCH	NRC LETTER

Item Number: 090748

Last Updated: 08/16/2010

Narrative:

The Department of Veterans Affairs reported that a patient being treated for metastatic thyroid carcinoma received less than the prescr bed dose of 7.4 GBq (200 mCi) of I-131 during an administration through a gastronomy feeding tube on 9/21/2009. The administered dose was 6.92 GBq (187 mCi). Daily measurements of the exposure rate at one meter from the patient were consistent with radioactive decay rather than the expected biological elimination rate. The patient's feeding tube was replaced on 9/25/2009. The activity in the feeding tube after removal from the patient was estimated at 5.92 GBq (160 mCi), and the patient received approximately 0.74 GBq (20 mCi). Veterans Affairs notified the patient and the referring physician of the incident. The National Health Physics Program performed a reactive inspection of the event. A detailed analysis estimated the average dose to the stomach wall to be between 16.7 to 19 Gy (1,670 to 1,900 rad), while the average skin dose over the entire region was 28 cGy (rad). Had this procedure been perform correctly, the dose to the stomach wall would have been 3.4 Gy (340 rad). No adverse effect to the patient was observed or expected. The feeding tube had a medication port, a feeding port, and a balloon port. It was determined that the technologist injected the I-131 into the balloon port rather than into the medication port as intended. The root causes of the incident were determined to be inadequate procedures and inadequate training of staff. The written policy/procedure did not adequately verify that the administered dosage was in accordance with the written directive during administrations involving feeding tubes. Corrective actions included developing a written procedure for gastric tube administrations and providing training to the nuclear medicine technologists. In addition, gastric tube administrations were temporarily suspended and one individual was suspended from participating in administrations requiring a written directive. The NRC contracted a medical consultant, who concurred with the dose estimates.

Event Date: 09/21/2009 **Discovery Date:** 09/25/2009 **Report Date:** 09/26/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: SAN DIEGO
State: CA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	PERSONNEL REPRIMANDED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 09/26/2009

Given:
Therapeutic Procedure: SODIUM IODIDE - A
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 20 mCi 740 MBq Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - A
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 200 mCi 7400 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 09/26/2009

Given:
Therapeutic Procedure: SODIUM IODIDE - A
Organ: STOMACH
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 166 mCi 6142 MBq Dose: 1900 rad 19 Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - A
Organ: STOMACH
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 200 mCi 7400 MBq Dose: 340 rad 3.4 Gy

% Dose Exceeds Prescribed: 458
% 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): I-131
Manufacturer: NR Activity: 0.2 Ci 7.4 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.

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:
EN45383	10/02/2009		DCH	EVENT NOTIFICATION
LTR091218	12/21/2009		DCH	NRC LETTER
LTR100121	01/22/2010		DCH	NRC LETTER
ML100200853	01/22/2010		RLS	ADAMS DOCUMENT PACKAGE
ML100200854	01/22/2010		RLS	NRC LETTER
ML100200860	01/22/2010		RLS	CONSULTANT REPORT

ML100251077	01/26/2010	RLS	NRC LETTER
ML100251093	01/26/2010	RLS	ADAMS DOCUMENT PACKAGE
ML100251094	01/26/2010	RLS	LICENSEE REPORT
ML100251105	01/26/2010	RLS	OTHER
ML100251120	01/26/2010	RLS	OTHER
ML100251132	01/26/2010	RLS	LICENSEE REPORT
ML100251144	01/26/2010	RLS	LICENSEE REPORT
LTR100216	02/17/2010	DCH	NRC LETTER
ML100640721	03/10/2010	RLS	INSPECTION REPORT
ML100640721	03/10/2010	RLS	NRC LETTER
ML100890426	04/08/2010	RLS	LICENSEE REPORT
ML101310311	05/14/2010	RLS	NRC LETTER
ML101310318	05/14/2010	RLS	ADAMS DOCUMENT PACKAGE
ML101310319	05/14/2010	RLS	CONSULTANT REPORT
ML101310319	05/14/2010	RLS	INSPECTION REPORT
ML101310319	05/14/2010	RLS	NRC LETTER
ML092820737	06/02/2010	RLS	LICENSEE REPORT
ML101540465	06/07/2010	RLS	NOTICE OF VIOLATION
ML101540465	06/07/2010	RLS	NRC LETTER
ML101580284	06/08/2010	RLS	NRC NEWS ANNOUNCEMENT
ML101470296	07/20/2010	RLS	NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION
09-03	08/16/2010	RLS	ABNORMAL OCCURRENCE NUMBER
ML102080078	08/16/2010	RLS	ABNORMAL OCCURRENCE NUMBER
ML102140389	08/16/2010	RLS	NRC LETTER
ML102140548	08/16/2010	RLS	LICENSEE REPORT
ML102140551	08/16/2010	RLS	LICENSEE REPORT

Item Number: 090732

Last Updated: 10/14/2009

Narrative:

Greenville Hospital System reported that a therapy patient was administered 1.7 GBq (45.9 mCi) of Y-90 SIR-Spheres (MDS Nordion) instead of the intended 0.939 GBq (25.38 mCi). The event occurred on 9/15/2009. The patient and the referring physician were notified on 9/17/2009. It was determined that the technologist mistakenly administered the wrong amount. Corrective actions included providing refresher training to involved staff members.

Event Date: 09/15/2009 **Discovery Date:** 09/15/2009 **Report Date:** 09/16/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	SC-0257	Name:	GREENVILLE HOSPITAL SYSTEM
NRC Docket Number:	NA	City:	GREENVILLE
NRC Program Code:	NA	State: SC	Zip Code: 29605
Respons ble NRC Region:	1		

Site of Event:

Site Name: GREENVILLE
State: SC

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 09/17/2009

Given:

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

Radionuclide:	Y-90	Activity:	45.9 mCi	1698.3 MBq	Dose:	NR rad	NR Gy

Intended:

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

Radionuclide:	Y-90	Activity:	25.38 mCi	939.06 MBq	Dose:	NR rad	NR Gy

% Dose Exceeds Prescribed: 81
% Dose is Less Than Prescribed: NA
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	MICROSPHERES	Radionuclide or Voltage (kVp/MeV):	Y-90		
Manufacturer:	MDS NORDION, INC.	Activity:	0.0459 Ci	1.6983	GBq
Model Number:	SIR-SPHERES				
Serial Number:	AGGREGATE				

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45355	09/23/2009		RLS	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
SC090007	10/14/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090706

Last Updated: 11/13/2009

Narrative:

Hardin Memorial Hospital reported that a patient received 26.9% more dose than prescr bed during a prostate seed implant procedure on 8/28/2009. The patient received I-125 brachytherapy seeds (Bard Brachytherapy model STM1251) with a total activity of 1.26 GBq (34.054 mCi) instead of the prescribed 0.99 GBq (26.825 mCi). It is believed that the medical physicist calculated dose to the prostate using air kerma instead of millicuries. All physicians and the patient have been notified of the mistake. The prescribed Matched Peripheral Dose to the prostate was 14,400 cGy (rad). A 30-day post-implant CT scan revealed a D90 dose to the prostate of 15,960 cGy (rad) and the volume of the prostate receiving 100% of the dose was 93.5%. Corrective actions included adding a separate time-out from the surgical time-out performed as a standard policy prior to the beginning of the procedure. That second time-out would be performed after the creation of an intra-operative plan, but before the implantation of any radioactive material.

Event Date: 08/28/2009 **Discovery Date:** 08/28/2009 **Report Date:** 08/28/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	KY-202-148-26	Name:	HARDIN MEMORIAL HOSPITAL
NRC Docket Number:	NA	City:	ELIZABETHTOWN
NRC Program Code:	NA	State: KY	Zip Code: 42701
Respons ble NRC Region:	1		

Site of Event:

Site Name: ELIZABETHTOWN
State: KY

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Y	NMED Record Complete:	Y
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: 08/28/2009

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 34.054 mCi 1259.998 MBq Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 26.825 mCi 992.525 MBq Dose: 14400 rad 144 Gy

% Dose Exceeds Prescribed: 26.9

% 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): I-125

Manufacturer: BARD BRACHYTHERAPY Activity: 0.034054 Ci 1.259998 GBq

Model Number: STM 1251

Serial Number: NA

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
LTR090828	09/09/2009		DCH	AGREEMENT STATE EVENT REPORT
KY0916	11/10/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR091109	11/10/2009		DCH	AGREEMENT STATE LETTER
EN45485	11/13/2009		RLS	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

Item Number: 090700

Last Updated: 01/12/2010

Narrative:

Karmanos Cancer Center reported that a patient received 8,500 cGy (rad) instead of the prescribed dose of 14,400 cGy (rad) to the prostate gland during a permanent seed implant procedure performed on 3/3/2009. The patient was treated with 58 I-125 brachytherapy seeds (Oncura model 6711) with an activity of 15.91 MBq (0.43 mCi), each. All seeds were implanted and an x-ray at the end of the procedure appeared to indicate a satisfactory distribution. During a post-implant dosimetry analysis on 4/3/2009, the authorized user found that some of the seeds were not at the pre-planned positions in the prostate, such that the dose to the prostate was only 59% of the prescr bed dose. This event was caused by human error in the placement of some of the seeds. During the implant, radiation oncology resident physicians being trained on the procedure were allowed to release some of the I-125 seeds from the needles into the prostate. However, the resident physicians' technique for releasing the seeds was inadequate and resulted in some of the seeds being implanted slightly out of position. The patient and prescribing physician were notified of the error on 4/3/2009. The patient underwent external radiation treatment to compensate. Although the authorized user was aware of this event on 4/3/2009, Karmanos Cancer Center did not determine that the event should have been reported until a review of prostate implant cases was performed on 8/27/2009. Corrective actions included revising the training methods for radiation oncology residents and developing a prostate brachytherapy checklist.

Event Date: 03/03/2009 **Discovery Date:** 04/03/2009 **Report Date:** 08/28/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-04127-06	Name:	KARMANOS CANCER CENTER
NRC Docket Number:	03009376	City:	DETROIT
NRC Program Code:	02310	State: MI	Zip Code: 48201
Respons ble NRC Region:	3		

Site of Event:

Site Name: DETROIT
State: MI

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

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: 04/03/2009

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 8500 rad 85 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 24.94 mCi 922.78 MBq Dose: 14400 rad 144 Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 41

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: ONCURA Activity: 0.02494 Ci 0.92278 GBq

Model Number: 6711

Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45308	09/08/2009		DCH	EVENT NOTIFICATION
ML092820076	10/13/2009		RLS	INSPECTION REPORT
ML092820076	10/13/2009		RLS	NOTICE OF VIOLATION
ML092820076	10/13/2009		RLS	NRC LETTER
LTR091110	11/11/2009		DCH	NRC LETTER
LTR091231	01/06/2010		DCH	NRC LETTER
LTR100112	01/12/2010		DCH	NRC LETTER

Item Number: 090692

Last Updated: 03/22/2010

Narrative:

Allegiance Health reported that a patient received 46.8% of the prescribed D90 dose on 4/16/2009 during a permanent prostate implant of I-125 seeds (model 6711). The prescribed dose was 14,500 cGy (rad) using 57 I-125 seeds, each with an activity of 21.35 MBq (577 uCi). Post-implant CT imaging on 4/17/2009 and dosimetry analysis on 4/22/2009 estimated the D90 dose to be 77.3% of the prescribed dose. This prompted further imaging, dosimetry analysis, and expert consultation. On 8/24/2009, the final determination of the D90 dose was 46.8% of the prescribed dose and the decision was made to proceed with a corrective implant procedure, which occurred on 9/28/2009. The referring physician and patient were notified of the error. This event occurred because the relative positions of the implanted seeds did not provide sufficient dose coverage of the prostate volume as specified by the written directive. A cold spot in the superior/base portion of the prostate was found. Pre-treatment plans were developed more than three weeks prior to the scheduled implant procedures, allowing time for the prostate volume to change. Corrective actions included performing the pre-planning ultrasound within three weeks of the implant date, ensuring that the authorized user has performed prostate seed implants (or has received documented training on seed implant procedures) with 18 months, and using appropriate imaging during to the implant procedure to ensure proper seed placement.

Event Date: 04/16/2009 **Discovery Date:** 08/24/2009 **Report Date:** 08/25/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-00258-06	Name:	ALLEGIANCE HEALTH
NRC Docket Number:	03001990	City:	JACKSON
NRC Program Code:	02120	State: MI	Zip Code: 49201
Respons ble NRC Region:	3		

Site of Event:

Site Name: JACKSON
State: MI

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

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: 08/24/2009

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 32.89 mCi 1216.93 MBq Dose: 6786 rad 67.86 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 32.89 mCi 1216.93 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 53.2

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: 0.03289 Ci 1.21693 GBq

Model Number: 6711

Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45295	09/02/2009		DCH	EVENT NOTIFICATION
LTR091005	10/06/2009		RLS	NRC LETTER
ML092520661	10/06/2009		RLS	LICENSEE REPORT
ML092990633	11/02/2009		RLS	INSPECTION REPORT
ML092990633	11/02/2009		RLS	NRC LETTER
LTR091102	11/03/2009		DCH	NRC LETTER
ML093521533	01/12/2010		RLS	LICENSEE REPORT
ML100070482	01/12/2010		RLS	NOTICE OF VIOLATION
ML100070482	01/12/2010		RLS	NRC LETTER
ML100750310	03/22/2010		RLS	INSPECTION REPORT

Item Number: 090691

Last Updated: 03/22/2010

Narrative:

Allegiance Health reported that a patient received 76.3% of the prescribed D90 dose on 4/16/2009 during a permanent prostate implant of I-125 seeds (model 6711). The prescribed dose was 14,500 cGy (rad) using 54 I-125 seeds, each with an activity of 25.12 MBq (679 uCi). Post-implant CT imaging on 4/17/2009 and dosimetry analysis on 4/22/2009 estimated the D90 dose to be 60.6% of the prescribed dose. This prompted further imaging, dosimetry analysis, and expert consultation. On 8/24/2009, the final determination of the D90 dose was 76.3% of the prescribed dose. The referring physician and patient were notified of the error. This event occurred because the relative positions of the implanted seeds did not provide sufficient dose coverage of the prostate volume as specified by the written directive. A slight cold spot in the anterior superior portion of the prostate was found. However, the patient's known location of prostate cancer were in an area well covered by the implant, so no additional implant was recommended. Corrective actions included performing the pre-planning ultrasound within three weeks of the implant date, ensuring that the authorized user has performed prostate seed implants (or has received documented training on seed implant procedures) with 18 months, and using appropriate imaging during to the implant procedure to ensure proper seed placement.

Event Date: 04/16/2009 **Discovery Date:** 08/24/2009 **Report Date:** 08/25/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-00258-06	Name:	ALLEGIANCE HEALTH
NRC Docket Number:	03001990	City:	JACKSON
NRC Program Code:	02120	State: MI	Zip Code: 49201
Respons ble NRC Region:	3		

Site of Event:

Site Name: JACKSON
State: MI

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

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: 08/24/2009

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 36.67 mCi 1356.79 MBq Dose: 11064 rad 110.64 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 36.67 mCi 1356.79 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 23.7

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: 0.03667 Ci 1.35679 GBq

Model Number: 6711

Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45294	08/31/2009		DCH	EVENT NOTIFICATION
LTR091005	10/06/2009		RLS	NRC LETTER
ML092520661	10/06/2009		RLS	LICENSEE REPORT
ML092990633	11/02/2009		RLS	INSPECTION REPORT
ML092990633	11/02/2009		RLS	NRC LETTER
LTR091102	11/03/2009		DCH	NRC LETTER
ML093521533	01/12/2010		RLS	LICENSEE REPORT
ML100070482	01/12/2010		RLS	NOTICE OF VIOLATION
ML100070482	01/12/2010		RLS	NRC LETTER
ML100750310	03/22/2010		RLS	INSPECTION REPORT

Item Number: 090668

Last Updated: 10/29/2009

Narrative:

Centura Health Penrose – Saint Francis Health Services reported that a patient, who was implanted with 70 Pd-103 brachytherapy seeds (IsoAid model IAPd103A, batch #024609), received an under-dose to the prostate gland. The activity of each seed was 71.41 MBq (1.93 mCi), for a total activity of 4.998 GBq (135.1 mCi). The implant was performed on 7/22/2009 with a Mick applicator, using intra-operative planning with a Variseed planning system. It was noted on the C-arm film taken at the completion of the implant that there was some clumping of the seeds in groups. A post implant CT scan was performed on 7/23/2009. The results of the computerized dosimetry plan was evaluated on 8/5/2009 and it was determined that the prostate gland only received 4,575 cGy (rad) or 36.6% of the prescr bed 12,500 cGy (rad) to 90% of the prostate volume (D90). The authorized user's written directive listed the expected range for D90 to be between 90 and 135%. Both the physician and the patient were notified of the incident. An additional brachytherapy procedure to complete the treatment was discussed with the patient, approved by the authorized user, and scheduled for September 2009. Corrective actions included imaging the seed deposition using real time fluoroscopy in conjunction with real time ultrasound images to provide additional visual feedback and to better confirm the tactile feedback provided by the Mick needles.

Event Date: 07/22/2009 **Discovery Date:** 08/05/2009 **Report Date:** 08/06/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CO-197-02	Name:	CENTURA HEALTH PENROSE - SAINT FRANCIS HEALTH SERV
NRC Docket Number:	NA	City:	COLORADO SPRINGS
NRC Program Code:	NA	State: CO	Zip Code: 80993
Respons ble NRC Region:	4		

Site of Event:

Site Name: COLORADO SPRINGS
State: CO

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW EQUIPMENT OBTAINED
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 08/06/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: PD-103 Activity: 135.1 mCi 4998.7 MBq Dose: 4575 rad 45.75 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: PD-103 Activity: 135.1 mCi 4998.7 MBq Dose: 12500 rad 125 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 63.4
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): PD-103
Manufacturer: ISOAID, L.L.C. Activity: 0.1351 Ci 4.9987 GBq
Model Number: IAPD-103A
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NA
Manufacturer: MICK RADIO-NUCLEAR Serial Number: NA

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
LTR090806	08/19/2009		DCH	AGREEMENT STATE EVENT REPORT
EN45275	08/25/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
CO09-M09-02	10/29/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090662

Last Updated: 06/02/2010

Narrative:

Valley Hospital reported the improper positioning of 46 Cs-131 brachytherapy seeds (IsoRay Medical model CS-1) during a prostate implant procedure on 7/29/2009. The error was suspected when the physician reviewed the CAT scan results on 8/6/2009, and was confirmed on 8/11/2009. It was determined that the seeds went into soft tissue 4 to 5 cm inferior to the prostate. Post-implant dosimetry calculations indicated that none of the prostate received the prescribed dose of 6,500 cGy (rad). The D90 value (the minimum dose received by 90% of the prostate volume) was 300 cGy (rad). An unintended volume of 30.1 ml of soft tissue received 100% of the prescribed dose of 6,500 cGy (rad). The patient was advised by the physician and elected to receive follow-on treatment with a linear accelerator. An NRC medical consultant concluded that the soft tissue dose could increase the risk of soft tissue fibrosis or impotency. This event was caused by inadequate ultrasound identification of the prostate during implant due to the patient's unusual anatomy and obesity. Corrective actions included procedure modification to include steps to ensure that the prostate and surrounding associated anatomy is adequately visualized prior to implant.

Event Date: 07/29/2009 **Discovery Date:** 08/06/2009 **Report Date:** 08/07/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	29-03845-01	Name:	VALLEY HOSPITAL
NRC Docket Number:	03002474	City:	RIDGEWOOD
NRC Program Code:	02230	State: NJ	Zip Code: 07450
Respons ble NRC Region:	1		

Site of Event:

Site Name: RIDGEWOOD
State: NJ

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

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: 08/11/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: CS-131 Activity: NR mCi NR MBq Dose: 300 rad 3 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: CS-131 Activity: NR mCi NR MBq Dose: 6500 rad 65 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 95
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 08/11/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PERI-PROSTATIC TISSUE
Radiopharmaceutical: NA
Radionuclide: CS-131 Activity: NR mCi NR MBq Dose: 6500 rad 65 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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-131
Manufacturer: ISORAY, INC. Activity: NR Ci NR GBq
Model Number: CS-1
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
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 prescr bed 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:
EN45250	08/13/2009		DCH	EVENT NOTIFICATION

ML092610296	09/21/2009	RLS	REGION REPORT
ML093270438	12/01/2009	RLS	ADAMS DOCUMENT PACKAGE
ML093270441	12/01/2009	RLS	NRC LETTER
ML093270449	12/01/2009	RLS	INSPECTION REPORT
LTR100526	06/02/2010	DCH	NRC LETTER

Item Number: 090659

Last Updated: 06/02/2010

Narrative:

Yale - New Haven Hospital (YNHH) reported an equipment malfunction involving an [redacted] gamma knife unit [redacted] serial #B2508) that occurred on 8/5/2009 and resulted in a patient rece ving an incorrect dose. According to the NRC Registry of Radioactive Sealed Sources and Devices, this unit contains 201 Co-60 sources [redacted] with a total maximum activity of 244.2 TBq (6,600 Ci). Two patients were scheduled for treatment on that day. While treating the first patient, the automatic positioning system (APS) reported positioning error codes to the treatment console and the operators called [redacted] for help. YNHH was told to undock the patient, reinitialize the APS, and then complete the treatment. The error happened again during the second patient treatment and the local [redacted] service person was called to inspect the unit. The service representative arrived after the completion of treatment to the second patient. It was noted that while trying to drive the APS back to its nominal position, one of the axis indicators was off by 4.5 mm. It was determined that the shift happened during patient treatment. The console logs were analyzed by [redacted] to see if the error occurred during treatment as a result of an APS malfunction. The patient was prescribed to receive 1,800 cGy (rad) at the 50% isodose line for six lesions in the brain. It was concluded that the intended treatment sites received less than 80% of the prescribed dose. It was also determined that unintended sites received greater than 50 cGy (rad) and greater than 50% of the intended dose. A medical consultant concurred with YNHH's assessment that the untreated area could be retreated and that no clinically significant side-effects from radiation damage to the unintended areas were expected. An NRC investigation determined that the dose error was caused by inadequate procedures that did not require a physical verification of the automatic position system coordinates against the electronic coordinates prior to treatment, and did not specify how personnel should respond to unexpected treatment console errors. Corrective actions included personnel training and procedure modification.

Event Date: 08/05/2009 **Discovery Date:** 08/05/2009 **Report Date:** 08/06/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	06-30445-01	Name:	YALE-NEW HAVEN HOSPITAL
NRC Docket Number:	03034705	City:	NEW HAVEN
NRC Program Code:	02310	State: CT	Zip Code: 06510
Respons ble NRC Region:	1		

Site of Event:

Site Name: NEW HAVEN
State: CT

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

Event Type:

EQP - EQUIPMENT
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: DEFECTIVE OR FAILED PART

MD2
Cause: DEFECTIVE OR INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	REPAIRS MADE WITHOUT ENGINEERING CHANGE TO SYSTEM
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 6600000 mCi 244200000 MBq Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 6600000 mCi 244200000 MBq Dose: 1800 rad 18 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: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 6600000 mCi 244200000 MBq Dose: NR rad NR 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:
EQP
Source Number: 1
Source/Radioactive Material: SEALED SOURCE GAMMA KNIFE Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: [redacted] Activity: 6600 Ci 244200 GBq
Model Number: [redacted]
Serial Number: AGGREGATE

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE GAMMA KNIFE Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: [redacted] Activity: 6600 Ci 244200 GBq
Model Number: [redacted]
Serial Number: AGGREGATE

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: B2508

MD2
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: B2508

Reporting Requirements:

EQP

Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

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 prescr bed 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:
EN45249	08/12/2009		DCH	EVENT NOTIFICATION
LTR100524	05/26/2010		DCH	NRC LETTER
ML101450038	06/02/2010		RLS	NOTICE OF VIOLATION
ML101450038	06/02/2010		RLS	NRC LETTER

Item Number: 090656

Last Updated: 11/04/2009

Narrative:

Emory University reported that during an embolization procedure on 8/5/2009, a patient received 67.3% of the Y-90 SIR-Spheres. The resulting dose delivered to the patient's liver was 3,500 cGy (rad) instead of the intended 5,200 cGy (rad). The cause was determined to be a leaking septum or v-vial. The material was captured in the crucible (secondary container) and did not enter the patient. The radiologist noticed the leak and stopped the procedure. Both the patient and referring physician were notified of the incident. The INL has requested additional information for this event.

Event Date: 08/05/2009 **Discovery Date:** 08/05/2009 **Report Date:** 08/05/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	GA-0153-1	Name:	EMORY UNIVERSITY
NRC Docket Number:	NA	City:	ATLANTA
NRC Program Code:	NA	State: GA	Zip Code: 30322
Respons ble NRC Region:	1		

Site of Event:

Site Name: ATLANTA
State: GA

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	Y	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: Y Date Informed: 08/05/2009

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: NR mCi NR MBq Dose: 3500 rad 35 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: NR mCi NR MBq Dose: 5200 rad 52 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 32.7
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	MICROSPHERES	Radionuclide or Voltage (kVp/MeV):	Y-90
Manufacturer:	NR	Activity:	NR Ci NR 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

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45246	08/11/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
GA-2009-09I	11/04/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090615

Last Updated: 01/19/2010

Narrative:

Centura Health Penrose – Saint Francis Health Services reported that a patient received 700 cGy (rad) to the wrong site, approximately 10 cm from the intended location, during a high dose rate (HDR) afterloader [redacted] procedure performed on 7/21/2009. The Ir-192 source [redacted] serial #02-01-1095-001-07100) contained an activity of 339.18 GBq (9.167 Ci). A positioning error resulted in the incident and delivered the dose to the entrance of the vagina rather than intrauteral. The applicator used in the procedure uses a collet to hold a 3-mm source tube in place. Subsequent investigation revealed that the collet on the applicator had not been tightened sufficiently to prevent movement of the source tube within the applicator. The patient and physician were notified. The patient was retreated with the prescribed dose three days later without incident. Corrective actions included generating a new procedure to measure the distance from the end of the source tube to the cylinder prior to patient treatment and providing additional training to all staff involved in HDR treatments.

Event Date: 07/21/2009 **Discovery Date:** 07/21/2009 **Report Date:** 07/22/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CO-197-01	Name:	CENTURA HEALTH PENROSE - SAINT FRANCIS HEALTH SERV
NRC Docket Number:	NA	City:	COLORADO SPRINGS
NRC Program Code:	NA	State: CO	Zip Code: 80993
Respons ble NRC Region:	4		

Site of Event:

Site Name: COLORADO SPRINGS
State: CO

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 07/21/2009

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 9167 mCi 339179 MBq Dose: 700 rad 7 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 07/21/2009

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: UTERUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 9167 mCi 339179 MBq Dose: 2 rad 0.02 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: UTERUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 9167 mCi 339179 MBq Dose: 700 rad 7 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 99.7
Effect on Patient:

Source of Radiation:
MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 9.167 Ci 339.179 GBq
Model Number: [redacted]
Serial Number: 02-01-1095-001-07100

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
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 prescr bed 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:

EN45221	07/28/2009	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
CO09-M09-01	08/26/2009	DCH	AGREEMENT STATE EVENT REPORT
LTR100119	01/19/2010	DCH	NRC LETTER

Item Number: 090597

Last Updated: 06/01/2010

Narrative:

Nanticoke Cook Memorial Hospital reported that a patient received only 39 of the intended 61 I-125 brachytherapy seeds in the prostate gland during implantation on 3/5/2009. Each seed (Bard Brachytherapy model STM-1251) contained an activity of 13.73 MBq (0.371 mCi). The remaining 22 seeds were implanted in the bladder and then retrieved. The patient returned to the hospital on 4/4/2009 for a post-implant CT scan. The CT scan was reviewed on 6/17/2009 and revealed that 32 of the 39 remaining seeds were displaced superiorly to the prostate, leaving 7 seeds implanted in the prostate. Dosimetry revealed an underdose to the prostate with a D90 isodose curve line of 2,670 cGy (rad). The prescribed dose for that same location was 14,500 cGy (rad). The seed distribution error was caused by the position of the needles in respect to depth when the seeds were released and possible patient movement. The patient received no ill effect, but required further therapeutic radiation. The patient was notified of the occurrence of the medical event and received additional radiation therapy at another facility. Corrective actions included personnel training and procedure revision to include routine use of sagittal views from an ultrasound probe, which allows for the visual confirmation of needle depth in relation to the position of the bladder and the base of the prostate gland. The NRC contracted a medical consultant to review this event. The medical consultant reported that the extra dose to the seminal vesicle is unlikely to cause medical problems.

Event Date: 03/05/2009 **Discovery Date:** 06/26/2009 **Report Date:** 07/15/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	07-17618-01	Name:	NANTICOKE COOK MEMORIAL HOSPITAL
NRC Docket Number:	03013060	City:	SEAFORD
NRC Program Code:	02120	State: DE	Zip Code: 19973
Respons ble NRC Region:	1		

Site of Event:

Site Name: SEAFORD
State: DE

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 03/05/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 2.597 mCi 96.089 MBq Dose: 2670 rad 26.7 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 22.631 mCi 837.347 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 81.6
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 03/05/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: SEMINAL VESICLE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 11.872 mCi 439.264 MBq Dose: NR rad NR Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: 0.022631 Ci 0.837347 GBq
Model Number: STM 1251
Serial Number: AGGREGATE

Reporting Requirements:
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 prescr bed 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:
EN45206	07/21/2009		DCH	EVENT NOTIFICATION
LTR090918	09/28/2009		DCH	NRC LETTER
ML092780505	10/15/2009		RLS	OTHER
LTR091119	11/23/2009		DCH	NRC LETTER
LTR091130	11/30/2009		DCH	NRC LETTER
ML100190821	01/25/2010		RLS	NRC LETTER

ML100190835	01/25/2010	RLS	INSPECTION REPORT
ML100330274	02/04/2010	RLS	NOTICE OF VIOLATION
ML100330274	02/04/2010	RLS	NRC LETTER
ML101410196	06/01/2010	RLS	OTHER

Item Number: 090580

Last Updated: 08/16/2010

Narrative:

The Gamma Knife Center of the Pacific (GKCP) reported that a patient received a gamma knife treatment on 7/2/2009 to two metastatic sites using the wrong collimator. The gamma knife unit contained 104.86 TBq (2,834 Ci) of Co-60. The treatment was prescribed for seven discrete brain metastatic sites using the 8-mm collimator. The prescribed dose was 2,400 cGy (rad) to each of the seven sites. After the second discrete site had been treated, it was determined that an 18-mm collimator had been used instead of the 8-mm collimator. Following the discovery, the collimator was changed to the 8-mm collimator. Treatment to the remaining five discrete sites was administered with the 8-mm collimator. The use of the 18-mm collimator instead of the 8-mm collimator increased the treatment site dose by 3%. The 18-mm collimator caused the volume of each of the two treatment areas to increase by 2.45 cm3. That additional tissue received a dose of 2,407 cGy (rad). If the 8-mm collimator had been used, that tissue would have received a dose of approximately 430 cGy (rad). Both the physician and patient were notified of the incident. The previous patient had been treated with the 18-mm collimator as prescribed, but the medical physicist neglected to change the collimator prior to treating this patient. Corrective actions included sending a notice to all neurosurgeons and radiation oncologists stressing that they should each independently check collimator size prior to each treatment. The NRC conducted a special inspection and contracted a medical consultant to review this event. The INL has requested additional information for this event.

Event Date: 07/02/2009 **Discovery Date:** 07/02/2009 **Report Date:** 07/03/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	53-11966-02	Name:	GAMMA KNIFE CENTER OF THE PACIFIC
NRC Docket Number:	03034629	City:	HONOLULU
NRC Program Code:	02310	State: HI	Zip Code: 96817
Respons ble NRC Region:	4		

Site of Event:

Site Name: HONOLULU
State: HI

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:	Y	Abnormal Occurrence:	Y
Agreement State Reportable Event:	N	Investigation:	Y
Atomic Energy Act Material:	Y	NMED Record Complete:	R
Consultant Hired:	Y	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	PERSONNEL RECEIVED ADDITIONAL TRAINING
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 07/03/2009

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 2407 rad 24.07 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 430 rad 4.3 Gy

% Dose Exceeds Prescribed: 458
% Dose is Less Than Prescribed: NA
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: 2834 Ci 104858 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
MD2

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:
EN45184	07/09/2009		DCH	EVENT NOTIFICATION
LTR090709	07/10/2009		DCH	NRC LETTER
EN45184A	07/20/2009		DCH	EVENT NOTIFICATION
LTR090720	07/20/2009		DCH	NRC LETTER
ML091980412	07/20/2009		DCH	LICENSEE REPORT
ML092080411	07/28/2009		RLS	NRC NEWS ANNOUNCEMENT
ML092020608	02/01/2010		RLS	NRC LETTER
ML100210537	02/01/2010		RLS	LICENSEE REPORT
ML100541944	03/09/2010		RLS	INSPECTION REPORT
ML100541944	03/09/2010		RLS	NRC LETTER
09-02	08/16/2010		RLS	ABNORMAL OCCURRENCE NUMBER
ML102080078	08/16/2010		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 090574

Last Updated: 06/24/2010

Narrative:

Karmanos Cancer Center reported that an administrative error occurred at their [redacted] Gamma Knife facility on 2/18/2008 that resulted in the total dose delivered differing from the written directive, but which agreed with the therapy that was intended and planned by the radiation oncologist authorized user (AU) and the neurosurgeon. The gamma knife unit used Co-60 sources [redacted] . The incident was discovered during the 2008 annual quality management review that was completed on 6/24/2009. The patient was being treated for metastatic brain tumors in the right cerebellum and right occipital lobe. Treatment plans were developed for treatment of both locations. The AU reviewed and initialed the treatment plans. The AU then completed the written directive for treatment of the right cerebellum. However, the AU failed to complete a written directive for treatment of the right occipital lobe. Treatment of both the right cerebellum and right occipital lobe occurred on 2/18/2009 and was performed in accordance with the respective treatment plans. The correct intended dose of 2,000 cGy (rad) to the 50% isodose was delivered. This event occurred due to lack of attention to administrative tasks. Corrective actions included personnel training, procedure modification to require a “time-out” prior to treatment to review all details of the treatment, competing a quality management review of each gamma knife treatment immediately prior to treatment by a second medical physicist, and revising the quality assurance form to include a review of the written directive with the treatment plan. The INL has requested additional information for this event.

Event Date: 02/18/2008 **Discovery Date:** 06/24/2009 **Report Date:** 06/30/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-04127-06	Name:	KARMANOS CANCER CENTER
NRC Docket Number:	03009376	City:	DETROIT
NRC Program Code:	02310	State: MI	Zip Code: 48201
Respons ble NRC Region:	3		

Site of Event:

Site Name: DETROIT
State: MI

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	N	Investigation:	Y
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: INATTENTION TO DETAIL

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW QUALITY MANAGEMENT PLAN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 2000 rad 20 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
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: [redacted] Activity: NR Ci NR GBq
Model Number: [redacted]
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: NR
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
MD2
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:
EN45174	07/06/2009		DCH	EVENT NOTIFICATION
ML091811198	07/16/2009		RLS	LICENSEE REPORT
LTR090727	08/04/2009		DCH	NRC LETTER
ML092440204	09/15/2009		RLS	INSPECTION REPORT
ML092440204	09/15/2009		RLS	NRC LETTER
LTR100623	06/24/2010		DCH	NRC LETTER

Item Number: 090571

Last Updated: 06/21/2010

Narrative:

Wheaton Franciscan Healthcare - Saint Joseph reported a medical event that occurred on 6/25/2009 and involved an HDR treatment to a patient's esophagus. The procedure involved a [redacted] HDR unit [redacted] serial #31421) and a 246.94 GBq (6.674 Ci) Ir-192 source [redacted] . The prescribed dose was 500 cGy (rad) to the lesion. The authorized user intended to insert the applicator 2 cm past the distal part of the esophageal tumor. A GI specialist verified the location prior to treatment using a scope. Post treatment location of the applicator was reviewed using an AP lateral film compared with barium swallow dictation/films. It was determined that the lesion was 21 cm from the tip of the nose and the catheter should have been approximately 23 cm long, for placement 2 cm past the distal end of the tumor. The catheter used was measured at 31 cm. The lesion only received 3% of the intended dose. The 500 cGy (rad) was received by tissue other than the intended treatment site. The patient was notified of the error on 6/26/2009 and returned for a second fraction on 7/9/2009. Corrective actions included creating a step-by-step written procedure for this type of treatment and using fluoroscopy and fiducial markers on the outside of the chest for verification of the catheter location. The Wisconsin Department of Health and Safety conducted an investigation of the incident on 6/29 and 7/10/2009.

Event Date: 06/25/2009 **Discovery Date:** 06/26/2009 **Report Date:** 06/26/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-079-1288-01	Name:	WHEATON FRANCISCAN HEALTHCARE - SAINT JOSEPH
NRC Docket Number:	NA	City:	MILWAUKEE
NRC Program Code:	NA	State: WI	Zip Code: 53210
Respons ble NRC Region:	3		

Site of Event:

Site Name: MILWAUKEE
State: WI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 06/26/2009

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: ESOPHAGUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6674 mCi 246938 MBq Dose: 500 rad 5 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 06/26/2009

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: ESOPHAGUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6674 mCi 246938 MBq Dose: 15 rad 0.15 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: ESOPHAGUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6674 mCi 246938 MBq Dose: 500 rad 5 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 97
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 6.674 Ci 246.938 GBq
Model Number: [redacted]
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31421

Reporting Requirements:
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 prescr bed 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:

EN45165	07/02/2009	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI090005	08/10/2009	DCH	AGREEMENT STATE EVENT REPORT
WI090005A	09/16/2009	DCH	AGREEMENT STATE EVENT REPORT
WI090005B	06/21/2010	DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090565

Last Updated: 08/04/2009

Narrative:

Hoag Memorial Hospital Presbyterian reported that a patient received a significant dose to an untargeted area during a gamma knife stereotactic radiosurgery on 3/20/2009. The incident involved an [redacted] gamma knife unit [redacted] serial #6021) that contained Co-60. The incident occurred due to an error in the imaging process used for treatment planning. The fiducial marker box used to register the CT images was misaligned. The CT locator box had not been firmly seated on the targeting frame, which resulted in a target shift of approximately 2 mm. Due to the small size of the target (7 mm by 4 mm by 3 mm) and the small size of the radiation shots (4 mm collimators), that shift of 2 mm resulted in only approximately 52% of the target receiving the prescribed dose of 1,100 cGy (rad). Normal tissue (temporal bone) outside of the intended treatment volume received a dose of 1,100 cGy (rad). The patient was prescr bed a single fraction treatment. No adverse consequences are expected from this event. The physician did not feel additional treatment was advisable and counseled the patient regarding the incident. Corrective actions included additional training for the CT technologist on correct placement of the fiducial box, the medical physicist will double check the box placement on all similar treatments in the future, and policies and procedures were updated. According to the NRC Registry of Radioactive Sealed Sources and Devices, this gamma knife unit contains Co-60 sources with a combined maximum activity of 244.2 TBq (6,600 Ci). The State of California is tracking the incident as number 032009.

Event Date: 03/20/2009 **Discovery Date:** 03/20/2009 **Report Date:** 06/20/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CA-0272-30	Name:	HOAG MEMORIAL HOSPITAL PRESBYTERIAN
NRC Docket Number:	NA	City:	NEWPORT BEACH
NRC Program Code:	NA	State: CA	Zip Code: NR
Respons ble NRC Region:	4		

Site of Event:

Site Name: NEWPORT BEACH
State: CA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 6600000 mCi 244200000 MBq Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 6600000 mCi 244200000 MBq Dose: 1100 rad 11 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BONE
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 6600000 mCi 244200000 MBq Dose: 1100 rad 11 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
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: 6600 Ci 244200 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: GAMMA KNIFE UNIT
Model Number: [redacted]
Manufacturer: [redacted]
Serial Number: 6021

Reporting Requirements:
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 prescr bed 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:

EN45160	06/30/2009	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR090730	08/04/2009	DCH	AGREEMENT STATE LETTER

Item Number: 090563

Last Updated: 08/19/2009

Narrative:

The Oregon Health Sciences University reported that a patient, being treated for liver cancer on 5/7/2009, received 34.2% less Y-90 SIR-Spheres than prescribed. The patient was informed and may be rescheduled to receive additional treatment. The Oregon Department of Health and Radiological Protection is investigating the incident. The INL has requested additional information for this event.

Event Date: 05/07/2009 **Discovery Date:** 05/07/2009 **Report Date:** 06/23/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OR-90013	Name:	OREGON HEALTH & SCIENCE UNIVERSITY
NRC Docket Number:	NA	City:	PORTLAND
NRC Program Code:	NA	State: OR	Zip Code: NR
Respons ble NRC Region:	4		

Site of Event:

Site Name: PORTLAND
State: OR

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

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:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: NR mCi NR MBq Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 34.2
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: MICROSPHERES
Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: NR
Activity: NR Ci NR 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

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45149	06/29/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR090818	08/19/2009		DCH	AGREEMENT STATE LETTER

Item Number: 090540

Last Updated: 07/10/2009

Narrative:

Mercy Fitzgerald Hospital reported that a patient only received 50 cGy (rad) instead of the prescribed 3,000 cGy (rad) during a Sr-90 pterygium eye treatment performed on 3/26/2009. The incident involved an ophthalmic applicator (Amersham model SLA20, serial #0874ML), which contained an activity of 1.49 GBq (40.2 mCi). It was determined that a technician failed to remove the filter and cap (guard ring) from the applicator prior to treatment. The patient and prescribing physician were notified of the incident. The patient was scheduled for additional treatments to complete delivery of the prescribed dose. Corrective actions included reviewing and revising policies and procedures.

Event Date: 03/26/2009 **Discovery Date:** 03/27/2009 **Report Date:** 04/09/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	PA-0082	Name:	MERCY FITZGERALD HOSPITAL
NRC Docket Number:	NA	City:	DARBY
NRC Program Code:	NA	State: PA	Zip Code: 19023
Respons ble NRC Region:	1		

Site of Event:

Site Name: DARBY
State: PA

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

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: 03/31/2009

Given:

Therapeutic Procedure: BRACHY, EYE APPLICATOR
Organ: EYE
Radiopharmaceutical: NA
Radionuclide: SR-90 Activity: 40.2 mCi 1487.4 MBq Dose: 50 rad 0.5 Gy

Intended:

Therapeutic Procedure: BRACHY, EYE APPLICATOR
Organ: EYE
Radiopharmaceutical: NA
Radionuclide: SR-90 Activity: 40.2 mCi 1487.4 MBq Dose: 3000 rad 30 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 98.3
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	SR-90	
Manufacturer:	NR	Activity:	0.0402 Ci	1.4874 GBq
Model Number:	NR			
Serial Number:	NR			

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	SLA20
Manufacturer:	AMERSHAM	Serial Number:	0874ML

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45125	06/17/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PA090015	06/17/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR090709	07/10/2009		DCH	AGREEMENT STATE LETTER

Item Number: 090497

Last Updated: 08/16/2010

Narrative:

The Urology Center reported that a patient received a 53% underdose during a prostate seed implant procedure on 5/11/2009. The patient was prescribed to receive 64 I-125 seeds (Core Oncology model 125SL). The seeds each contained an activity of 16.428 MBq (0.444 mCi), for a total activity of 1.052 GBq (28.422 mCi). The prescribed dose to the prostate was 14,400 cGy (rad) and the administered dose was approximately 6,768 cGy (rad). The post-plan CT was evaluated on 5/12/2009 and determined that the prostate volume that received the prescribed dose was 47% (i.e. V100%=47%). Evaluation of the post-procedure ultrasound revealed that 30 of the prescribed 64 seeds were implanted in the prostate, while 34 were delivered outside the prostate gland. According to the Urology Center, the incident was the result of the patient's prostate being smaller than normal. The unintended site received a dose of approximately 7,600 cGy (rad) with the majority of the dose delivered to the urethra and bulb of the penis. The patient and physician were notified. The patient returned on 5/19/2009 for a second treatment to compensate for the underdose. The Ohio Department of Health investigated the incident on 6/12/2009 and determined that the cause was miscalculation of the size of the patient's prostate gland. Corrective actions taken by the Urology Center included modifying procedures to require agreement by both the urologist and radiation oncologist on placement of seeds for patients with small prostate gland size (20 cc or less).

Event Date: 05/11/2009 **Discovery Date:** 05/12/2009 **Report Date:** 05/12/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02200310002	Name:	UROLOGY CENTER
NRC Docket Number:	NA	City:	CINCINNATI
NRC Program Code:	NA	State: OH	Zip Code: 45212
Respons ble NRC Region:	3		

Site of Event:

Site Name: CINCINNATI
State: OH

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

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: 05/12/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 28.422 mCi 1051.614 MBq Dose: 6768 rad 67.68 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 28.422 mCi 1051.614 MBq Dose: 14400 rad 144 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 53
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 06/12/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: URETHRA
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 28.422 mCi 1051.614 MBq Dose: 7600 rad 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): I-125
Manufacturer: CORE ONCOLOGY Activity: 0.028422 Ci 1.051614 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Reporting Requirements:
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 prescr bed 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:
EN45061	05/19/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH090005	05/21/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR090709	07/09/2009		DCH	AGREEMENT STATE LETTER
OH090005A	07/09/2009		DCH	AGREEMENT STATE EVENT REPORT
OH090005B	07/20/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR100121	01/26/2010		DCH	NRC LETTER

AS 09-06	08/16/2010	RLS	ABNORMAL OCCURRENCE NUMBER
ML102080078	08/16/2010	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 090481

Last Updated: 08/16/2010

Narrative:

Indiana University Medical Center (IUMC) reported that a patient prescribed to receive 2.27 GBq (61.3 mCi) of Y-90 TheraSpheres (MDS Nordion) to deliver approximately 11,763 cGy (rad) only received 8,660 cGy (rad) (approximately 73.6%) of the intended dose. The dose vial was assayed on 4/29/2009 to contain 2.22 GBq (60.1 mCi). Based on a radiation monitoring device affixed to the TheraSphere delivery system, the pretreatment reading was 7 mR/hour. Following administration and four subsequent flushings of the delivery system, the radiation monitor read 2 mR/hour. It was determined that 0.60 GBq (16.2 mCi) remained in the delivery system. MDS Nordion was notified of the incident on 4/29/2009. Their opinion was that residual TheraSpheres were attached to the septum of the dose vial due to the package being inverted during shipment. For future treatments, MDS Nordion suggested that the dose vial be shaken and tapped on a firm surface upon receipt. They also suggested that during the administration process, gently rock the dose vial prior to placement in the delivery box, and, if there appears to be residual dose after administration, open the delivery box and gently agitate the dose vial. Those suggestions were incorporated into the IUMC written procedures for TheraSphere treatments. The referring physician and patient's wife were notified of the event on 4/30/2009. No negative effect to the patient is expected as a result of this event.

Event Date: 04/29/2009 **Discovery Date:** 04/29/2009 **Report Date:** 04/30/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-02752-03	Name:	INDIANA UNIVERSITY MEDICAL CENTER
NRC Docket Number:	03001609	City:	INDIANAPOLIS
NRC Program Code:	02110	State: IN	Zip Code: 46202
Respons ble NRC Region:	3		

Site of Event:

Site Name: INDIANAPOLIS
State: IN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 04/30/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 43.9 mCi 1624.3 MBq Dose: 86.6 rad 0.866 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 61.3 mCi 2268.1 MBq Dose: 117.6 rad 1.176 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 26.4
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES
Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: MDS NORDION, INC.
Activity: 0.0613 Ci 2.2681 GBq
Model Number: THERASPHERE
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR
Model Number: NR
Manufacturer: MDS NORDION, INC.
Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN45034	05/06/2009		DCH	EVENT NOTIFICATION
ML091630740	06/16/2009		RLS	INSPECTION REPORT
ML091630740	06/16/2009		RLS	NRC LETTER
LTR100728	08/16/2010		DCH	NRC LETTER

Item Number: 090471

Last Updated: 05/12/2009

Narrative:

The University of Kentucky reported that a nine-month-old infant was administered a 1,291 MBq (34.9 mCi) dose of Tc-99m Sestam bi for a cardiac scan, instead of the prescr bed 74 MBq (2 mCi) dose of Tc-99m DMSA for a renal-glomerular filtration study. The incident occurred on 4/22/2009 and the patient's legal guardian was notified on that same date. The administered dose exceeded the prescribed dose by 1,650%. It was estimated that the patient's heart received a dose of 3.68 cSv (rem), small intestine received 1.09 cSv (rem), gall bladder received 3.99 cSv (rem), kidney received 1.86 cSv (rem), and the whole body received a dose of 5.22 cSv (rem). The effect on the patient is unknown. The cause of the incident was human error. Corrective actions included reprimanding personnel, modifying procedures, providing additional training to personnel, obtaining new equipment, and improving radioactive material labeling and handling.

Event Date: 04/22/2009 **Discovery Date:** 04/22/2009 **Report Date:** 04/22/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	KY-202-049-22	Name:	UNIVERSITY OF KENTUCKY
NRC Docket Number:	NA	City:	LEXINGTON
NRC Program Code:	NA	State: KY	Zip Code: 40506
Respons ble NRC Region:	1		

Site of Event:

Site Name: LEXINGTON
State: KY

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	IMPROVE RADIOACTIVE MATERIAL LABELING AND HANDLING
2	NEW EQUIPMENT OBTAINED
3	PERSONNEL RECEIVED ADDITIONAL TRAINING
4	PERSONNEL REPRIMANDED
5	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 04/22/2009

Given:

Diagnostic Study: CARDIAC SCAN

Radiopharmaceutical: SESTAMIBI/CARDIOLITE

Radionuclide: TC-99M Activity: 34.9 mCi 1291.3 MBq

Intended:

Diagnostic Study: RENAL-GLOMERULAR FILTRATION

Radiopharmaceutical: DMSA (DIMERCAPTOSUCCINIC ACID)

Radionuclide: TC-99M Activity: 2 mCi 74 MBq

% Dose Exceeds Prescribed: NA

% 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): TC-99M

Manufacturer: NR Activity: 0.0349 Ci 1.2913 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.

Reporting Requirement: 35.3045(a)(2)(i) - Administration of a wrong radioactive drug containing byproduct material that results in a dose that exceeds 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:
EN45011	04/29/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
KY0901	05/12/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR090508	05/12/2009		DCH	NRC LETTER

Item Number: 090466

Last Updated: 08/16/2010

Narrative:

Cancer Care Northwest PET Center reported an equipment malfunction involving a [redacted] HDR unit [redacted] serial #221) that resulted in a medical event. The incident occurred on 4/14/2009 during a patient prostate treatment. The aluminum connector to needle 13 detached from the plastic guide tube. The HDR was connected to the plastic guide tube, the plastic guide tube was attached (glued) to the aluminum connector, and the aluminum connector screwed into the needles that were implanted in the patient. As a result, the 185 GBq (5 Ci) Ir-192 source wire [redacted] serial #02-01-0080-001-0121) failed to enter the needle and hung about six inches past the disconnected guide tube in open air. The source wire was supposed to be in needle 13 for 32 seconds. The source wire retracted normally after the incident. The event did not interfere with the remaining treatment needles. The dose differed by approximately 180 cGy (rad) to a small volume of the prostate in the vicinity of needle 13. The total dose to the prostate differed from the prescribed dose by less than 5%. The incident also resulted in as much as 1,250 cGy (rad) to a small area of skin on the patient's inner thigh. However, several subsequent inspections of the patient have not identified any skin reactions. The attending physician does not believe there was any clinically significant effect to the patient. The root causes of the failure of the adhesive that attached the aluminum connector to the plastic extension adaptor was sterilization of the extension adaptor (the manufacturer's written product information cautions that sterilization may cause adhesive failure) and reuse of extension adaptors (the manufacturer's written product information recommends that they are for single use only). Corrective actions included procedure modification, including (1) requiring the staff to sign the patient quality assurance list when they check the applicators, transfer guide tubes, and aluminum connectors; (2) inspecting the guide tube catheters daily and examining the aluminum connectors prior to patient use; and (3) revising the refresher training to include new procedures for staff prior to patient treatment.

Event Date: 04/14/2009 **Discovery Date:** 04/14/2009 **Report Date:** 04/15/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WA-WN-M0227	Name:	CANCER CARE NORTHWEST PET CENTER
NRC Docket Number:	NA	City:	SPOKANE
NRC Program Code:	NA	State: WA	Zip Code: 99202
Respons ble NRC Region:	4		

Site of Event:

Site Name: SPOKANE
State: WA

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

Event Type:

EQP - EQUIPMENT
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: EQUIPMENT MISUSE

MD2
Cause: EQUIPMENT MISUSE

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LEG
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 5000 mCi 185000 MBq Dose: 1250 rad 12.5 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Source of Radiation:
EQP
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 5 Ci 185 GBq
Model Number:
Serial Number: 02-01-0080-001-0121

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 5 Ci 185 GBq
Model Number:
Serial Number: 02-01-0080-001-0121

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 221

MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 221

Reporting Requirements:
EQP
Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

MD2
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:
EN45007	04/28/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WA090015	04/28/2009		DCH	AGREEMENT STATE EVENT REPORT
EN45007A	07/02/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WA090015A	07/02/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR100119	01/19/2010		DCH	NRC LETTER
LTR100723	07/23/2010		RLS	NRC LETTER

AS 09-05	08/16/2010	RLS	ABNORMAL OCCURRENCE NUMBER
ML102080078	08/16/2010	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 090465

Last Updated: 01/06/2010

Narrative:

The Hahnemann University Hospital reported that a patient received 1.85 GBq (50 mCi) of I-125 monoclonal antibody subcutaneously instead of intravenously on 12/22/2008. It was determined that the nurse involved did not have the patient remove their shirt, so the port was not completely visualized and the nurse did not palpate the site as well as possible. The patient was notified at the time of the event that the injection was subcutaneous rather than intravenous. The estimated skin dose was between 360 and 710 cGy (rad). The patient's doctor is confident that the therapeutic effects of the dosage were received. There has been no noted skin affects reported. Corrective actions included retraining of staff that patients with ports are to disrobe completely to allow better visualization of port sites. Also, ports will be palpated to ensure the injection is occurring within the port.

Event Date: 12/22/2008 **Discovery Date:** 12/22/2008 **Report Date:** 04/10/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	PA-0927	Name:	HAHNEMANN UNIVERSITY HOSPITAL
NRC Docket Number:	NA	City:	PHILADELPHIA
NRC Program Code:	NA	State: PA	Zip Code: 19102
Respons ble NRC Region:	1		

Site of Event:

Site Name: PHILADELPHIA
State: PA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 12/22/2008

Given:

Therapeutic Procedure: RADIOPHARMACEUTICAL - T

Organ: SKIN

Radiopharmaceutical: LABELED ANTIBODY

Radionuclide: I-125 Activity: 50 mCi 1850 MBq Dose: 710 rad 7.1 Gy

Intended:

A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100

% 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): I-125

Manufacturer: NR Activity: 0.05 Ci 1.85 GBq

Model Number: NA

Serial Number: NA

Reporting Requirements:

MD2

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:
EN45005	04/27/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PA090013	04/27/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR090616	06/25/2009		DCH	NRC LETTER
LTR091210	12/15/2009		DCH	AGREEMENT STATE LETTER
PA090013A	12/15/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR091222	01/06/2010		DCH	AGREEMENT STATE LETTER

Item Number: 090460

Last Updated: 04/21/2009

Narrative:

A medical facility reported that a 47-year-old patient with a history of thyroid cancer was prescr bed to receive a quantitative thyroglobulin antibody blood test (non-radioactive), but was administered 184.6 MBq (4.99 mCi) of I-131 on 5/23/2007. An error occurred in scheduling, when an administrative clerk scheduled a thyroid scan instead of the requested quantitative blood test. Facility staff stated that the trained and experienced nuclear medicine scheduling clerk read the order correctly for blood work, but got distracted and generated a script for an I-131 scan. The attending physician signed the script, but apparently failed to review the patient's chart. Following recognition of the error (after administration) the attending physician, in consultation with the endocrinologist, determined that it would be appropriate to scan for residual tumors at that time. The scan was performed on 5/25/2007. The patient's planned I-131 scan for November 2007 was canceled. Both the patient and referring physician were informed of the event. Corrective actions included requiring that the attending nuclear medicine physician check and review the patient's medical record prior to performing I-131 patient exams.

Event Date: 05/23/2007 **Discovery Date:** 05/23/2007 **Report Date:** 05/23/2007

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
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:	Y	Abnormal Occurrence:	P
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: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed:

Given:

Diagnostic Study: THYROID CANCER WORK-UP

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 4.99 mCi 184.63 MBq

Intended:

A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: NA

% 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): I-131

Manufacturer: NR Activity: 0.0049 Ci 0.1813 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:
NY-552	04/21/2009		DCH	AGREEMENT STATE EVENT REPORT
NYDOH-09-08	04/21/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090448

Last Updated: 06/18/2009

Narrative:

The University of North Carolina Hospital (UNCH) reported that a patient only received an estimated 76% of a prescr bed Y-90 microsphere dosage (lot #999008) on 4/8/2009. The prescribed dosage was 2.26 GBq (61 mCi) and it is estimated that approximately 1.70 GBq (46 mCi) was administered. The intended dose to the liver was 12,000 cGy (rad), with an estimated delivery dose of approximately 9,100 cGy (rad). The UNCH stated that there was no equipment malfunction and no leakage of radioactive material from the delivery device. Proper administration protocol was followed and the administration was unremarkable. Four flushes of the vial were performed. The dosimeter mounted on the delivery device read 0 mR after flushing, which typically indicates adequate delivery of the microspheres. The dose vial was also inverted several times during the procedure to agitate and remove any microspheres, which sometimes remain in the vial. The patient was notified and there are no plans to perform a second administration. MDS Nordion was contacted and responded to the site to assist in an investigation. MDS Nordion recommended that UNCH not invert the microsphere vial because that may cause the microspheres to adhere to the vial septum. They stated that tilting or tapping the bottom of the vial on a hard surface is still the best method for making sure the microspheres are washed from the septum. They also recommended promptly starting the administration once the catheter is in place. They stated that browning of the dose vial in this case suggests that microspheres remained in the vial up and around the septum.

Event Date: 04/08/2009 **Discovery Date:** 04/08/2009 **Report Date:** 04/09/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NC-068-0565-1	Name:	UNIVERSITY OF NORTH CAROLINA HOSPITAL
NRC Docket Number:	NA	City:	CHAPEL HILL
NRC Program Code:	NA	State: NC	Zip Code: 27514
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHAPEL HILL
State: NC

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: OTHER

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 04/09/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 46 mCi 1702 MBq Dose: 9100 rad 91 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 61 mCi 2257 MBq Dose: 12000 rad 120 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 24
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: MDS NORDION, INC. Activity: 0.061 Ci 2.257 GBq
Model Number: THERASPHERE
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MDS NORDION, INC. Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44979	04/15/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC090022	06/18/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090416

Last Updated: 04/01/2009

Narrative:

A medical facility reported that a 45-year-old male patient diagnosed with prostate cancer only received approximately 50% of the prescribed dose to the prostate during I-125 seed implant on 12/17/2007. The patient was prescribed a dose of 14,400 cGy (rad) to be delivered using 50 I-131 seeds, each with an activity of 15.9 MBq (0.43 mCi). A significant number of seeds were placed inferior to the prostate gland. The misplacement was a result of misidentification of the prostate by the radiation oncologist who performed the procedure. Ultrasound and C-arm fluoroscopy systems were used to aid with positioning the seeds. A post implant confirmatory fluoroscopic image was obtained and the radiation oncologist observed that the seeds appeared to be low relative to the pelvic bones, due to hematoma secondary to repeated punctures of the prostate. All 50 seeds were identified on the film, with five recovered later during cystoscopy. A post implant CT scan was performed on 1/21/2008. The radiation oncologist stated that the seeds appeared to have slipped lower, perhaps due to hematoma. For unknown reasons, the radiation oncologist did not inform the patient of the potential problem until 4/11/2008. At that time the patient was informed that he needed an MRI to evaluate seed placement. The treating radiation oncologist did not inform the director of radiation oncology, who was also the RSO. On 4/16/2008, the director/RSO learned of the incident through the patient's wife. The RSO reviewed the chart including films and identified the medical event. The radiation oncologist and patient were informed of the incident. The patient was referred to a leading cancer treatment center for evaluation. Their finding was that the tumor was underdosed by about 50% and vital structures such as the rectum and urethra were at levels of maximum tolerance. It was concluded that additional radiation to the base of the prostate was not an option and that the patient needed to be followed to monitor levels of Prostate Specific Antigen. An MRI at the cancer treatment center revealed residual tumor at the base of the prostate. Contrary to facility policy, contrast was not injected into the balloon to delineate the bladder. Also, hospital policy did not require that the urologist be present for the entire procedure. The urologist left immediately after the stabilizing needles were placed and returned later to perform the cystoscopy. Corrective actions included requiring that the injection of contrast into the balloon be documented and that the fluoroscopic image be saved in the PACS system. The Department of Radiology will interpret all fluoroscopic images that are taken in the snapshot mode. Although the localization of the prostate is the respons bility of the authorized user, the medical facility will require that the urologist document the verification of the setup and the identification of the prostate. The post-implant CT scan will be interpreted by the Department of Radiology for seed positioning and post-implant dosimetry will be performed promptly and documented in the patient's medical record.

Event Date: 12/17/2007 **Discovery Date:** 04/16/2008 **Report Date:** 04/17/2008

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:	Y	Abnormal Occurrence:	P
Agreement State Reportable Event:	Y	Investigation:	Y
Atomic Energy Act Material:	Y	NMED Record Complete:	N
Consultant Hired:	Y	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: 04/17/2008

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

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 21.5 mCi 795.5 MBq Dose: 14400 rad 144 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 50
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 04/17/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: NR rad NR 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: 1B
Patient Informed: Y Date Informed: 04/17/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: URETHRA
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: NR rad NR 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):	I-125		
Manufacturer:	NR	Activity:	0.0215 Ci	0.7955	GBq
Model Number:	NR				
Serial Number:	AGGREGATE				

Reporting Requirements:

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 prescr bed 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:
NY-600	04/01/2009		DCH	AGREEMENT STATE EVENT REPORT
NYDOH-09-05	04/01/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090415

Last Updated: 04/01/2009

Narrative:

A medical facility reported that a patient was prescribed 11.1 MBq (300 uCi) of I-123, but was administered 72.5 MBq (1.96 mCi) of I-131 on 12/29/2008. A referring physician requested an uptake study and scan to be followed by an I-131 therapy for thyrotoxicosis. The authorized user (AU) directed the secretary to schedule the uptake study using I-123. However, the secretary scheduled the patient for a whole body scan using I-131. On the day of the study, the nuclear medicine technologist took the patient's history, which included the fact that she still had her thyroid. The technologist failed to seek clarification from the AU and did not review the AU's approval. The technologist proceeded with the whole body study using the I-131. Upon discovery of the error, the AU had an uptake study performed. The AU notified the patient and referring physician. Results of the uptake study revealed that the patient was thyrotoxic. The AU prescribed a therapy dose of 370 MBq (10 mCi) of I-131. An error in scheduling precipitated this event. The failure of the technologist to seek clarification and review the physician's order caused the event. Corrective actions included a requirement for verification of the prescription by two technologists and the need to consult with the AU if there are any questions regarding the ordered procedure.

Event Date: 12/29/2008 **Discovery Date:** 12/29/2008 **Report Date:** 01/05/2009

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:	Y	Abnormal Occurrence:	P
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: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Diagnostic Study: WHOLE BODY I-131/THYROID

Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 1.96 mCi 72.52 MBq

Intended:
Diagnostic Study: THYROID UPTAKE MEASUREMENT

Radiopharmaceutical: SODIUM IODIDE

% Dose Exceeds Prescribed: NR
% 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): I-131
Manufacturer: NR Activity: 0.00196 Ci 0.07252 GBq
Model Number: NA
Serial Number: NA

Reporting Requirements:
MD2
Reporting Requirement: 35.3045(a)(2)(i) - Administration of a wrong radioactive drug containing byproduct material that results in a dose that exceeds 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:
NY-669	04/01/2009		DCH	AGREEMENT STATE EVENT REPORT
NYDOH-09-04	04/01/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090412

Last Updated: 05/12/2009

Narrative:

During a routine audit of the nuclear medicine program on 3/27/2009, Medical Physics Consultants notified Regional Medical Imaging (RMI) that a patient received 0.57 GBq (15.5 mCi) of I-131 for the treatment of hyperthyroidism instead of the prescr bed 0.44 GBq (12 mCi) on 1/2/2009. As a result, the patient received 29.2% more dose than prescribed. When RMI requested the dose from the pharmacy, a 0.56 GBq (15 mCi) dose was mistakenly requested. When the patient arrived for treatment, the technologist preparing the dose measured it, but did not realize or confirm that it differed from the prescribed dose. RMI informed the patient and the referring physician of the incident. Corrective actions included modified procedures to include dual verification of the dosage to be administered versus the prescribed dosage and training personnel on the revised procedure.

Event Date: 01/02/2009 **Discovery Date:** 03/27/2009 **Report Date:** 03/27/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-26076-01	Name:	REGIONAL MEDICAL IMAGING
NRC Docket Number:	03031367	City:	FLINT
NRC Program Code:	02200	State: MI	Zip Code: 48532
Respons ble NRC Region:	3		

Site of Event:

Site Name: FLINT
State: MI

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	N	Investigation:	Y
Atomic Energy Act Material:	Y	NMED Record Complete:	Y
Consultant Hired:	Y	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
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 15.5 mCi 573.5 MBq Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 12 mCi 444 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 29.2
% 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): I-131
Manufacturer: NR Activity: 0.0155 Ci 0.5735 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:
EN44941	04/01/2009		DCH	EVENT NOTIFICATION
ML091250113	05/12/2009		RLS	INSPECTION REPORT
ML091250113	05/12/2009		RLS	NOTICE OF VIOLATION
ML091250113	05/12/2009		RLS	NRC LETTER

Item Number: 090395

Last Updated: 11/02/2009

Narrative:

Virtua Health System (VHS) reported that I-125 seeds were implanted outside the target organ during a prostate seed brachytherapy implant procedure performed on 1/19/2009. The incident was initially suspected on 2/23/2009 and was confirmed on 3/19/2009. None of the 93 seeds were implanted in the prostate gland. The seeds retained their planned pattern grouping, with the superior end of the seed cloud being approximately 2 cm from the apex of the prostate gland. The seeds appeared distal to the prostate and the dose appeared to be maximally confined to soft tissue, including muscle and subcutaneous fat. An NRC medical consultant concluded that the prostate did not receive sufficient dose to effectively treat the patient's cancer; the prostate received approximately 1,000 cGy (rad) instead of the intended 14,500 cGy (rad). The probability of other long-lasting negative health effects to the patient is low. This event was caused by the failure to adequately visualize and identify the prostate prior to implant. Corrective actions included procedure modification and personnel training. The INL has requested additional information for this event.

Event Date: 01/19/2009 **Discovery Date:** 03/19/2009 **Report Date:** 03/19/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	29-01862-02	Name:	VIRTUA HEALTH SYSTEM
NRC Docket Number:	03002443	City:	VOORHEES
NRC Program Code:	02120	State: NJ	Zip Code: 08043
Respons ble NRC Region:	1		

Site of Event:

Site Name: MARLTON
State: NJ

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:	Y	Abnormal Occurrence:	P
Agreement State Reportable Event:	N	Investigation:	Y
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: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 03/19/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 1000 rad 10 Gy

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

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 93
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 03/19/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PERI-PROSTATIC TISSUE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 14500 rad 145 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): I-125
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Reporting Requirements:
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 prescr bed 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:
EN44918	03/24/2009		DCH	EVENT NOTIFICATION
ML092520195	09/17/2009		RLS	INSPECTION REPORT
ML092950189	11/02/2009		RLS	NOTICE OF VIOLATION
ML092950189	11/02/2009		RLS	NRC LETTER

Item Number: 090391

Last Updated: 12/10/2009

Narrative:

Western Pennsylvania Hospital reported that a patient received an HDR mammosite treatment to the wrong site between 2/23 and 2/27/2009. The patient was to receive treatment twice a day for a total of 10 fractions with an expected dose of 3,400 cGy (rad) to the intended site. A [redacted] HDR [redacted] serial #VS353) was used, along with a 184.223 GBq (4.979 Ci) Ir-192 source. A dummy wire was inserted into the balloon to check and measure the tube length for dose calculations. A CT scan was performed daily to verify the position of the treatment site. Treatment calculations were performed, reviewed, and approved, and treatment began on 2/23/2009. On 2/27/2009, a different therapy physicist was checking the patient's charts and thought that there may have been an error. On 3/2/2009, the original physicist checked the findings and discovered that there had been an error in the placement of the source during treatments. The source was not fully inserted into the balloon, but was 3 cm from where it should have been. That incorrect source placement resulted in the tumor site only receiving 1,010 cGy (rad), 30% of the intended dose. An unintended site received the total treatment. The patient is being followed for any sequelae (pathological conditions) to the event. The oncologist discussed the event with the patient. Corrective actions included modifying the mammosite worksheet to add the expected catheter length of 95 cm beside the block where the measured catheter length is recorded, requiring that the catheter measurement wire be kept in place during CT simulation following catheter measurement, and reviewing and revising all mammosite policies and procedures to strengthen accuracy of measurement, planning, treatment, and quality control.

Event Date: 02/23/2009 **Discovery Date:** 03/02/2009 **Report Date:** 03/02/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	PA-0121	Name:	THE WESTERN PENNSYLVANIA HOSPITAL
NRC Docket Number:	NA	City:	ALLEGHENY
NRC Program Code:	NA	State: PA	Zip Code: 15224
Respons ble NRC Region:	1		

Site of Event:

Site Name: ALLEGHENY
State: PA

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

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:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 4979 mCi 184223 MBq Dose: 1010 rad 10.1 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 4979 mCi 184223 MBq Dose: 3400 rad 34 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 70
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 3400 rad 34 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): IR-192
Manufacturer: NR Activity: 4.979 Ci 184.223 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: VS353

Reporting Requirements:
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 prescr bed 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:

EN44911	03/24/2009	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PA090011	04/23/2009	DCH	AGREEMENT STATE EVENT REPORT
LTR090515	05/19/2009	DCH	AGREEMENT STATE LETTER
LTR090527	05/28/2009	DCH	AGREEMENT STATE LETTER
LTR091210	12/10/2009	DCH	AGREEMENT STATE LETTER

Item Number: 090385

Last Updated: 08/10/2009

Narrative:

Aurora Health Care (AHC) reported that a prostate brachytherapy implant patient was administered a dose of 14,500 cGy (rad) instead of the prescribed dose of 10,700 cGy (rad) on 3/9/2009. The event involved I-125 seeds (Bard Brachytherapy model STM1251) and occurred at the Lombardi Cancer Center, which is affiliated with AHC. AHC performs two types of prostate implant, one prescr bing approximately 14,500 cGy (rad) and one prescribing 67% of 14,500 cGy (rad). The procedure prescribing 67% is used when the patient receives separate external beam therapy. The patient had already received external beam therapy. A volume study was performed on the patient to determine the number of seeds required to deliver the intended dose to the prostate gland. The authorized user verbally informed the dosimetrist of his intent to perform a 67% strength therapy. That correction factor was omitted from the calculation during the seed ordering process, resulting in the number of seeds ordered being that for a 14,500 cGy (rad) procedure. That error was not identified during the review by two individuals. The patient was notified on 3/10/2009. The referring urologist and the patient's primary care provider were also notified. Several items of non-compliance were identified during the Wisconsin Department of Health Services (DHS) investigation. AHC did not have written directives signed and dated by an authorized user prior to therapy, the document being used as a written directive did not contain all information required in a directive, no written procedures were in place for permanent brachytherapy implants, there was no established criteria in place for releasing patients receiving permanent implants, and exposure rate surveys of the patient prior to release did not include listing the instrument used. Corrective actions included updating written directive and treatment planning forms, generating a procedure for permanent brachytherapy implants, revising patient survey records, and providing additional training to personnel. AHC also acted upon recommendations by DHS for improving their program.

Event Date: 03/09/2009 **Discovery Date:** 03/09/2009 **Report Date:** 03/10/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-117-1022-01	Name:	AURORA HEALTH CARE CENTRAL
NRC Docket Number:	NA	City:	SHEBOYGAN
NRC Program Code:	NA	State: WI	Zip Code: 53083
Respons ble NRC Region:	3		

Site of Event:

Site Name: SHEBOYGAN
State: WI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	NEW QUALITY MANAGEMENT PLAN
3	PERSONNEL RECEIVED ADDITIONAL TRAINING
4	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 03/10/2009

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 27.8 mCi 1028.6 MBq Dose: 14500 rad 145 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 25.7 mCi 950.9 MBq Dose: 10700 rad 107 Gy

% Dose Exceeds Prescribed: 35.51

% 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): I-125

Manufacturer: BARD BRACHYTHERAPY Activity: 0.0278 Ci 1.0286 GBq

Model Number: STM 1251

Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44895	03/17/2009		RLS	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI090003	03/23/2009		DCH	AGREEMENT STATE EVENT REPORT
WI090003A	06/01/2009		DCH	AGREEMENT STATE EVENT REPORT
WI090003B	08/10/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090381

Last Updated: 06/18/2009

Narrative:

The University of North Carolina Hospital (UNCH) reported that a patient only received an estimated 73.6% of a prescribed Y-90 microsphere dosage (lot #999019) on 3/5/2009. The prescribed dosage was 1.65 GBq (44.7 mCi) and it is estimated that approximately 1.22 GBq (32.9 mCi) was administered. The intended dose to the right lobe of the liver was 12,000 cGy (rad) with an estimated delivery dose of approximately 8,830 cGy (rad). Proper administration protocol was followed. Four flushes of the vial were performed. The dose vial was also inverted several times during the procedure to agitate and remove any microspheres, which sometimes remain in the vial. The patient was notified and there are no plans to perform a second administration. MDS Nordion was contacted and responded to the site on 3/19/2009, to assist in an investigation. MDS Nordion recommended that UNCH not invert the microsphere vial because that may cause the microspheres to adhere to the vial septum. They stated that tilting or tapping the bottom of the vial on a hard surface is still the best method for making sure the microspheres are washed from the septum. They also recommended promptly starting the administration once the catheter is in place. They stated that browning of the dose vial in this case suggests that microspheres did remain in the vial up and around the septum.

Event Date: 03/05/2009 **Discovery Date:** 03/05/2009 **Report Date:** 03/05/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NC-068-0565-1	Name:	UNIVERSITY OF NORTH CAROLINA HOSPITAL
NRC Docket Number:	NA	City:	CHAPEL HILL
NRC Program Code:	NA	State: NC	Zip Code: 27514
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHAPEL HILL
State: NC

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: OTHER

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 32.9 mCi 1217.3 MBq Dose: 8830 rad 88.3 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 44.7 mCi 1653.9 MBq Dose: 12000 rad 120 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 26.4
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: MDS NORDION, INC. Activity: 0.0447 Ci 1.6539 GBq
Model Number: THERASPHERE
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MDS NORDION, INC. Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44893	03/10/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN44893A	03/25/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC090017	06/18/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090198

Last Updated: 07/28/2009

Narrative:

City of Hope/Beckman Research Institute reported that a high dose rate (HDR) treatment was administered to the wrong site on 2/4/2009. The HDR [redacted] serial #600323) contained a 264.18 GBq (7.14 Ci) Ir-192 source (serial #02-01-1380-001-122308-10689-35). The patient was scheduled for groin sarcoma therapy treatment. The treatment planning comprised of administration of approximately 4,000 cGy (rad) to the tumor. The dose was to be administered in 10 fractions of 400 cGy/fraction (rad/fraction) at two fractions per day for five days. Six catheters were to be administered per fraction. An error was made in the interpretation of the CT data and the wrong distance was calculated. On 2/4/2009, the first day of treatment, the catheters administered went to the body, past the tumor site, then outside of the thigh. The RSO stated that there was no dose administered to the tumor; the entire dose was administered to the skin of the thigh. The patient received approximately 800 cGy (rad) to the skin of the thigh. Corrective actions included changing Radiation Oncology Department policy to require a walkthrough of procedures by all staff involved in the treatment plan and to require placement of brachytherapy buttons for HDR procedures (other than mammosite procedures), sending a memo to all medical physicists reminding them of the importance of fully reviewing all aspects of the treatment plan, and developing a checklist. In addition, [redacted] was informed of the error and asked to review their procedures and provide updates as necessary.

Event Date: 02/04/2009 **Discovery Date:** 02/05/2009 **Report Date:** 02/05/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CA-0307-19	Name:	CITY OF HOPE/BECKMAN RESEARCH INSTITUTE
NRC Docket Number:	NA	City:	DUARTE
NRC Program Code:	NA	State: CA	Zip Code: 91010
Respons ble NRC Region:	4		

Site of Event:

Site Name: DUARTE
State: CA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 7140 mCi 264180 MBq Dose: 800 rad 8 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: GROIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 7140 mCi 264180 MBq Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: GROIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 7140 mCi 264180 MBq Dose: 800 rad 8 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 7.14 Ci 264.18 GBq
Model Number: NR
Serial Number: 02011380001122308106

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 600323

Reporting Requirements:
MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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:
CA-XCA1363	02/12/2009		DCH	AGREEMENT STATE EVENT REPORT

EN44834	02/12/2009	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR090413	04/17/2009	DCH	AGREEMENT STATE LETTER
LTR090415	04/17/2009	DCH	AGREEMENT STATE LETTER
LTR090723	07/28/2009	DCH	AGREEMENT STATE LETTER

Item Number: 090151

Last Updated: 03/10/2009

Narrative:

The Charlotte-Meckenburg Hospital Authority (dba Carolinas Medical Center) reported that a patient received only 65% of the intended Y-90 Therasphere dose on 1/27/2009. The prescribed dose was 11,000 cGy (rad) using 1.67 GBq (45 mCi) of Y-90. However, the delivered dose was only 7,000 cGy (rad) using 1.07 GBq (29 mCi). The delivery apparatus was assembled according to manufacturer (MDS Nordion) instructions without incident. The treatment was initiated. During the first infusion, the authorized user noticed fluid leakage from the outlet flow line and needle insertion at the source vial. The RSO was contacted and an attempt was made to continue the infusion. The liquid continued to leak at the outlet flow line and needle junction. The procedure was terminated. The manufacturer was notified of the device problem on 1/28/2009. All liquid and contamination was contained by Radiation Safety personnel. This was the second treatment for the patient. The patient's doctor will decide whether an additional treatment is needed.

Event Date: 01/27/2009 **Discovery Date:** 01/27/2009 **Report Date:** 02/02/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NC-060-0014-3	Name:	CHARLOTTE-MECKLENBURG HOSPITAL
NRC Docket Number:	NA	City:	CHARLOTTE
NRC Program Code:	NA	State: NC	Zip Code: 28203
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHARLOTTE
State: NC

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR FAILED PART

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	EQUIPMENT RETURNED TO MANUFACTURER FOR REPAIR OR DISPOSAL

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 01/28/2009

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: LIVER

Radiopharmaceutical: NA

Radionuclide: Y-90 Activity: 29 mCi 1073 MBq Dose: 7000 rad 70 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: LIVER

Radiopharmaceutical: NA

Radionuclide: Y-90 Activity: 45 mCi 1665 MBq Dose: 11000 rad 110 Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 35.6

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90

Manufacturer: MDS NORDION, INC. Activity: 0.029 Ci 1.073 GBq

Model Number: THERASPHERE

Serial Number: AGGREGATE

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: APPLICATOR Model Number: NR

Manufacturer: MDS NORDION, INC. Serial Number: NR

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:
EN44823	02/05/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
EN44823A	02/09/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC090011	03/10/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090094

Last Updated: 04/14/2009

Narrative:

Mary Bird Perkins Cancer Center (MBPCC) reported that a patient received a high dose rate (HDR) brachytherapy treatment of 500 cGy (rad) to the wrong site. The HDR device [redacted], serial #VS331) utilized a 221.6 GBq (5.99 Ci) Ir-192 source [redacted] . The patient had completed 4,600 cGy (rad) of external beam radiation therapy on 9/11/2008, for papillary serous adenocarcinoma of the uterus. She was prescribed three HDR fractions, approximately 3 cm in length, at 500 cGy/fraction (rad/fraction). Prior to the patient's second HDR treatment on 1/2/2009, a review of the first HDR procedure revealed that the tandem was not fully inserted into the cylinder on 12/23/2008. The visualization on the CT scan of the placement of the tandem being partially inserted was not recognized by the planner or reviewer of the plan. The dwell positions were therefore placed in the airspace, where the tandem should have been inserted, versus at the retracted location. The first fraction was delivered approximately 6 cm distal to the intended site. The x-ray (port film) also showed the tandem not fully inserted into the cylinder. The patient received dose to the distal vagina versus the proximal vagina as prescribed. The radiation oncologist was immediately notified of the tandem placement after discovery. The prescribing physician (radiation oncologist) notified the patient and referring physician. The radiation oncologist decided to continue the third HDR fraction. Corrective actions included requiring the nurse that assembles the applicator to measure the tandem length outside the cylinder to ensure the tandem has been inserted properly, the dosimetry and physics staff will receive an in-service on CT images of proper and improper inserted tandems, and the physicists will begin looking at the pre-treatment x-ray (port film) along with the radiation oncologist prior to initiating treatment. The State is tracking the incident as number LA090007.

Event Date: 12/23/2008 **Discovery Date:** 01/02/2009 **Report Date:** 01/20/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	LA-2651-L01	Name:	MARY BIRD PERKINS CANCER CENTER
NRC Docket Number:	NA	City:	BATON ROUGE
NRC Program Code:	NA	State: LA	Zip Code: 70809
Respons ble NRC Region:	4		

Site of Event:

Site Name: BATON ROUGE
State: LA

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	Y	Investigation:	N
Atomic Energy Act Material:	Y	NMED Record Complete:	Y
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
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 500 rad 5 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 500 rad 5 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 5.99 Ci 221.63 GBq
Model Number: [redacted]
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: VS331

Reporting Requirements:
MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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:

EN44788	01/23/2009	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR090409	04/14/2009	DCH	AGREEMENT STATE LETTER

Item Number: 090079

Last Updated: 09/01/2010

Narrative:

The VA Medical Center reported that a patient, who had undergone permanent implant prostate seed brachytherapy using I-125 seeds (IsoAid model IAI-125A) on 12/18/2008, received less than 80% of the prescribed D90 dose to the treatment site. The incident occurred at the VA Medical Center in Durham, North Carolina, and was discovered on 1/15/2009. The treatment plan called for 81 seeds, each containing 13.32 MBq (0.36 mCi), for a total of 1.08 GBq (29.16 mCi). The intended prostate dose was 14,500 cGy (rad). A radiograph at the end of the procedure showed no evidence of seeds outside the target volume. The next morning, a CT of the patient's abdomen revealed that eight seeds had migrated inferior to the prostate. A CT performed on 12/23/2008 showed that four more seeds had migrated inferiorly. A CT performed on 1/15/2009 showed no further seed migration. The dose to the prostate was determined to be 8,200 cGy (rad), which is 56% of the prescribed dose. Doses to the bladder wall, rectum, and peri-prostatic tissue were evaluated for the seeds that migrated out of the target volume. Those doses were all below levels of concern (i.e. less than 150% of expected dose). The cause of the seed migration is unknown, so no corrective actions were planned or taken.

Event Date: 12/18/2008 **Discovery Date:** 01/15/2009 **Report Date:** 01/15/2009

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: DURHAM
State: NC

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: OTHER

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NO CORRECTIVE ACTION TAKEN

Patient Information:

Patient Number: 1

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 24.84 mCi 919.08 MBq Dose: 82 rad 0.82 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 29.16 mCi 1078.92 MBq Dose: 145 rad 1.45 Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 44

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: ISOAID, L.L.C. Activity: 0.02916 Ci 1.07892 GBq

Model Number: IAI-125A

Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44779	01/21/2009		DCH	EVENT NOTIFICATION
ML090290240	02/10/2009		RLS	LICENSEE REPORT
ML101440380	05/26/2010		RLS	INSPECTION REPORT
ML101440380	05/26/2010		RLS	NRC LETTER
LTR100708	07/15/2010		DCH	NRC LETTER
ML101880329	07/20/2010		RLS	ENFORCEMENT CONFERENCE
ML101880329	07/20/2010		RLS	NRC LETTER
ML101970407	08/16/2010		RLS	LICENSEE REPORT
ML102350127	08/24/2010		RLS	NOTICE OF VIOLATION
ML102350127	08/24/2010		RLS	NRC LETTER
ML102350261	08/24/2010		RLS	NRC NEWS ANNOUNCEMENT
ML102300006	09/01/2010		RLS	NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION
ML102430195	09/01/2010		RLS	LICENSEE REPORT

Item Number: 090076

Last Updated: 01/12/2010

Narrative:

The University of Pittsburgh Medical Center reported that a patient only received 43.8% of the prescribed Y-90 microspheres (Sirtex model SIR-Spheres) during a colorectal treatment on 12/4/2009. The patient was prescribed to receive 447.7 MBq (12.1 mCi) of Y-90, but only received 196.1 MBq (5.3 mCi). The treatment catheter became occluded and prevented further delivery of the SIR-Spheres. It was determined that blood clotted at the end of the catheter. Both the referring physician and the patient were notified of the incident.

Event Date: 12/04/2008 **Discovery Date:** 12/04/2008 **Report Date:** 12/05/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	PA-0190	Name:	UNIVERSITY OF PITTSBURGH MEDICAL CENTER
NRC Docket Number:	NA	City:	PITTSBURGH
NRC Program Code:	NA	State: PA	Zip Code: 15261
Respons ble NRC Region:	1		

Site of Event:

Site Name: PITTSBURGH
State: PA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: PATIENT OTHER

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	EQUIPMENT RETURNED TO MANUFACTURER FOR REPAIR OR DISPOSAL

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 12/04/2008

Given:

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

Radionuclide:	Y-90	Activity:	5.3 mCi	196.1 MBq	Dose:	NR rad	NR Gy

Intended:

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

Radionuclide:	Y-90	Activity:	12.1 mCi	447.7 MBq	Dose:	NR rad	NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 56.2
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	MICROSPHERES	Radionuclide or Voltage (kVp/MeV):	Y-90
Manufacturer:	SIRTEX MEDICAL	Activity:	0.0053 Ci 0.1961 GBq
Model Number:	SIR-SPHERES		
Serial Number:	AGGREGATE		

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	SIRTEX MEDICAL	Serial Number:	NR

Device Number: 2

Device Name:	CATHETER	Model Number:	NR
Manufacturer:	NR	Serial Number:	NA

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
PA080033	01/20/2009		DCH	AGREEMENT STATE EVENT REPORT
EN44800	01/26/2009		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR100107	01/12/2010		DCH	AGREEMENT STATE LETTER

Item Number: 090030

Last Updated: 01/13/2009

Narrative:

The Murray County Calloway Hospital reported that a patient received 14,500 cGy (rad) during a prostate I-125 seed implant procedure instead of the prescribed 11,000 cGy (rad). The implant procedure occurred on 9/18/2008. The incident was discovered on 12/15/2008 during a routine post review by the radiation technologist. The patient was notified on 12/16/2008, as well as the attending urologist. The cause of the incident was determined to be human error. Corrective actions taken by the hospital include procedure modifications. The hospital is performing a root cause analysis to determine additional modifications to be implemented. The INL has requested additional information for this event.

Event Date: 09/18/2008 **Discovery Date:** 12/15/2008 **Report Date:** 12/26/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	KY-202-120-26	Name:	MURRAY COUNTY CALLOWAY HOSPITAL
NRC Docket Number:	NA	City:	MURRAY
NRC Program Code:	NA	State: KY	Zip Code: 42071
Respons ble NRC Region:	1		

Site of Event:

Site Name: MURRAY
State: KY

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	Y	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: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 12/16/2008

Given:

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

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 11000 rad 110 Gy

% Dose Exceeds Prescribed: 31.8
% 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):	I-125	
Manufacturer:	NR	Activity:	NR Ci	NR GBq
Model Number:	NR			
Serial Number:	AGGREGATE			

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
KY080007	01/13/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 090019

Last Updated: 08/16/2010

Narrative:

Presbyterian Healthcare System reported that a patient received 1,495 cGy (rad) to the wrong cranial nerve during a gamma knife treatment on 12/2/2008. Essentially, the seventh cranial nerve was mistakenly targeted for treatment for a trigeminal procedure instead of the intended fifth cranial nerve. The treatment typically prescr bes an 8,000 cGy (rad) dose within a 4 mm sphere. The [redacted] gamma knife unit [redacted] serial #LJ 1-201), containing 125.8 TBq (3,400 Ci) of Co-60 [redacted], was improperly prepared and the wrong nerve was designated for treatment. Fortunately, the authorized neurosurgeon instructed the licensed medical physicist to pause the treatment 9.17 minutes into the 45 minute regime. He then consulted with the neuroradiologist on the case and they both determined that the slice used in the treatment plan was incorrect. It was concluded by the clinical staff that the root cause was a misidentification of the anatomical target site as listed on the written directive. The patient treatment continued on the correct anatomical site with success. Corrective actions included a change in the written procedures to include a verification of the target site by the neuroradiologist, and a modified written directive to document the new procedural change to ensure that the correct treatment site is targeted and treated. The department will conduct a review of at least 20% of past cases to ensure that the error had not occurred before.

Event Date: 12/02/2008 **Discovery Date:** 12/02/2008 **Report Date:** 12/03/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TX-L04288	Name:	PRESBYTERIAN HOSPITAL OF DALLAS
NRC Docket Number:	NA	City:	DALLAS
NRC Program Code:	NA	State: TX	Zip Code: 75231
Respons ble NRC Region:	4		

Site of Event:

Site Name: DALLAS
State: TX

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

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: 12/02/2008

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 3400000 mCi 125800000 MBq Dose: 20 rad 0.2 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 3400000 mCi 125800000 MBq Dose: 8000 rad 80 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 99.75
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 12/02/2008

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 3400000 mCi 125800000 MBq Dose: 1495 rad 14.95 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
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: [redacted] Activity: 3400 Ci 125800 GBq
Model Number: [redacted]
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: LJ 1-201

Reporting Requirements:
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 prescr bed 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:
TX080046	01/08/2009		DCH	AGREEMENT STATE EVENT REPORT

TX080046A	01/08/2009	DCH	AGREEMENT STATE EVENT REPORT
TX-I-8585	01/08/2009	DCH	AGREEMENT STATE EVENT REPORT
TX-I-8585A	01/08/2009	DCH	AGREEMENT STATE EVENT REPORT
LTR090311	03/24/2009	DCH	AGREEMENT STATE LETTER
EN45622	01/19/2010	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
TX-I-8585B	01/19/2010	DCH	AGREEMENT STATE EVENT REPORT
AS 09-04	08/16/2010	RLS	ABNORMAL OCCURRENCE NUMBER
ML102080078	08/16/2010	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 080896

Last Updated: 01/25/2010

Narrative:

The Chippenham & Johnston-Willis Hospital (dba CJW Medical Center) reported that a patient prescribed a gamma knife procedure to treat trigeminal neuralgia on the right side of the face was instead treated on the left side on 12/16/2008. The gamma knife [redacted] serial #4308) contained 121.88 TBq (3,294 Ci) of Co-60. The prescribed dose was 4,000 cGy (rad) to 50% isodose and the patient received 4,000 cGy (rad) to the wrong site. The patient was notified of the incident and elected to receive an additional treatment to the intended treatment site that same day. No adverse effects were observed or are expected. A site inspection was performed on 12/18/2009. The cause was determined to be human error and inadequate procedures in that they did not require verification of the treatment site. The treatment planning sheet had been mismarked as to the location of the treatment and review of the document did not identify the error. Corrective actions included implementing stricter verification procedures, requiring that the physician order accompany the patient during each phase of their treatment, and requiring that multiple individuals verify that the site referred to in the physician order matches the site being treated.

Event Date: 12/16/2008 **Discovery Date:** 12/16/2008 **Report Date:** 12/17/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	45-15249-01	Name:	CHIPPENHAM AND JOHNSTON-WILLIS HOSPITALS, INC.
NRC Docket Number:	03008805	City:	RICHMOND
NRC Program Code:	02310	State: VA	Zip Code: 23235
Respons ble NRC Region:	1		

Site of Event:

Site Name: RICHMOND
State: VA

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

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: 12/17/2008

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: FACE
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 3294000 mCi 121878000 MBq Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: FACE
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 3294000 mCi 121878000 MBq Dose: 4000 rad 40 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 12/17/2008

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: FACE
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 3294000 mCi 121878000 MBq Dose: 4000 rad 40 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
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: 3294 Ci 121878 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: GAMMA KNIFE UNIT
Model Number: [redacted]
Manufacturer: [redacted]
Serial Number: 4308

Reporting Requirements:
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 prescr bed 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:
EN44727	12/22/2008		DCH	EVENT NOTIFICATION

LTR090417	04/22/2009	DCH	NRC LETTER
LTR090622	06/26/2009	DCH	NRC LETTER
ML100220930	01/25/2010	RLS	NOTICE OF VIOLATION
ML100220930	01/25/2010	RLS	NRC LETTER

Item Number: 080803

Last Updated: 09/01/2010

Narrative:

The Department of Veterans Affairs reported that a patient received less than 80% of the prescribed D90 dose to the treatment site at the VA New York Harbor Healthcare System in Brooklyn, New York. The treatment involved permanent implant prostate brachytherapy using I-125 seeds to deliver a prescr bed dose of 144 Gy (14,400 rad). The patient was implanted on 9/18/2008. The implant consisted of preloaded needles containing 60 seeds, for a total activity of 1.01 GBq (27.18 mCi). As the authorized user withdrew two needles to place seeds in the anterior region of the prostate, he believed that he had failed to advance the plungers prior to withdrawing the needles. As a result, three seeds were mistakenly placed in the patient's perineum and two seeds had to be removed from the patient's perineal skin. The authorized user attempted to implant additional seeds to compensate for this error. A post-plan review on 10/10/2008 determined that the administered dose was 69% of the D90 dose. A supplemental implant procedure of ten additional seeds was performed on 10/30/2008 in order to achieve an acceptable D90 dose. The dose to the patient's peri-prostatic tissues was calculated to be 152 Gy (15,200 rad). As a result of an ongoing review of the incident involved in NMED Item 080296, it was determined that this was a reportable event on 11/17/2008. This event occurred because three seeds were placed lower in the prostate region than intended.

Event Date: 09/18/2008 **Discovery Date:** 10/10/2008 **Report Date:** 11/18/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

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

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:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 27.18 mCi 1005.66 MBq Dose: 9936 rad 99.36 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 27.18 mCi 1005.66 MBq Dose: 14400 rad 144 Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 31

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: BARD BRACHYTHERAPY Activity: 0.02718 Ci 1.00566 GBq

Model Number: STM 1251

Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44663	11/24/2008		DCH	EVENT NOTIFICATION
ML083370167	12/08/2008		RLS	LICENSEE REPORT
ML083380327	12/09/2008		RLS	LICENSEE REPORT
ML101440380	05/26/2010		RLS	INSPECTION REPORT
ML101440380	05/26/2010		RLS	NRC LETTER
LTR100603	06/09/2010		DCH	NRC LETTER
LTR100629	07/08/2010		DCH	NRC LETTER
ML101880329	07/20/2010		RLS	ENFORCEMENT CONFERENCE
ML101880329	07/20/2010		RLS	NRC LETTER
ML101970407	08/16/2010		RLS	LICENSEE REPORT
ML102350127	08/24/2010		RLS	NOTICE OF VIOLATION
ML102350127	08/24/2010		RLS	NRC LETTER
ML102350261	08/24/2010		RLS	NRC NEWS ANNOUNCEMENT
ML102300006	09/01/2010		RLS	NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION
ML102430195	09/01/2010		RLS	LICENSEE REPORT

Item Number: 080707

Last Updated: 08/16/2010

Narrative:

Saint Mary's Medical Center (SMMC) reported that a patient received an unintended dose of 1,798 cGy (rad) to the esophagus. The patient was being treated for a thyroid condition with a capsule containing 5.58 GBq (150.7 mCi) of I-131. The patient attempted to swallow the capsule on 10/15/2008, but it became lodged in the patient's throat due to an esophageal obstruction. SMMC staff attempted to aid the patient in swallowing the capsule by providing soda and applesauce. The patient coughed up the soda and applesauce, which were surveyed and found to be radioactive. More soda and applesauce were given to dissolve the capsule, which eventually passed the obstruction after approximately 2.5 hours. If the capsule had not become lodged in the esophagus, the esophagus would have received a dose of 1,012 cGy (rad). Therefore, this event resulted in an additional dose to the esophagus of 786 cGy (rad), or 77.7% more than intended. The event was discussed with the patient during a follow-up visit with the physician on 10/22/2008. Potential adverse effects include esophagitis and radiation fibrosis. This event was caused human error in failing to recognize that the esophageal obstruction might interfere with the patient's ability to swallow the capsule. Corrective actions included procedure modification to include a pre-therapy esophageal dilation for patients known to have difficulty swallowing. Also, patients known to have difficulty swallowing will be evaluated for other options, like smaller capsules, liquid I-131, etc. An NRC medical consultant concluded that no significant adverse effect to the patient is expected.

Event Date: 10/15/2008 **Discovery Date:** 10/15/2008 **Report Date:** 10/22/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	47-09576-01	Name:	SAINT MARY'S MEDICAL CENTER
NRC Docket Number:	03003388	City:	HUNTINGTON
NRC Program Code:	02120	State: WV	Zip Code: 25702
Respons ble NRC Region:	1		

Site of Event:

Site Name: HUNTINGTON
State: WV

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:	Y	Abnormal Occurrence:	Y
Agreement State Reportable Event:	N	Investigation:	Y
Atomic Energy Act Material:	Y	NMED Record Complete:	Y
Consultant Hired:	Y	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: 10/22/2008

Given:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: ESOPHAGUS
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 150.7 mCi 5575.9 MBq Dose: 1798 rad 17.98 Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: ESOPHAGUS
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 150.7 mCi 5575.9 MBq Dose: 1012 rad 10.12 Gy

% Dose Exceeds Prescribed: 77.7
% 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): I-131
Manufacturer: NR Activity: 0.1507 Ci 5.5759 GBq
Model Number: NA
Serial Number: NA

Reporting Requirements:

MD2

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:
EN44589	10/28/2008		DCH	EVENT NOTIFICATION
ML083190312	11/20/2008		RLS	OTHER
ML090160532	02/02/2009		RLS	LICENSEE REPORT
ML090160532	02/02/2009		RLS	REGION REPORT
ML090430194	02/20/2009		RLS	NRC LETTER
ML090430207	02/20/2009		RLS	INSPECTION REPORT
09-01	08/16/2010		RLS	ABNORMAL OCCURRENCE NUMBER
ML102080078	08/16/2010		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 080694

Last Updated: 08/16/2010

Narrative:

Saint Vincent's Medical Center reported that a patient received 3,400 cGy (rad) to unintended tissue during several breast cancer therapy treatments from 9/10 to 9/17/2008. The patient was being treated with a high dose rate (HDR) afterloader unit [redacted] serial #31318) containing a 199.8 GBq (5.4 Ci) Ir-192 source. Symptoms of erythema were identified by the patient on10/16/2009. The medical physicist reviewed the records and determined that the HDR afterloader was programmed with an incorrect catheter length, causing the source to stop 10 cm short of the intended tumor site in the right breast. As a result, the entire dose intended for the tumor was administered to the skin of the left breast, which was not intended to be treated. The authorized user concluded that no chronic health effect to the patient was expected. The Commonwealth of Florida dispatched an inspector to the facility to investigate the incident. Corrective actions included generating a catheter worksheet, requiring that two individuals measure the length of the catheter, requiring that both the physicist and physician review the worksheet, and requiring that the length of the catheter be measured a second time prior to each treatment.

Event Date: 09/10/2008 **Discovery Date:** 10/16/2008 **Report Date:** 10/17/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-0014-6	Name:	SAINT VINCENT'S MEDICAL CENTER, INC.
NRC Docket Number:	NA	City:	JACKSONVILLE
NRC Program Code:	NA	State: FL	Zip Code: 32203
Respons ble NRC Region:	1		

Site of Event:

Site Name: JACKSONVILLE
State: FL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 5400 mCi 199800 MBq Dose: 3400 rad 34 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: U Date Informed:

Given:
A therapeutic procedure/diagnostic study was not given.

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 5400 mCi 199800 MBq Dose: 3400 rad 34 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 5.4 Ci 199.8 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31318

Reporting Requirements:
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 prescr bed 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:

EN44578	10/22/2008	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR090210	02/10/2009	DCH	AGREEMENT STATE LETTER
FL08-138	02/26/2009	DCH	AGREEMENT STATE EVENT REPORT
AS 09-03	08/16/2010	RLS	ABNORMAL OCCURRENCE NUMBER
ML102080078	08/16/2010	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 080693

Last Updated: 04/23/2009

Narrative:

The University of Mississippi Medical Center reported that a patient prescribed to receive 2 GBq (54 mCi) of Y-90 SIR-Spheres only received approximately 1.5 GBq (40.5 mCi). The patient was to receive 1 GBq (27 mCi) instilled into the right hepatic artery and 1 GBq (27 mCi) instilled into the left hepatic artery. After instilling 1 GBq (27 mCi) into the right hepatic artery, a smaller catheter was used to instill the Y-90 into the left hepatic artery, due to anatomy concerns and to get to the segment feeding the hepatic tumor. While attempting to instill the Y-90 into the left hepatic artery, over-pressurization caused the three-way valve in the containment box to give way and resulted in the release of 50% of the 1 GBq (27 mCi) dose into the containment box. The procedure was terminated and the delivery box was bagged and held for decay in storage. The patient and referring physician were notified of the incident and of additional future treatment. The cause is believed to be the size of catheter, a kink in the catheter, or the smaller syringe used. As a result, the treatment team will review the delivery system setup before pressure is applied to ensure the flow of the SIR-Spheres will not be impeded within the catheter.

Event Date: 10/09/2008 **Discovery Date:** 10/09/2008 **Report Date:** 10/10/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	MS-MBL-01	Name:	UNIVERSITY OF MISSISSIPPI MEDICAL CENTER
NRC Docket Number:	NA	City:	JACKSON
NRC Program Code:	NA	State: MS	Zip Code: 39216
Respons ble NRC Region:	4		

Site of Event:

Site Name: JACKSON
State: MS

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

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:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 54 mCi 1998 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 25
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: SIRTEX MEDICAL Activity: 0.054 Ci 1.998 GBq
Model Number: SIR-SPHERES
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: SIRTEX MEDICAL Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44577	10/22/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR090422	04/23/2009		DCH	AGREEMENT STATE LETTER

Item Number: 080646

Last Updated: 09/15/2010

Narrative:

The Department of Veterans Affairs (VA) reported that seven patients prescr bed permanent implant prostate brachytherapy procedures at the VA Medical Center in Cincinnati, Ohio, received D90 doses less than 80% of the prescribed doses using I-125 seeds. However, the doses for three of the patients were later determined to not meet the reportability criteria. Three of the medical events were discovered on 10/7/2008 as a result of an ongoing review of the incident involved in NMED Item 080296. The fourth medical event was discovered on 7/22/2009 and involved an implant performed on 5/22/2008. The D90 doses for all four patients were based on CT scans performed one day after the implants, when the prostate is subject to edema from the procedure that often causes underestimation of the true D90. Thus, most, if not all of these patients likely received clinically adequate dose distributions. No adverse biological effects to these patients are expected. The prostate brachytherapy program was suspended in October 2008 pending further review. Corrective actions included procedure modification. On March 30, 2010, the prostate brachytherapy program was resumed.

Event Date: 10/07/2008 **Discovery Date:** 10/07/2008 **Report Date:** 10/07/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: CINCINNATI
State: OH

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

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:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12600 rad 126 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 32.58 mCi 1205.46 MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 21.25
Effect on Patient:

Patient Number: 2
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12800 rad 128 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 28.18 mCi 1042.66 MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 20
Effect on Patient:

Patient Number: 3
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12200 rad 122 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 37.26 mCi 1378.62 MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 23.75
Effect on Patient:

Patient Number: 4
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 11200 rad 112 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 22.21 mCi 821.77 MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 30
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: MEDI+PHYSICS Activity: 0.03258 Ci 1.20546 GBq
Model Number: 6711
Serial Number: AGGREGATE

Source Number: 2
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: MEDI+PHYSICS Activity: 0.02785 Ci 1.03045 GBq
Model Number: 6711
Serial Number: AGGREGATE

Source Number: 3
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: MEDI+PHYSICS Activity: 0.03726 Ci 1.37862 GBq
Model Number: 6711
Serial Number: AGGREGATE

Source Number: 4
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: MEDI+PHYSICS Activity: 0.02221 Ci 0.82177 GBq
Model Number: 6711
Serial Number: AGGREGATE

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44548	10/14/2008		DCH	EVENT NOTIFICATION
ML082880041	11/03/2008		RLS	LICENSEE REPORT
ML082880717	11/03/2008		RLS	CONFIRMATORY ACTION LETTER
ML082890402	11/03/2008		RLS	NRC NEWS ANNOUNCEMENT
ML083030638	12/08/2008		RLS	LICENSEE REPORT
EN44548A	07/27/2009		DCH	EVENT NOTIFICATION
ML092160948	08/17/2009		RLS	LICENSEE REPORT
ML101440380	05/26/2010		RLS	INSPECTION REPORT
ML101440380	05/26/2010		RLS	NRC LETTER
LTR100603	06/09/2010		DCH	NRC LETTER

LTR100629	07/08/2010	DCH	NRC LETTER
ML101880329	07/20/2010	RLS	ENFORCEMENT CONFERENCE
ML101880329	07/20/2010	RLS	NRC LETTER
ML101970407	08/16/2010	RLS	LICENSEE REPORT
ML102350127	08/24/2010	RLS	NOTICE OF VIOLATION
ML102350127	08/24/2010	RLS	NRC LETTER
ML102350261	08/24/2010	RLS	NRC NEWS ANNOUNCEMENT
ML102300006	09/01/2010	RLS	NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION
ML102430195	09/01/2010	RLS	LICENSEE REPORT
ML101650788	09/15/2010	RLS	ENFORCEMENT CONFERENCE
ML102520231	09/15/2010	RLS	INSPECTION REPORT
ML102520231	09/15/2010	RLS	NRC LETTER

Item Number: 080606

Last Updated: 10/05/2010

Narrative:

The Department of Veterans Affairs (VA) reported that ten patients prescribed permanent implant prostate brachytherapy procedures at the G.V. (Sonny) Montgomery VA Medical Center in Jackson, Mississippi, received D90 doses less than 80% of the prescribed doses. The prescribed dose for each patient was 145 Gy (14,500 rad) using I-125 seeds and occurred between 4/6/2005 and 8/25/2008. Seven of these medical events were discovered on 9/24/2008 as a result of a review of the incident involved in NMED Item 080296; the other three medical events were identified during subsequent reviews. It was later determined that only six of the events were reportable. The permanent implant prostate seed brachytherapy program at this medical center was terminated on 5/4/2009. The medical center believes that the medical events were the result a disagreement between two physicians regarding the exact size of the prostate during re-contouring and not due to misplaced seeds. The re-contouring resulted in a decrease of the administered dose to the treatment site to less than 80% of the prescribed dose. An NRC investigation determined that these events were caused by inadequate procedures. Corrective actions included procedure modification.

Event Date: 09/24/2008 **Discovery Date:** 09/24/2008 **Report Date:** 09/25/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: JACKSON
State: MS

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 09/26/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 11020 rad 110.2 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 30.24 mCi 1118.88 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 24
Effect on Patient:

Patient Number: 2
Patient Informed: Y Date Informed: 09/26/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 8120 rad 81.2 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 32.89 mCi 1216.93 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 44
Effect on Patient:

Patient Number: 3
Patient Informed: Y Date Informed: 09/26/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 10300 rad 103 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 23.81 mCi 880.97 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 29
Effect on Patient:

Patient Number: 4
Patient Informed: Y Date Informed: 10/10/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 10880 rad 108.8 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 32.74 mCi 1211.38 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 25
Effect on Patient:

Patient Number: 5
Patient Informed: Y Date Informed: 10/30/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 8850 rad 88.5 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 29.11 mCi 1077.07 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 39
Effect on Patient:

Patient Number: 6
Patient Informed: Y Date Informed: 12/17/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 8850 rad 88.5 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 30.26 mCi 1119.62 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 39
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY
Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY
Activity: 0.02986 Ci 1.10482 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 2

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY
Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY
Activity: 0.03553 Ci 1.31461 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 3

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY
Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY
Activity: 0.02155 Ci 0.79735 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 4

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY
Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY
Activity: 0.03274 Ci 1.21138 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 5

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY
Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY
Activity: 0.02911 Ci 1.07707 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 6

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY
Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY
Activity: 0.03026 Ci 1.11962 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44522	10/01/2008		DCH	EVENT NOTIFICATION
EN44522A	10/09/2008		DCH	EVENT NOTIFICATION
ML082880656	10/27/2008		RLS	LICENSEE REPORT
EN44522B	10/31/2008		DCH	EVENT NOTIFICATION
ML082880041	11/03/2008		RLS	LICENSEE REPORT
ML082880717	11/03/2008		RLS	CONFIRMATORY ACTION LETTER
ML082890402	11/03/2008		RLS	NRC NEWS ANNOUNCEMENT
ML083010509	12/08/2008		RLS	LICENSEE REPORT
ML083150936	12/08/2008		RLS	LICENSEE REPORT
EN44522C	12/18/2008		DCH	EVENT NOTIFICATION
ML082831719	08/03/2009		RLS	LICENSEE REPORT
ML082970886	09/28/2009		RLS	LICENSEE REPORT
ML100601306	03/09/2010		RLS	LICENSEE REPORT
ML101440380	05/26/2010		RLS	INSPECTION REPORT
ML101440380	05/26/2010		RLS	NRC LETTER
LTR100603	06/09/2010		DCH	NRC LETTER
LTR100629	07/08/2010		DCH	NRC LETTER
ML101880329	07/20/2010		RLS	ENFORCEMENT CONFERENCE

ML101880329	07/20/2010	RLS	NRC LETTER
ML101970407	08/16/2010	RLS	LICENSEE REPORT
ML102350127	08/24/2010	RLS	NOTICE OF VIOLATION
ML102350127	08/24/2010	RLS	NRC LETTER
ML102350261	08/24/2010	RLS	NRC NEWS ANNOUNCEMENT
ML102300006	09/01/2010	RLS	NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION
ML102430195	09/01/2010	RLS	LICENSEE REPORT
EN46236	09/15/2010	DCH	EVENT NOTIFICATION
ML101650788	09/15/2010	RLS	ENFORCEMENT CONFERENCE
ML102520333	09/15/2010	RLS	INSPECTION REPORT
ML102520333	09/15/2010	RLS	NRC LETTER
ML102660637	10/05/2010	RLS	LICENSEE REPORT

Item Number: 080555

Last Updated: 02/01/2010

Narrative:

Lehigh Valley Hospital reported that a patient prescribed to receive 0.74 GBq (20 mCi) of I-131 was administered 2.78 GBq (75 mCi) of I-131 on 7/17/2008. Two patients were scheduled for different I-131 therapy doses and the doses were switched. The patient was given a blocking agent of 130 mg potassium iodide approximately one hour after the I-131 administration. The next day, measurements indicated a 74 MBq (2 mCi) uptake to the patient's thyroid and a 370 MBq (10 mCi) whole body retention, resulting in a thyroid dose of 2,600 cGy (rad) and a whole body effective dose equivalent of 8.7 cGy (rad). Both patients and their physicians were notified. Because of the administration of potassium iodide, no significant adverse health effect to the patient is expected. Corrective actions included procedure modifications.

Event Date: 07/17/2008 **Discovery Date:** 07/17/2008 **Report Date:** 07/17/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	PA-0232	Name:	LEHIGH VALLEY HOSPITAL
NRC Docket Number:	NA	City:	ALLENTOWN
NRC Program Code:	NA	State: PA	Zip Code: 18105
Respons ble NRC Region:	1		

Site of Event:

Site Name: ALLENTOWN
State: PA

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

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: 07/17/2008

Given:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: 2600 rad 26 Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 20 mCi 740 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 275
% 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):	I-131		
Manufacturer:	NR	Activity:	0.075 Ci	2.775	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:
PA080021	09/17/2008		DCH	AGREEMENT STATE EVENT REPORT
AS 08-05	06/10/2009		RLS	ABNORMAL OCCURRENCE NUMBER
ML091540747	06/10/2009		RLS	ABNORMAL OCCURRENCE NUMBER
EN45656	02/01/2010		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

Item Number: 080508

Last Updated: 12/02/2008

Narrative:

The University of Virginia Medical Center reported that a male patient, prescribed to receive 1.83 GBq (49.46 mCi) of Y-90 TheraSpheres (Nordion) to the right liver lobe for liver cancer, only received 37% to the target organ on 8/28/2008. The written directive specified a radiation dose to the right liver lobe of 9,200 cGy (rad). However, the authorized user failed to turn the blue stopcock on the delivery device, which directed the majority of the TheraSpheres into the waste vial instead of into the patient. From waste container measurements, it was determined that 0.68 GBq (18.38 mCi) was implanted into the patient's right liver lobe, with 0.12 GBq (3.24 mCi) going to the patient's lungs. Therefore, 1.03 GBq (27.84 mCi) went into the waste vial. The calculated dose was 3,430 cGy (rad) to the patient's liver. The calculated dose to the patient's lungs was 1,320 cGy (rad), which was less than they would have received had the procedure been performed correctly. The INL has requested additional information for this event.

Event Date: 08/28/2008 **Discovery Date:** 08/28/2008 **Report Date:** 08/29/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	45-00034-26	Name:	UNIVERSITY OF VIRGINIA
NRC Docket Number:	03003296	City:	CHARLOTTESVILLE
NRC Program Code:	02110	State: VA	Zip Code: 22903
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHARLOTTESVILLE
State: VA

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:	Y	Abnormal Occurrence:	N
Agreement State Reportable Event:	N	Investigation:	Y
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: HUMAN ERROR

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: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 3430 rad 34.3 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 49.46 mCi 1830.02 MBq Dose: 9200 rad 92 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 63
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: MDS NORDION, INC. Activity: 0.04946 Ci 1.83002 GBq
Model Number: THERASPHERE
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MDS NORDION, INC. Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44449	09/04/2008		DCH	EVENT NOTIFICATION
ML083250273	12/02/2008		RLS	NOTICE OF VIOLATION
ML083250273	12/02/2008		RLS	NRC LETTER

Item Number: 080460

Last Updated: 10/16/2008

Narrative:

Cleveland Clinic Foundation reported a possible medical event due to an equipment malfunction on 8/7/2008. A patient was being treated for rectal cancer using a [redacted] high dose rate remote afterloading brachytherapy unit [redacted] serial #A943623) and a 379.62 GBq (10.26 Ci) Ir-192 source [redacted], serial #D36B-5073). The prescribed treatment consisted of the administration of 29 catheter doses of Ir-192. During the 12th catheter dose, an equipment malfunction caused a failure of the administered treatment. The failure mode was code 200; "no radiation detected." The failure mode caused the unit to stop treatment by not proceeding to the next catheter. The patient and physician were notified of the incident on 8/7/2008. [redacted] was immediately contacted. A service technician responded on 8/8/2008 to repair of the unit. The cause was determined to be a failed radiation detector in the HDR unit, which caused the source to retract and stop further treatment. The part was replaced and checked for proper operation. The patient's written directive and treatment plans were revised and the patient received the full dose as indicated in the revised directive. The State of Ohio sent an inspector to the facility on 8/11/2008.

Event Date: 08/07/2008 **Discovery Date:** 08/07/2008 **Report Date:** 08/08/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02110180013	Name:	CLEVELAND CLINIC FOUNDATION
NRC Docket Number:	NA	City:	CLEVELAND
NRC Program Code:	NA	State: OH	Zip Code: NR
Respons ble NRC Region:	3		

Site of Event:

Site Name: CLEVELAND
State: OH

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

Event Type:

EQP - EQUIPMENT
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: DEFECTIVE OR FAILED PART

MD2
Cause: DEFECTIVE OR FAILED PART

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	REPAIRS MADE WITHOUT ENGINEERING CHANGE TO SYSTEM
MD2	
1	REPAIRS MADE WITHOUT ENGINEERING CHANGE TO SYSTEM

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 08/07/2008

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 10260 mCi 379620 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): IR-192
Manufacturer: [redacted] Activity: 10.26 Ci 379.62 GBq
Model Number: [redacted]
Serial Number: D36B-5073

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 10.26 Ci 379.62 GBq
Model Number: [redacted]
Serial Number: D36B-5073

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: A943623

MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: A943623

Reporting Requirements:
EQP
Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

MD2
Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44397	08/13/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH080002	10/09/2008		DCH	AGREEMENT STATE EVENT REPORT
OH080002A	10/16/2008		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 080406

Last Updated: 01/14/2009

Narrative:

The University of Wisconsin reported that a patient being treated with high dose rate (HDR) partial breast irradiation to the right breast, using a [redacted] balloon, did not receive her first fraction of 365 cGy (rad). The patient was prescribed to receive nine fractions for a total dose of 3,285 cGy (rad) to the planning target volume. After the planning was complete, the length of each of the five catheters was measured using the [redacted] Source Position Simulator. The readings were found to be 1,154 mm each. The treatment file in the HDR treatment console was modified from its default value of 1,500 mm to 1,154 mm and the patient was treated. Her first fraction was intended to be delivered on 7/14/2008 on HDR unit A [redacted] serial #31282) using a 222.74 GBq (6.02 Ci) Ir-192 source [redacted] serial #D36B-5080). On 7/15/2008, the patient s second fraction was scheduled to be delivered on HDR unit B. Since the Ir-192 sources were different in activity, a total time check was performed and the measured catheter lengths were compared. The [redacted] Source Position Simulator was checked and it was noted that there was an obstruction at the 1,154 mm reading. Review of the actual delivered dose during the first fraction revealed that the source did not enter the patient's body. A small region of the skin surface received some radiation dose, but the clinical impact was insignificant. Investigation of the [redacted] Source Position Simulator revealed that a welded junction in the cable of the measuring device was kinked. It was immediately replaced with a new one. The kinked one was returned to the manufacturer for analysis. The University also developed a new quality assurance procedure and form, which will be exclusively used for [redacted] balloons and incorporates the expected length for the five catheters. The patient and referring physician were notified of the incident on 7/15/2008.

Event Date: 07/14/2008 **Discovery Date:** 07/15/2008 **Report Date:** 07/16/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-025-1323-01	Name:	UNIVERSITY OF WISCONSIN
NRC Docket Number:	NA	City:	MADISON
NRC Program Code:	NA	State: WI	Zip Code: 53715
Respons ble NRC Region:	3		

Site of Event:

Site Name: MADISON
State: WI

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

Event Type:

EQP - EQUIPMENT
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: DEFECTIVE OR FAILED PART

MD2
Cause: DEFECTIVE OR FAILED PART

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	NEW EQUIPMENT OBTAINED
2	NEW QUALITY MANAGEMENT PLAN
3	PROCEDURE MODIFIED
MD2	
1	NEW EQUIPMENT OBTAINED
2	NEW QUALITY MANAGEMENT PLAN
3	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 07/15/2008

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6020 mCi 222740 MBq Dose: 365 rad 3.65 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): IR-192
Manufacturer: NUCLETRON Activity: 6.02 Ci 222.74 GBq
Model Number: 105.002
Serial Number: D36B-5080

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NUCLETRON Activity: 6.02 Ci 222.74 GBq
Model Number: 105.002
Serial Number: D36B-5080

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31282

Device Number: 2
Device Name: CATHETER Model Number: NR
Manufacturer: NR Serial Number: NR

MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31282

Device Number: 2
Device Name: CATHETER Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
EQP
Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

MD2
Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:
Reference Number: **Entry Date:** **Retraction Date:** **Coder Initials:** **Reference Type:**

EN44353	07/23/2008	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI080018	09/02/2008	DCH	AGREEMENT STATE EVENT REPORT
WI080018A	11/11/2008	DCH	AGREEMENT STATE EVENT REPORT
WI080018B	01/14/2009	DCH	AGREEMENT STATE EVENT REPORT

Item Number: 080380

Last Updated: 09/18/2008

Narrative:

Baylor University Medical Center (BUMC) reported that a patient being treated with Y-90 Therasphere microspheres (MDS Nordion) on 7/2/2008 for liver cancer only received 49.58 MBq (1.34 mCi) instead of the prescribed 495.8 MBq (13.4 mCi). When the microspheres were delivered, the three-way stopcock was set erroneously and almost the entire dose was collected in the vent vial. Attempts to recover and deliver the misdirected dose were very limited. Post-administration, the residual activity in the original dose vial, the vent vial, and contaminated effects (catheter line, tubing, needles, towels, gauze pads, etc.) totaled 445.85 MBq (12.05 mCi). Therefore, the estimated administered activity was approximately 49.58 MBq (1.34 mCi). That translates to a delivered dose of approximately 870 cGy (rad) instead of the prescr bed 10,000 cGy (rad) to the treatment site, or 8.7% of the prescribed dose. Corrective actions included procedure modifications that now require two independent verifications of the correct set-up of equipment prior to administration. BUMC is continuing the investigation.

Event Date: 07/02/2008 **Discovery Date:** 07/02/2008 **Report Date:** 07/03/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TX-L01290	Name:	BAYLOR UNIVERSITY MEDICAL CENTER
NRC Docket Number:	NA	City:	DALLAS
NRC Program Code:	NA	State: TX	Zip Code: 75226
Respons ble NRC Region:	4		

Site of Event:

Site Name: DALLAS
State: TX

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

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: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 870 rad 8.7 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 13.4 mCi 495.8 MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 91.3
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: MDS NORDION, INC. Activity: 0.00134 Ci 0.04958 GBq
Model Number: THERASPHERE
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MDS NORDION, INC. Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44335	07/09/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
TX080018	07/09/2008		DCH	AGREEMENT STATE EVENT REPORT
TX-I-8522	07/09/2008		DCH	AGREEMENT STATE EVENT REPORT
TX080018B	09/18/2008		DCH	AGREEMENT STATE EVENT REPORT
TX-I-8522B	09/18/2008		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 080371

Last Updated: 10/01/2008

Narrative:

The Regents of the University of California – Los Angeles (UCLA) reported a 50% under dose to a patient prescribed to receive 300 cGy (rad) during whole body irradiation using a Co-60 teletherapy unit [redacted] serial #001) on 6/23/2008. The Co-60 sources contained a total activity of 138.08 TBq (3,732 Ci). The prescription was for total body irradiation at 17.12 minutes anterior posterior (AP), then 17.13 minutes AP, then 17.12 minutes posterior anterior (PA), then 17.13 minutes PA. The therapist only treated 17.13 minutes AP and 17.13 minutes PA for a total dose of 150 cGy (rad). The patient was seen by the attending physician on 6/25/2008. There is no plan to re-treat the patient. The attending physician and patient have been notified. The cause of the incident was determined to be human error; the therapist misread the treatment sheet. Corrective actions included revising the treatment sheet to specifically indicate the treatment times from the AP and PA directions, revising the split times per side to include the total treatment time from each side, counseling the therapist, verifying treatment records by two treating therapists, and training all therapy personnel on revised forms and procedures. The State of California is tracking the incident as number 062508.

Event Date: 06/23/2008 **Discovery Date:** 06/25/2008 **Report Date:** 06/25/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CA-1335-19	Name:	REGENTS OF THE UNIVERSITY OF CALIFORNIA - LA
NRC Docket Number:	NA	City:	LOS ANGELES
NRC Program Code:	NA	State: CA	Zip Code: 90095
Respons ble NRC Region:	4		

Site of Event:

Site Name: LOS ANGELES
State: CA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: INATTENTION TO DETAIL

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: TELETHERAPY
Organ: WHOLE BODY
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: 150 rad 1.5 Gy

Intended:
Therapeutic Procedure: TELETHERAPY
Organ: WHOLE BODY
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 3732000 mCi 138084000 MBq Dose: 300 rad 3 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 50
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE TELETHERAPY Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: NR Activity: 3732 Ci 138084 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: TELETHERAPY UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 001

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44321	07/03/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080718	07/22/2008		DCH	AGREEMENT STATE LETTER
LTR080722	07/23/2008		DCH	AGREEMENT STATE LETTER
LTR080926	10/01/2008		DCH	AGREEMENT STATE LETTER

Item Number: 080337

Last Updated: 06/10/2009

Narrative:

Bon Secours Virginia Health Source reported that a patient received doses differing from prescribed during a breast cancer treatment using high dose rate (HDR) mammosite balloon brachytherapy on 5/1/2008. The patient was prescribed 10 fractions using a 165.4 GBq (4.47 Ci) Ir-192 source [redacted] serial #B36B-6017). The HDR [redacted] serial #D36B-4935) was manufactured by [redacted] The target site was prescr bed to receive 340 cGy (rad) during each fraction, for a total dose of 3,400 cGy (rad). During administration of the first fraction, the physicist received an error message from the HDR computer indicating friction or obstruction in the HDR catheter. The cause of the error message was not investigated and the physicist attempted to resolve the problem by incorrectly changing the catheter length value at the treatment console by 20 mm instead of the intended 2 mm. This event was identified during a subsequent review of the first treatment and the cause of the error message. The displacement of the source by 20 mm put it at the skin entry point of the catheter, resulting in an underdose to the target site and an overdose to the skin. The actual dose to some areas of the target site was 86 cGy (rad). The doses administered during the ninth and tenth fractions were adjusted so that the total dose to the target site was 3,400 cGy (rad). Dose to the unintended site was prescribed as 148 cGy (rad) for the first fraction, but 1,142 cGy (rad) was administered. The intended dose to that unintended site for all ten fractions was 1,484 cGy (rad), but the site actually received 2,370 cGy (rad). The patient will be notified of the incident and the doctor will monitor the skin for ill effects. An NRC medical consultant concluded that no significant adverse health effect to the patient was expected due to this event. Corrective actions included procedure changes and training to personnel on those changes. The authorized use and authorized medical physicist are to be physically present during the procedure and upon receipt of an error message they will investigate and determine the cause prior to continuing the treatment.

Event Date: 05/01/2008 **Discovery Date:** 05/01/2008 **Report Date:** 06/06/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	45-25187-01	Name:	BON SECOURS VIRGINIA HEALTH SOURCE
NRC Docket Number:	03032638	City:	MIDLOTHIAN
NRC Program Code:	02230	State: VA	Zip Code: 23114
Respons ble NRC Region:	1		

Site of Event:

Site Name: RICHMOND
State: VA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 86 rad 0.86 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 4470 mCi 165390 MBq Dose: 340 rad 3.4 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 75
Effect on Patient:

Patient Number: 1A
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 1142 rad 11.42 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 4470 mCi 165390 MBq Dose: 148 rad 1.48 Gy

% Dose Exceeds Prescribed: 672
% 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): IR-192
Manufacturer: [redacted] Activity: 4.47 Ci 165.39 GBq
Model Number: [redacted]
Serial Number: D36B-6017

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: D36B-4935

Reporting Requirements:
MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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:
EN44275	06/12/2008		DCH	EVENT NOTIFICATION

LTR080930	10/07/2008	DCH	NRC LETTER
ML082880481	10/23/2008	RLS	NOTICE OF VIOLATION
ML082880481	10/23/2008	RLS	NRC LETTER
08-05	06/10/2009	RLS	ABNORMAL OCCURRENCE NUMBER
ML091540747	06/10/2009	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 080296

Last Updated: 10/18/2010

Narrative:

The Department of Veterans Affairs (VA) reported 97 medical events involving patients prescribed permanent implant prostate brachytherapy procedures at the VA Medical Center in Philadelphia, Pennsylvania. The medical events involved doses less than 80% of the prescr bed dose and doses to an organ or tissue other than the intended treatment site (the rectum, perineum, and/or the bladder), with 17 exceeding the AO criteria. (Two of these events were reported in NMED Item 050671 and 030135.) In general, each patient was prescribed a dose of 160 Gy (16,000 rad) using I-125 seeds with standard seed strengths of 14.06 MBq (0.38 mCi) per seed. This event was discovered when the medical center performed an implant on 5/5/2008 using seeds of a lower apparent activity than prescribed because the wrong seeds were ordered; post-treatment plan results indicated that the D90 was 37.5% less than prescribed. The VA National Health Physics Program initiated a reactive inspection on 5/28/2008. A review of all 116 procedures (performed on 114 patients) since the inception of the cancer treatment program on 2/25/2002 resulted in the identification of these additional medical events. All of the patients and their referring physicians were notified. The prostate cancer treatment program was suspended by the VA director in June 2008 pending an investigation. The NRC contracted a medical consultant to review a sample of these medical events. The medical consultant noted that the seed placement was quite erratic and not consistent with current medical standards, but generally agreed with the VA's dose estimates. These medical events were caused by multiple programmatic deficiencies, including the failure to follow procedures, inadequate training, human error on the part of the physician inserting the needles, and inadequate procedures to ensure that the administered dose was in accordance with the written directives. Corrective actions included procedure modification, personnel training, and replacing several key personnel involved in the procedures.

Event Date: 05/05/2008 **Discovery Date:** 05/15/2008 **Report Date:** 05/16/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: PHILADELPHIA
State: PA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: MANAGEMENT DEFICIENCY

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	PERSONNEL TERMINATED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 16000 rad 160 Gy

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

Patient Number: 2
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PERI-PROSTATIC TISSUE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: NR rad NR Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): I-125
Manufacturer: NR
Activity: 0.00038 Ci 0.01406 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

Reporting Requirements:
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 prescr bed 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:
EN44219	05/22/2008		DCH	EVENT NOTIFICATION

EN44219A	06/09/2008	DCH	EVENT NOTIFICATION
EN44219B	06/17/2008	DCH	EVENT NOTIFICATION
EN44219C	06/23/2008	DCH	EVENT NOTIFICATION
EN44219D	06/26/2008	DCH	EVENT NOTIFICATION
EN44219E	07/03/2008	DCH	EVENT NOTIFICATION
EN44219F	07/09/2008	DCH	EVENT NOTIFICATION
EN44219G	07/14/2008	DCH	EVENT NOTIFICATION
EN44219H	07/16/2008	DCH	EVENT NOTIFICATION
EN44219I	07/21/2008	DCH	EVENT NOTIFICATION
EN44219J	07/23/2008	DCH	EVENT NOTIFICATION
EN44219K	07/28/2008	DCH	EVENT NOTIFICATION
EN44219L	08/07/2008	RLS	EVENT NOTIFICATION
EN44219M	08/14/2008	DCH	EVENT NOTIFICATION
EN44219N	08/28/2008	DCH	EVENT NOTIFICATION
ML082530237	09/10/2008	RLS	NRC NEWS ANNOUNCEMENT
LTR080923	09/30/2008	DCH	NRC LETTER
EN44219O	10/06/2008	DCH	EVENT NOTIFICATION
LTR081023	11/03/2008	RLS	NRC LETTER
ML082880041	11/03/2008	RLS	LICENSEE REPORT
ML082880717	11/03/2008	RLS	CONFIRMATORY ACTION LETTER
ML082890402	11/03/2008	RLS	NRC NEWS ANNOUNCEMENT
ML082900902	11/03/2008	RLS	LICENSEE REPORT
ML082950794	11/03/2008	RLS	NRC LETTER
LTR081231	01/09/2009	RLS	NRC LETTER
ML083650335	01/09/2009	RLS	CONSULTANT REPORT
ML090160211	01/29/2009	RLS	LICENSEE REPORT
ML081970249	04/06/2009	RLS	LICENSEE REPORT
ML081980758	04/06/2009	RLS	LICENSEE REPORT
ML082030634	04/06/2009	RLS	LICENSEE REPORT
ML082041000	04/06/2009	RLS	LICENSEE REPORT
ML082130613	04/06/2009	RLS	LICENSEE REPORT
ML082140835	04/06/2009	RLS	LICENSEE REPORT
ML082190411	04/06/2009	RLS	LICENSEE REPORT
ML082240300	04/06/2009	RLS	LICENSEE REPORT
ML082390235	04/06/2009	RLS	LICENSEE REPORT
ML090900382	04/06/2009	RLS	INSPECTION REPORT
ML090900382	04/06/2009	RLS	NRC LETTER
ML090910694	04/06/2009	RLS	LICENSEE REPORT
ML091120160	05/06/2009	RLS	NRC LETTER
08-02	06/09/2009	RLS	ABNORMAL OCCURRENCE NUMBER
ML091540747	06/09/2009	RLS	ABNORMAL OCCURRENCE NUMBER
ML091750854	06/26/2009	RLS	OTHER
ML091880588	07/15/2009	RLS	NRC LETTER
ML091940392	08/03/2009	RLS	OTHER
ML092110542	08/03/2009	RLS	LICENSEE REPORT
EN44219P	08/13/2009	DCH	EVENT NOTIFICATION
ML082410293	09/28/2009	RLS	LICENSEE REPORT
ML093020636	11/03/2009	RLS	CONSULTANT REPORT
ML092430206	11/30/2009	RLS	LICENSEE REPORT
ML093080147	11/30/2009	RLS	LICENSEE REPORT
ML093210599	11/30/2009	RLS	INSPECTION REPORT
ML093210599	11/30/2009	RLS	NRC LETTER
ML093210611	11/30/2009	RLS	NRC NEWS ANNOUNCEMENT
ML093220187	11/30/2009	RLS	ADAMS DOCUMENT PACKAGE
EN44219Q	12/08/2009	DCH	EVENT NOTIFICATION
ML093440822	12/14/2009	RLS	NRC NEWS ANNOUNCEMENT
ML093490877	12/16/2009	RLS	ENFORCEMENT CONFERENCE
ML093490891	12/16/2009	RLS	ENFORCEMENT CONFERENCE

ML093570466	01/07/2010	RLS	NRC LETTER
ML093580162	01/07/2010	RLS	NRC LETTER
ML100060316	01/07/2010	RLS	ENFORCEMENT CONFERENCE
ML100150326	01/22/2010	RLS	LICENSEE REPORT
ML100190247	01/22/2010	RLS	LICENSEE REPORT
ML092990551	02/03/2010	RLS	LICENSEE REPORT
ML100260528	02/03/2010	RLS	LICENSEE REPORT
ML100260547	02/03/2010	RLS	LICENSEE REPORT
ML100331994	02/25/2010	RLS	LICENSEE REPORT
ML100710692	03/22/2010	RLS	NOTICE OF VIOLATION
ML100710692	03/22/2010	RLS	NRC LETTER
ML100760426	03/22/2010	RLS	NRC NEWS ANNOUNCEMENT
ML100820091	04/06/2010	RLS	OTHER
ML101030828	04/19/2010	RLS	LICENSEE REPORT
ML100700572	05/04/2010	RLS	NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION
ML101440380	05/26/2010	RLS	INSPECTION REPORT
ML101440380	05/26/2010	RLS	NRC LETTER
ML093451474	06/02/2010	RLS	LICENSEE REPORT
LTR100629	07/08/2010	DCH	NRC LETTER
LTR100701	07/08/2010	DCH	NRC LETTER
ML102810376	10/18/2010	RLS	INSPECTION REPORT
ML102810376	10/18/2010	RLS	NRC LETTER

Item Number: 080279

Last Updated: 01/14/2009

Narrative:

Norton Suburban Hospital reported that Patient A was prescribed a dosimetric Bexxar I-131 dosage of 0.19 GBq (5 mCi) for a lymphatic cancer uptake study, but received an I-131 dosage of 1.65 GBq (44.5 mCi). The administered dose was actually intended for Patient B. Patient A had taken a thyroid blocking agent prior to the administration. The doctor notified Patient A of the incident. The State of Kentucky Radiation Health Department conducted an investigation and determined that the cause was oversight by the technologist. The administered dose was received for Patient B on 4/25/2008. However, Patient B's treatment was canceled and the dose was placed in the hot laboratory to be returned to the radiopharmacy. The intended dose for Patient A was not received from the radiopharmacy. The mistake occurred when the call was received to dose Patient A on 4/28/2008. The technologist took the dose from the container left from the cancelled procedure. Norton Suburban Hospital changed their process of receiving, handling, and returning doses to the radiopharmacy. A labeling system was instituted on the dose and canister to let staff know the status of the dose. The technologist and nurse are responsible for performing checks. Patient A was subsequently administered a therapeutic dose of I-131 for lymphatic cancer.

Event Date: 04/28/2008 **Discovery Date:** 04/28/2008 **Report Date:** 05/08/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	KY-202-099-26	Name:	NORTON SUBURBAN HOSPITAL
NRC Docket Number:	NA	City:	LOUISVILLE
NRC Program Code:	NA	State: KY	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: LOUISVILLE
State: KY

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	IMPROVE RADIOACTIVE MATERIAL LABELING AND HANDLING
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:
Diagnostic Study: LYMPHOSCINTIGRAPHY

Radiopharmaceutical: NR

% Dose Exceeds Prescribed: 790
% 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): I-131
Manufacturer: NR Activity: 0.0445 Ci 1.6465 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:
EN44193	05/14/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080821	09/02/2008		DCH	AGREEMENT STATE LETTER
LTR090112	01/14/2009		DCH	AGREEMENT STATE LETTER

Item Number: 080278

Last Updated: 12/10/2008

Narrative:

Bridgeport Hospital reported that two patients received less dose than prescr bed during four Cs-137 manual brachytherapy treatments for cancer of the cervix. The medical events were discovered on 5/7/2008. One patient was prescribed to receive 3,001 and 2,552 cGy (rad; right point A and left point A, respectively) on 12/10/2007, but was administered 1,256 and 1,231 cGy (rad; right point A and left point A, respectively). On 1/2/2008, that patient was prescr bed to receive 1,887 and 2,020 cGy (rad; right point A and left point A, respectively), but was administered 1,042 and 1,116 cGy (rad; right point A and left point A, respectively). The second patient was prescribed to receive 2,276 and 2,672 cGy (rad; right point A and left point A, respectively) on 1/9/2008, but was administered 948 and 1,296 cGy (rad; right point A and left point A, respectively). On 1/30/2008, that patient was prescr bed to receive 2,292 and 2,232 cGy (rad; right point A and left point A, respectively), but was administered 876 and 988 cGy (rad; right point A and left point A, respectively). The cause was human error involving incorrect implementation of a new method to input geometric data into the treatment planning computer, which resulted in use of an incorrect magnification factor in the dose calculations. The patient's referring physician and oncologist were informed. The patients were not informed and received additional treatment. Corrective actions included modifying procedures for treatment planning, adding calculation double-checks, and hiring a consultant to perform an independent review of the brachytherapy program.

Event Date: 12/10/2007 **Discovery Date:** 05/07/2008 **Report Date:** 05/08/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	06-01060-01	Name:	BRIDGEPORT HOSPITAL
NRC Docket Number:	03001247	City:	BRIDGEPORT
NRC Program Code:	02120	State: CT	Zip Code: 06610
Respons ble NRC Region:	1		

Site of Event:

Site Name: BRIDGEPORT
State: CT

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	INCREASED MONITORING BY OUTSIDE AGENCIES TO ENSURE COMPLIANCE

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 1256 rad 12.56 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: NR mCi NR MBq Dose: 3001 rad 30.01 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 58
Effect on Patient:

Patient Number: 1A
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 1231 rad 12.31 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: NR mCi NR MBq Dose: 2552 rad 25.52 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 51.8
Effect on Patient:

Patient Number: 1B
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 1042 rad 10.42 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: NR mCi NR MBq Dose: 1887 rad 18.87 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 44.8
Effect on Patient:

Patient Number: 1C
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 1116 rad 11.16 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: NR mCi NR MBq Dose: 2020 rad 20.2 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 44.8
Effect on Patient:

Patient Number: 2
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 948 rad 9.48 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: NR mCi NR MBq Dose: 2276 rad 22.76 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 58.4
Effect on Patient:

Patient Number: 2A
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 1296 rad 12.96 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: NR mCi NR MBq Dose: 2672 rad 26.72 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 51.5
Effect on Patient:

Patient Number: 2B
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 876 rad 8.76 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: NR mCi NR MBq Dose: 2292 rad 22.92 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 61.8
Effect on Patient:

Patient Number: 2C
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 988 rad 9.88 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: NR mCi NR MBq Dose: 2232 rad 22.32 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 55.7
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: NR Ci NR GBq
Model Number: NR
Serial Number: NR

Source Number: 2
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NR
Serial Number: NR

Source Number: 3
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NR
Serial Number: NR

Source Number: 4
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NR
Serial Number: NR

Source Number: 5

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	CS-137	
Manufacturer:	NR	Activity:	NR Ci	NR GBq
Model Number:	NR			
Serial Number:	NR			

Source Number: 6

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	CS-137	
Manufacturer:	NR	Activity:	NR Ci	NR GBq
Model Number:	NR			
Serial Number:	NR			

Source Number: 7

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	CS-137	
Manufacturer:	NR	Activity:	NR Ci	NR GBq
Model Number:	NR			
Serial Number:	NR			

Source Number: 8

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	CS-137	
Manufacturer:	NR	Activity:	NR Ci	NR GBq
Model Number:	NR			
Serial Number:	NR			

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44192	05/14/2008		DCH	EVENT NOTIFICATION
LTR080815	08/21/2008		DCH	NRC LETTER
LTR081023	10/28/2008		DCH	NRC LETTER
LTR081023A	10/28/2008		DCH	NRC LETTER
ML083170815	11/19/2008		RLS	NOTICE OF VIOLATION
ML083170815	11/19/2008		RLS	NRC LETTER
LTR081201	12/02/2008		DCH	NRC LETTER
LTR081203	12/10/2008		DCH	NRC LETTER

Item Number: 080262

Last Updated: 06/25/2008

Narrative:

Geisinger Wyoming Valley Hospital (GWVH) reported that a patient was administered 0.37 GBq (10 mCi) of I-131 for treatment of a hyperactive thyroid on 2/7/2008, instead of the prescr bed 0.37 MBq (10 uCi). The incident was not discovered until 4/25/2008 during a review of written directives administered. GWVH stated that the written directive incorrectly prescribed 0.37 MBq (10 uCi). The authorized user realized his error in prescr bing 0.37 MBq (10 uCi) and telephoned the nuclear medicine technician to change the activity to the correct dosage of 0.37 GBq (10 mCi). However, neither a new or revised written directive was issued. The prescribing physician was notified of the incident on the date of discovery. The patient was not notified because it served no beneficial purpose. Corrective actions included counseling the technician on following procedures, revising the written directive form to exclude a choice of units, and enforcing that no telephone requests from an authorized user will be carried out until a new or revised written directive is issued.

Event Date: 02/07/2008 **Discovery Date:** 04/25/2008 **Report Date:** 04/25/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	PA-0006	Name:	GEISINGER WYOMING VALLEY HOSPITAL
NRC Docket Number:	NA	City:	WILKES-BARRE
NRC Program Code:	NA	State: PA	Zip Code: 17822
Respons ble NRC Region:	1		

Site of Event:

Site Name: WILKES-BARRE
State: PA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 0.01 mCi 0.37 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 99900
% 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): I-131
Manufacturer: NR Activity: 0.01 Ci 0.37 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:
EN44173	05/05/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PA080010	05/22/2008		DCH	AGREEMENT STATE EVENT REPORT
PA080010A	06/25/2008		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 080230

Last Updated: 06/09/2009

Narrative:

The University of Mississippi Medical Center reported an error during a gynecological brachytherapy treatment using a [redacted] high dose rate (HDR) unit [redacted] with a 185 GBq (5 Ci) Ir-192 source [redacted] serial #085). The patient was prescr bed to receive five fractional treatments of 600 cGy (rad) each, for a total treatment of 3,000 cGy (rad). The treatments began on 12/11/2007 and were scheduled to occur over six days. Three fractional treatments were administered, but the patient did not return for the final two treatment fractions due to reasons not associated with the HDR treatments. On 3/25/2008, measurements of the tandem and ovoid applicators indicated that the length of the source wire entered into the treatment planning system should have been 128 cm; however, a length of 120 cm was used. Further inspection revealed that the tandem catheter should have been used with a different applicator. These errors resulted in the dose for the three fractions being delivered 86 mm inferior to the intended treatment site. Therefore, the patient received a total dose of only 470 cGy (rad) to the treatment site. The vaginal region inferior to the intended treatment site received an unintended dose of 1,300 cGy (rad). The referring physician and the patient were notified. The patient is not expected to experience adverse health effects due to this event. This event was caused by the failure to measure the catheters. Corrective actions included checking all catheters for integrity and length prior to treatment, ordering and using a single set of catheters for the transfer tubes, better verification of the treatment plan and catheters prior to each treatment, and reviewing the existing quality assurance plan and modifying if needed to ensure accuracy. A full time certified medical physicist was also hired.

Event Date: 12/11/2007 **Discovery Date:** 03/25/2008 **Report Date:** 03/26/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	MS-MBL-01	Name:	UNIVERSITY OF MISSISSIPPI MEDICAL CENTER
NRC Docket Number:	NA	City:	JACKSON
NRC Program Code:	NA	State: MS	Zip Code: 39216
Respons ble NRC Region:	4		

Site of Event:

Site Name: JACKSON
State: MS

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	NEW PERSONNEL HIRED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 470 rad 4.7 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 1800 rad 18 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 74
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 1300 rad 13 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): IR-192
Manufacturer: [redacted] Activity: 5 Ci 185 GBq
Model Number: [redacted]
Serial Number: 085

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
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 prescr bed 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:

EN44137	04/17/2008	RLS	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MS08004	04/18/2008	RLS	AGREEMENT STATE EVENT REPORT
LTR080609	06/12/2008	DCH	AGREEMENT STATE LETTER
LTR090422	04/23/2009	DCH	AGREEMENT STATE LETTER
AS 08-02	06/09/2009	RLS	ABNORMAL OCCURRENCE NUMBER
ML091540747	06/09/2009	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 080156

Last Updated: 05/29/2008

Narrative:

The Appleton Medical Center reported patient underdoses to up to eight patients treated with Sm-153 since late 2006. When a nuclear medicine technologist was preparing a recent dose of Sm-153 the activity measured in the dose calibrator did not read as expected. After review, Appleton Medical Center determined that the dose calibrator was set up to measure Sm-153 in a vial, but the technologist had measured the activity in a syringe. The dosage was re-measured properly prior to administration. Further review of previous cases identified up to eight instances where the activity of Sm-153 may have been measured in a syringe instead of in a vial. When the activity is measured in a syringe, the attenuation and volume geometry is estimated to result in administered activities of approximately 30% less than prescr bed in the written directives. The Wisconsin Department of Health and Family Services performed a reactive inspection on 3/17/2008. The activity of Sm-153 prescr bed to each patient was 37 MBq/kg (1 mCi/kg) patient weight. Since Appleton Medical Center could verify neither the exact dose administered nor which of the eight patients were affected, it was assumed all eight patients were affected. Appleton Medical Center reinstructed their nuclear medicine technologists in the proper method of measuring Sm-153 activity. They also revised several procedures. Four of the eight patients are deceased and the remaining four have not been notified.

Event Date: 03/06/2008 **Discovery Date:** 03/06/2008 **Report Date:** 03/06/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-087-1014-01	Name:	APPLETON MEDICAL CENTER
NRC Docket Number:	NA	City:	APPLETON
NRC Program Code:	NA	State: WI	Zip Code: 54911
Respons ble NRC Region:	3		

Site of Event:

Site Name: APPLETON
State: WI

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:	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:	Y

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVE NEW TRAINING
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 30
Effect on Patient:

Patient Number: 2
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 30
Effect on Patient:

Patient Number: 3
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 30
Effect on Patient:

Patient Number: 4
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 30
Effect on Patient:

Patient Number: 5
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 30
Effect on Patient:

Patient Number: 6
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 30
Effect on Patient:

Patient Number: 7
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 30
Effect on Patient:

Patient Number: 8
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 30
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): SM-153
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NA
Serial Number: NA

Source Number: 2
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): SM-153
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NA
Serial Number: NA

Source Number: 3
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): SM-153
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NA
Serial Number: NA

Source Number: 4
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): SM-153
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NA
Serial Number: NA

Source Number: 5

Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM
Radionuclide or Voltage (kVp/MeV): SM-153
Manufacturer: NR
Activity: NR Ci NR GBq
Model Number: NA
Serial Number: NA

Source Number: 6

Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM
Radionuclide or Voltage (kVp/MeV): SM-153
Manufacturer: NR
Activity: NR Ci NR GBq
Model Number: NA
Serial Number: NA

Source Number: 7

Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM
Radionuclide or Voltage (kVp/MeV): SM-153
Manufacturer: NR
Activity: NR Ci NR GBq
Model Number: NA
Serial Number: NA

Source Number: 8

Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM
Radionuclide or Voltage (kVp/MeV): SM-153
Manufacturer: NR
Activity: NR Ci NR GBq
Model Number: NA
Serial Number: NA

Device/Associated Equipment:

MD2

Device Number: 1
Device Name: SYRINGE
Model Number: NA
Manufacturer: NR
Serial Number: NA

Device Number: 2
Device Name: SYRINGE
Model Number: NA
Manufacturer: NR
Serial Number: NA

Device Number: 3
Device Name: SYRINGE
Model Number: NA
Manufacturer: NR
Serial Number: NA

Device Number: 4
Device Name: SYRINGE
Model Number: NA
Manufacturer: NR
Serial Number: NA

Device Number: 5
Device Name: SYRINGE
Model Number: NA
Manufacturer: NR
Serial Number: NA

Device Number: 6
Device Name: SYRINGE
Model Number: NA
Manufacturer: NR
Serial Number: NA

Device Number: 7
Device Name: SYRINGE
Model Number: NA
Manufacturer: NR
Serial Number: NA

Device Number: 8
Device Name: SYRINGE
Model Number: NA
Manufacturer: NR
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:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44045	03/13/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI080005	05/07/2008		DCH	AGREEMENT STATE EVENT REPORT
LTR080527	05/29/2008		DCH	AGREEMENT STATE LETTER
WI080005A	05/29/2008		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 080146

Last Updated: 08/05/2009

Narrative:

Skyridge Medical Center (SMC) reported that a patient treated with MDS Nordion Y-90 microspheres was only administered 4,560 cGy (rad) instead of the prescribed 10,000 cGy (rad) on 3/5/2008. The problem was identified at the conclusion of the procedure when staff noted that 54.4% of the Y-90 microspheres were still in the application kit. The activity that was administered to the patient was 2.46 GBq (66.4 mCi). The patient was informed of the event. Following investigation, SMC determined that the cause of the incident was human error. Corrective actions included generating a new quality management plan, modifying procedures, and providing training to personnel. Those corrective actions included verifying the correct operation of the stopcock during priming of the lines. Part of that test will be to ensure that the stopcock lever is in the correct position. The Colorado Department of Health investigated the incident.

Event Date: 03/05/2008 **Discovery Date:** 03/05/2008 **Report Date:** 03/05/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CO-1053-01	Name:	SKYRIDGE MEDICAL CENTER
NRC Docket Number:	NA	City:	LONE TREE
NRC Program Code:	NA	State: CO	Zip Code: 80124
Respons ble NRC Region:	4		

Site of Event:

Site Name: LONE TREE
State: CO

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW QUALITY MANAGEMENT PLAN
2	PROCEDURE MODIFIED
3	PERSONNEL RECEIVE NEW TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 03/05/2009

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 4560 rad 45.6 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 122 mCi 4514 MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 54.4
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: MDS NORDION, INC. Activity: 0.0664 Ci 2.4568 GBq
Model Number: THERASPHERE
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MDS NORDION, INC. Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN44033	03/10/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
CO08-M08-01	08/05/2009		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 080132

Last Updated: 06/10/2009

Narrative:

Reid Hospital & Health Care Services (RHHCS) reported that 37 I-125 brachytherapy seeds were implanted approximately 2 cm below the patient's prostate on 2/27/2008. Each seed contained an activity of 11.66 MBq (0.315 mCi). The patient was prescribed to receive a dose of 11,000 cGy (rad) to the prostate through the placement of 62 seeds. After 37 seeds were implanted, the location of the implanted seeds was verified to be below the prostate and the procedure was terminated. A dose assessment determined that the region of the perineum where the seeds were implanted received a dose of 5,500 cGy (raf), while the prostate received a dose of 300 to 1,500 cGy (rad). The patient and physicians were notified. This event was caused by misidentification of the patient's prostate through ultrasound due to inadequate procedures, resulting in poor image quality. The patient's prostate will be treated with external beam radiation therapy. The patient may develop complications including f brosis and necrosis of the tissue in the perineum where the seeds were implanted. The NRC contracted a medical consultant, who generally agreed with the dose estimates. Corrective actions included revising the policy and procedure for prostate seed implants to ensure that the location of the needle in the prostate is verified by x-ray imaging prior to implanting seeds.

Event Date: 02/27/2008 **Discovery Date:** 02/27/2008 **Report Date:** 02/29/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-03284-02	Name:	REID HOSPITAL & HEALTH CARE SERVICES
NRC Docket Number:	03001614	City:	RICHMOND
NRC Program Code:	02230	State: IN	Zip Code: 47374
Respons ble NRC Region:	3		

Site of Event:

Site Name: RICHMOND
State: IN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 02/29/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PERINEUM
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 5500 rad 55 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 02/29/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 300 rad 3 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 19.53 mCi 722.61 MBq Dose: 11000 rad 110 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 97
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: 0.011655 Ci 0.431235 GBq
Model Number: NR
Serial Number: AGGREGATE

Reporting Requirements:
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 prescr bed 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:
EN44021	03/04/2008		DCH	EVENT NOTIFICATION
ML080730251	04/08/2008		RLS	LICENSEE REPORT
LTR080429	05/13/2008		RLS	NRC LETTER
ML081200060	05/13/2008		RLS	ADAMS DOCUMENT PACKAGE
ML081200064	05/13/2008		RLS	INSPECTION REPORT
ML081200064	05/13/2008		RLS	NRC LETTER

ML081200121	05/13/2008	RLS	CONSULTANT REPORT
ML081480323	06/11/2008	RLS	LICENSEE REPORT
ML081960765	08/04/2008	RLS	NOTICE OF VIOLATION
ML081960765	08/04/2008	RLS	NRC LETTER
ML082240332	08/13/2008	RLS	INSPECTION REPORT
08-04	06/10/2009	RLS	ABNORMAL OCCURRENCE NUMBER
ML091540747	06/10/2009	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 080119

Last Updated: 08/06/2008

Narrative:

Virginia Commonwealth University Medical Center (VCU) reported that a patient being treated for liver cancer on 2/20/2008 only received 42% of the prescribed dose of Y-90 microspheres. VCU calculated that the patient received 0.58 GBq (15.68 mCi) for a dose of 1,600 cGy (rad) instead of the prescribed 1.4 GBq (37.84 mCi) for a dose of 3,800 cGy (rad). The treatment was intended to be performed in three flushes. The first two flushes were intended to deliver the microspheres and the third flush was intended to ensure all prescribed medication was delivered to the patient. The patient received the first flush, but the second flush would not go through the tubing and the treatment was terminated. Both the patient and prescr bing physician were notified of the problem. An investigation determined that the cause was the improper assembly of the equipment when the three-way stopcock was put in backwards. This caused crimping of the outlet tubes when the beta shield was inserted, thus restricting flow of the microspheres to the patient during the second flush. While this did not affect the first flush, the additional pressure applied during the second flush was enough to crimp the tubes. VCU reviewed the incident with all personnel involved and staff that might be part of a future procedure. The three-way stopcock was modified, locking it in place. Directional arrows were placed on the device to ensure proper assembly. The patient received the remainder of the treatment on 3/4/2008.

Event Date: 02/20/2008 **Discovery Date:** 02/20/2008 **Report Date:** 02/21/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	45-00048-17	Name:	VIRGINIA COMMONWEALTH UNIVERSITY
NRC Docket Number:	03003297	City:	RICHMOND
NRC Program Code:	02230	State: VA	Zip Code: 23298
Respons ble NRC Region:	1		

Site of Event:

Site Name: RICHMOND
State: VA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING
2	NEW EQUIPMENT OBTAINED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 02/20/2008

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 1600 rad 16 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 37.84 mCi 1400.08 MBq Dose: 3800 rad 38 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 58
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: NR Activity: 0.01568 Ci 0.58016 GBq
Model Number: NA
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43999	02/27/2008		DCH	EVENT NOTIFICATION
LTR080711	07/16/2008		DCH	NRC LETTER
ML081540325	08/06/2008		RLS	ADAMS DOCUMENT PACKAGE
ML081640166	08/06/2008		RLS	NOTICE OF VIOLATION
ML081640166	08/06/2008		RLS	NRC LETTER
ML081840117	08/06/2008		RLS	LICENSEE REPORT
ML082140866	08/06/2008		RLS	NRC LETTER

Item Number: 080053

Last Updated: 06/10/2009

Narrative:

Southern Baptist Hospital (dba Baptist Medical Center) reported that the wrong radionuclide was administered to a patient. On 1/14/2008, a physician gave a verbal order to a nurse, who wrote the order for an I-123 uptake scan. However, the nurse inadvertently scheduled an I-131 uptake scan and the physician never reviewed the order. The patient was administered 173.9 MBq (4.7 mCi) of I-131. This resulted in the patient receiving 6,100 cGy (rad) to the thyroid and a whole body effective dose equivalent of 180 cGy (rad). On 1/16/2008, the physician reviewed the results and realized that the wrong radionuclide had been administered. The patient was notified. No significant adverse health effect to the patient is expected. Corrective actions included policy and procedure modifications to require that the physician fill out all orders.

Event Date: 01/14/2008 **Discovery Date:** 01/16/2008 **Report Date:** 01/24/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-2213-1	Name:	SOUTHERN BAPTIST HOSPITAL
NRC Docket Number:	NA	City:	JACKSONVILLE
NRC Program Code:	NA	State: FL	Zip Code: 32207
Respons ble NRC Region:	1		

Site of Event:

Site Name: JACKSONVILLE
State: FL

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

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:

Given:

Diagnostic Study: THYROID UPTAKE MEASUREMENT

Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131

Intended:

Diagnostic Study: THYROID UPTAKE MEASUREMENT

Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-123 Activity: 4.7 mCi 173.9 MBq

% Dose Exceeds Prescribed: NA
% 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):	I-131		
Manufacturer:	NR	Activity:	0.0047 Ci	0.1739	GBq
Model Number:	NA				
Serial Number:	NA				

Reporting Requirements:

MD2

Reporting Requirement: 35.3045(a)(2)(i) - Administration of a wrong radioactive drug containing byproduct material that results in a dose that exceeds 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:
EN43930	01/30/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080225	02/25/2008		RLS	NRC LETTER
FL08-011	04/08/2008		DCH	AGREEMENT STATE EVENT REPORT
LTR080407	04/08/2008		DCH	AGREEMENT STATE LETTER
AS 08-04	06/10/2009		RLS	ABNORMAL OCCURRENCE NUMBER
ML091540747	06/10/2009		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 080041

Last Updated: 07/29/2008

Narrative:

Owensboro Medical Health Systems reported incorrectly implanting 74 I-125 seeds (Isoaid Advantage model IAI-125A, lot #7556), with an average activity of 11.1 MBq (300 uCi), 2.5 cm interior to the base of a patient's prostate gland on 12/20/2007. On 1/10/2008, a four-week follow up CT-based post prostate seed implant plan was performed and reviewed by the prescribing physician. Upon completion of the review, it was determined that the seeds had been implanted in the wrong location. The prescribed dose was 14,500 cGy (rad). The post plan dosimetry revealed that the prostate on received 5,945 cGy (rad). The nearby organs at risk (bladder and rectum) were not affected by the misplacement of the seeds. The prescribing physician notified the attending urologist on 1/11/2008. The urologist will notify the patient. The cause was determined to be human error; the sheath was accidentally partially withdrawn when the needle was pulled from it. Corrective actions included updating procedures to require the use of fluoroscopy, in addition to ultrasound, to check placement during treatment. The State of Kentucky is tracking the incident as number KY082.

Event Date: 12/20/2007 **Discovery Date:** 01/10/2008 **Report Date:** 01/15/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	KY-202-161-26	Name:	OWENSBORO MEDICAL HEALTH SYSTEMS
NRC Docket Number:	NA	City:	OWENSBORO
NRC Program Code:	NA	State: KY	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: OWENSBORO
State: KY

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

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: N Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Dose: 5945 rad 59.45 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 22.2 mCi 821.4 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 59

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: ISOAID, L.L.C. Activity: 0.0222 Ci 0.8214 GBq

Model Number: IAI-125A

Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43905	01/22/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080409	04/14/2008		DCH	AGREEMENT STATE LETTER
LTR080729	07/29/2008		DCH	AGREEMENT STATE LETTER

Item Number: 080024

Last Updated: 04/17/2008

Narrative:

Hackley Hospital reported that a patient prescr bed to receive 3.7 GBq (100 mCi) of I-131 (sodium iodine) for thyroid ablation only received 0.79 GBq (21.39 mCi) on 12/13/2007. The nuclear medicine technologist was unaware that the package contained three capsules, due to lack of visualization and failure to read the vial label. The technologist administered one capsule with an activity of 0.79 GBq (21.39 mCi). The package containing the remaining two capsules was sent back to the pharmacy without a survey. The mistake was recognized the next morning when pharmacy personnel found the two capsules in the returned package. The radiologist was made aware of the situation and the patient was notified. The patient returned the morning of 12/14/2007 and was administered the remaining two capsules totaling 2.58 GBq (69.7 mCi). Therefore, the patient ultimately received a total of 3.37 GBq (91.09 mCi) over the course of 17 hours. No adverse consequences to the patient are anticipated. Corrective actions included disciplining the technician and revising procedures to include verification of the number of capsules received and administered. Personnel were also re-trained on the requirements to survey and wipe test packages prior to any shipment to the nuclear pharmacy.

Event Date: 12/13/2007 **Discovery Date:** 12/14/2007 **Report Date:** 01/04/2008

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-04125-01	Name:	HACKLEY HOSPITAL
NRC Docket Number:	03002044	City:	MUSKEGON
NRC Program Code:	02120	State: MI	Zip Code: 49443
Respons ble NRC Region:	3		

Site of Event:

Site Name: MUSKEGON
State: MI

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

Event Type:

LAS - LOST/ABANDONED/STOLEN
MD2 - MEDICAL EVENT

Event Cause:

LAS
Cause: HUMAN ERROR

MD2
Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
LAS	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	PERSONNEL REPRIMANDED
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	PERSONNEL REPRIMANDED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 12/14/2007

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - A
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 100 mCi 3700 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 78.61
Effect on Patient:

Source of Radiation:
LAS
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.0697 Ci 2.5789 GBq
Model Number: NA
Serial Number: AGGREGATE

MD2
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.02139 Ci 0.79143 GBq
Model Number: NA
Serial Number: NA

Device/Associated Equipment:
LAS
Device Number: 1
Device Name: CONTAINER, SHIPPING Model Number: NR
Manufacturer: NR Serial Number: NA

Reporting Requirements:
LAS
Reporting Requirement: 20.2201(a)(1)(i) - Lost, stolen, or missing licensed material in a quantity greater than or equal to 1,000 times the Appendix C quantities.

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.

Keywords:
LAS
MATERIAL LOST AND FOUND

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43882	01/10/2008		DCH	EVENT NOTIFICATION
ML080460666	02/25/2008		RLS	INSPECTION REPORT
ML080460666	02/25/2008		RLS	NOTICE OF VIOLATION
ML080460666	02/25/2008		RLS	NRC LETTER
ML080500412	02/27/2008		RLS	LICENSEE REPORT
ML080730094	04/08/2008		RLS	LICENSEE REPORT
ML080840255	04/09/2008		RLS	NRC LETTER
LTR080416	04/17/2008		RLS	NRC LETTER

Item Number: 080007

Last Updated: 06/09/2009

Narrative:

Southwest Volusia Healthcare Corporation (dba Florida Hospital Fish Memorial) reported that a patient was administered 81.4 MBq (2.2 mCi) of I-131 for a whole body scan instead of the intended I-123 for a thyroid uptake scan. This resulted in a dose of 1,760 cGy (rad) to the thyroid and a whole body effective dose equivalent of 1.034 cGy (rad). The doctor ordered an iodine thyroid uptake scan for the patient without specifying the radionuclide in the written directive. The facility uses I-123 for thyroid uptake scans and I-131 for whole body scans. The administration occurred on 12/17/2007 and the error was discovered on 12/25/2007. The patient and doctor were notified. This event was caused by scheduling the incorrect examination, the failure of the patient to present a prescription from the doctor, ordering a radionuclide without verifying the prescription, and the failure of the technologist to recognize the error when the written directive was presented. Corrective actions included re-training scheduling personnel to verify an order before scheduling patients for a procedure and re-training technologists to read the written directive prior to patient administration.

Event Date: 12/17/2007 **Discovery Date:** 12/25/2007 **Report Date:** 12/28/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-2467-1	Name:	SOUTHWEST VOLUSIA HEALTHCARE CORP.
NRC Docket Number:	NA	City:	ORANGE CITY
NRC Program Code:	NA	State: FL	Zip Code: 32763
Respons ble NRC Region:	1		

Site of Event:

Site Name: ORANGE CITY
State: FL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Diagnostic Study: WHOLE BODY I-131/THYROID

Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131

Intended:
Diagnostic Study: THYROID UPTAKE MEASUREMENT

Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-123 Activity: 2.2 mCi 81.4 MBq

% Dose Exceeds Prescribed: NA
% 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): I-131
Manufacturer: NR Activity: 0.0022 Ci 0.0814 GBq
Model Number: NR
Serial Number: NR

Reporting Requirements:
MD2
Reporting Requirement: 35.3045(a)(2)(i) - Administration of a wrong radioactive drug containing byproduct material that results in a dose that exceeds 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:
EN43872	01/03/2008		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL07-205	04/08/2008		DCH	AGREEMENT STATE EVENT REPORT
AS 08-03	06/09/2009		RLS	ABNORMAL OCCURRENCE NUMBER
ML091540747	06/09/2009		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 070755

Last Updated: 03/06/2008

Narrative:

The Baptist Hospital reported that a patient received 10,000 cGy (rad) to the prostate gland instead of the prescribed 14,000 cGy (rad) on 12/11/2007. The patient was prescribed to receive 92 I-125 interstitial brachytherapy seeds, each containing an activity of 10.92 MBq (0.295 mCi). A computer failure caused the plan to default to a dose of 10,000 cGy (rad), which went unnoticed. The patient and doctor were notified of the incident. Corrective actions included requiring the document/plan packet be reviewed and signed by a physician and two dosimetrists, requiring a physicist to review and sign the plan prior to surgery, requiring physician approval to update department policy to any original or amended plan, forming a Root Cause Analysis Team to present analysis to the Baptist Hospital Patient Safety Committee, and randomly reviewing 10 charts per month.

Event Date: 12/11/2007 **Discovery Date:** 12/11/2007 **Report Date:** 12/12/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-0158-1	Name:	BAPTIST HOSPITAL
NRC Docket Number:	NA	City:	PENSACOLA
NRC Program Code:	NA	State: FL	Zip Code: 32501
Respons ble NRC Region:	1		

Site of Event:

Site Name: PENSACOLA
State: FL

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:	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:	Y

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	NEW PERSONNEL HIRED

Patient Information:

Patient Number: 1

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Dose: 10000 rad 100 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: 27.14 mCi 1004.18 MBq Dose: 14000 rad 140 Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 28.6

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: 0.02714 Ci 1.00418 GBq

Model Number: NR

Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43838	12/17/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL07-193	01/10/2008		DCH	AGREEMENT STATE EVENT REPORT
LTR080303	03/06/2008		DCH	AGREEMENT STATE LETTER

Item Number: 070737

Last Updated: 05/05/2008

Narrative:

Longmont United Hospital reported that a patient receiving I-125 brachytherapy seeds to the prostate gland only received a mean dose of 1,440 cGy (rad), instead of the prescribed dose of 16,000 cGy (rad). In the course of the operative procedure, some of the seeds were placed inferior to the prostate rather than in the prostate gland. A total of 63 seeds (Bard Brachytherapy model STM 1251) were implanted and each seed contained an activity of 13.5 MBq (0.365 mCi). The mean dose to the rectum was 4,470 cGy (rad) and the mean dose to the urethra was 7,340 cGy (rad). Longmont United Hospital determined that the cause of the incident was displacement of the prostate gland, which was not detected by image guidance due to substantial peri-prostatic bleeding and hematoma formation. The tissues adjacent to the prostate provided an image with features mimicking the appearance of the prostate, though with non-distinct borders. Due to the bleeding, even the non-distinct borders were expected. Enough plaus ble indicators of correct positioning were present, so the surgical team proceeded with the implant until the misplacement of the seeds was discovered. Due to the unusual circumstances of the specific procedure, no underlying deficiencies in the prostate brachytherapy program were indicated. The program has since implemented the use of stabilization needles at initiation of the implantation procedure. The primary element deserving of attention lies in the inherent dependence upon the ultrasound image. The spouse of the patient and the patient were informed of the incident.

Event Date: 08/08/2007 **Discovery Date:** 08/08/2007 **Report Date:** 11/29/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CO-073-01	Name:	LONGMONT UNITED HOSPITAL
NRC Docket Number:	NA	City:	LONGMONT
NRC Program Code:	NA	State: CO	Zip Code: 80501
Respons ble NRC Region:	4		

Site of Event:

Site Name: LONGMONT
State: CO

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 08/09/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 1440 rad 14.4 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 23 mCi 851 MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 08/09/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: URETHRA
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 7340 rad 73.4 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: 1B
Patient Informed: Y Date Informed: 08/09/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 4470 rad 44.7 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):	I-125	
Manufacturer:	BARD BRACHYTHERAPY	Activity:	0.023 Ci	0.851 GBq
Model Number:	STM 1251			
Serial Number:	AGGREGATE			

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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:
EN43819	12/06/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
CO07-M07-02	05/05/2008		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070724

Last Updated: 03/24/2008

Narrative:

Nuclear Oncology reported that a patient received 34 cGy/fraction (rad/fraction) instead of the prescr bed 340 cGy/fraction (rad/fraction) during the first six HDR treatment fractions to the breast. A [redacted] remote afterloader [redacted], serial #270) was used with 370 GBq (10 Ci) of Ir-192. Patient treatment began on 11/19/2007 and, following six treatments, the patient had received 204 cGy (rad). The original written directive was to have a post surgical total dose of 3,400 cGy (rad) delivered in 10 fractions over the course of five days. The attending oncologist was immediately notified and treatments were suspended. The patient was also notified of the error. It was determined that the treatment provided to date was an ineffective post surgical procedure and the patient should be retreated. A revised treatment plan was prepared and the first six fractions of a revised 10-fraction treatment were completed. Investigation by the treatment team revealed that the dosimetrist who entered the data for the original treatment failed to enter the proper dose per fraction after applying a dose optimization plan. Nor was the error caught during a routine review of the plan by the treatment team prior to loading the plan from the planning system. It was noted that this was the first multi-fractionated treatment that the dosimetrist had prepared. Corrective actions included producing a new procedure, providing additional training to personnel, and improved supervision.

Event Date: 11/19/2007 **Discovery Date:** 11/21/2007 **Report Date:** 11/21/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	IL-01641-01	Name:	NUCLEAR ONCOLOGY S.C.
NRC Docket Number:	NA	City:	WINFIELD
NRC Program Code:	NA	State: IL	Zip Code: 60190
Respons ble NRC Region:	3		

Site of Event:

Site Name: WINFIELD
State: IL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	PERSONNEL RECEIVE IMPROVED SUPERVISION

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 11/19/2007

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 204 rad 2.04 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 10000 mCi 370000 MBq Dose: 2040 rad 20.4 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90
Effect on Patient:

Source of Radiation:
MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 10 Ci 370 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 270

Reporting Requirements:
MD2
Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43805	12/03/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IL070062	01/15/2008		DCH	AGREEMENT STATE EVENT REPORT
IL070062A	01/21/2008		DCH	AGREEMENT STATE EVENT REPORT
LTR080128	01/28/2008		DCH	AGREEMENT STATE LETTER
IL070062B	03/24/2008		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070672

Last Updated: 06/09/2009

Narrative:

Karmanos Cancer Center reported that a gamma knife treatment to a 63-year-old female patient's brain was delivered to the wrong location on 10/24/2007. The patient was being treated for a metastatic brain tumor in the right cerebellum. The gamma knife unit [redacted] serial #4202) was manufactured by [redacted] and contained Co-60 sources with a total activity of 227.96 TBq (6,161 Ci). While taking an MRI image of the patient's brain in preparation for the treatment, the left and right sides of the brain were reversed in the image due to human error. This resulted in a treatment of 1,800 cGy (rad) being delivered to the wrong location. The left/right image reversal resulted in an 18-mm shift of the isocenter. The collimator size was 18-mm, resulting in some overlap of the delivered 50% isodose volume with the correct target lesion volume. Approximately 9% of the lesion volume received the prescribed dose of 1,800 cGy (rad), rather than the intended 95% of the lesion volume. The patient was informed of the event. The NRC hired a medical consultant to review the consequences of the event, who concluded that no significant deterministic effects were expected. The reversal of the images was caused by the MRI technologist performing the MRI scans in the "Caudal" mode (from the jaw to the top of the head) rather than the "cranial" mode (from the top of the head to the jaw). Corrective actions included procedure modification, additional reviews of left/right alignment of MRI images, and personnel training.

Event Date: 10/24/2007 **Discovery Date:** 10/24/2007 **Report Date:** 10/25/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-04127-06	Name:	KARMANOS CANCER CENTER
NRC Docket Number:	03009376	City:	DETROIT
NRC Program Code:	02310	State: MI	Zip Code: 48201
Respons ble NRC Region:	3		

Site of Event:

Site Name: DETROIT
State: MI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: 1800 rad 18 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 6161000 mCi 227957000 MBq Dose: 1800 rad 18 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
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: 6161 Ci 227957 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: GAMMA KNIFE UNIT
Model Number: [redacted]
Manufacturer: [redacted]
Serial Number: 4202

Reporting Requirements:
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 prescr bed 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:
EN43746	11/02/2007		RLS	EVENT NOTIFICATION

ML073030270	11/02/2007	RLS	PRELIMINARY NOTIFICATION
PN307013	11/02/2007	RLS	PRELIMINARY NOTIFICATION
LTR071106	11/12/2007	DCH	NRC LETTER
LTR080114	01/15/2008	DCH	NRC LETTER
LTR080118	01/21/2008	DCH	NRC LETTER
ML080100438	01/21/2008	RLS	INSPECTION REPORT
ML080100438	01/21/2008	RLS	NRC LETTER
ML080420010	02/22/2008	RLS	LICENSEE REPORT
ML080580302	03/04/2008	RLS	CONSULTANT REPORT
ML080580534	03/04/2008	RLS	LICENSEE REPORT
ML080920995	04/14/2008	RLS	NRC LETTER
ML081010416	04/14/2008	RLS	NOTICE OF VIOLATION
ML081010416	04/14/2008	RLS	NRC LETTER
ML080950215	05/14/2008	RLS	NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION
08-03	06/09/2009	RLS	ABNORMAL OCCURRENCE NUMBER
ML091540747	06/09/2009	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 070641

Last Updated: 04/09/2008

Narrative:

The Oncology Institute of Greater Lafayette (aka Clarian Arnett Cancer Care Center) reported a medical event involving a patient receiving three vaginal cylinder HDR treatments on 8/14, 8/28, and 9/11/2007. The incident involved a [redacted] HDR unit [redacted] serial #31024). The prescribed dose per fraction was 700 cGy (rad) using a 236.8 GBq (6.4 Ci) Ir-192 source. The treatment was planned with a source dwell position spacing of 5 mm and 13 dwell positions, for a treatment length of 6.5 cm. The electronic transfer of spacing information from the planning console to the treatment console did not function properly, so the source spacing was manually entered into the treatment console. However, the spacing was inadvertently entered as 2.5 mm with 13 dwell positions, for a treatment length of 3.25 cm. In addition, shielding for the posterior vaginal wall and rectum further reduced the dose to the tumor. This resulted in a dose 30% greater than prescribed to the vaginal apex and anterior superior vagina. Additionally, the dose to the inferior posterior vaginal wall (which contained the tumor) was 50 to 96% less than prescribed. An NRC inspection conducted on 10/16/2007 identified the error. The NRC contracted with a medical consultant to review this event. The medical consultant concluded that the overdose to the vaginal vault is unlikely to result in necrosis, but the underdose to part of the tumor area increases the risk of tumor recurrence. The patient will be clinically checked at regular intervals for radiation morbidity and tumor recurrence. Corrective actions included setting the device default dwell spacing at 5 mm, revising procedures, and training personnel.

Event Date: 08/14/2007 **Discovery Date:** 10/16/2007 **Report Date:** 10/17/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-32087-01	Name:	ONCOLOGY INSTITUTE OF GREATER LAFAYETTE
NRC Docket Number:	03034812	City:	LAFAYETTE
NRC Program Code:	03810	State: IN	Zip Code: 47904
Respons ble NRC Region:	3		

Site of Event:

Site Name: LAFAYETTE
State: IN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 2730 rad 27.3 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6400 mCi 236800 MBq Dose: 2100 rad 21 Gy

% Dose Exceeds Prescribed: 30
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 84 rad 0.84 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6400 mCi 236800 MBq Dose: 2100 rad 21 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 96
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 6.4 Ci 236.8 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31024

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43727	10/23/2007		DCH	EVENT NOTIFICATION
ML073110149	11/14/2007		RLS	NRC LETTER
ML073310366	12/05/2007		RLS	CONSULTANT REPORT
ML073050457	01/10/2008		RLS	LICENSEE REPORT

ML073180320	01/10/2008	RLS	CONSULTANT REPORT
LTR080114	01/14/2008	DCH	NRC LETTER
LTR080107	01/15/2008	RLS	NRC LETTER
ML080070444	01/15/2008	RLS	ADAMS DOCUMENT PACKAGE
ML080070451	01/15/2008	RLS	INSPECTION REPORT
ML080070451	01/15/2008	RLS	NRC LETTER
ML080840539	04/09/2008	RLS	CONSULTANT REPORT
ML080930558	04/09/2008	RLS	NOTICE OF VIOLATION
ML080930558	04/09/2008	RLS	NRC LETTER

Item Number: 070620

Last Updated: 12/10/2007

Narrative:

The University of North Carolina Hospital reported that a patient administered Y-90 microspheres for liver cancer received a 29% underdose on 9/13/2007. The patient was prescribed to receive approximately 2.46 GBq (66.6 mCi) and only received 1.75 GBq (47.3 mCi). The determined dose to the patient's liver was 8,500 cGy (rad) instead of the intended 12,000 cGy (rad). An MDS Nordion TheraSphere delivery system was being used to deliver the microspheres to the patient. There was no equipment malfunction and no leakage of radioactive material. The patient was notified of the incident on 9/14/2007 and there are no plans to perform a second administration. The cause was determined to be a failure to verify that the entire dose was administered. Corrective actions included reviewing the procedure.

Event Date: 09/13/2007 **Discovery Date:** 09/13/2007 **Report Date:** 09/14/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NC-068-0565-1	Name:	UNIVERSITY OF NORTH CAROLINA HOSPITAL
NRC Docket Number:	NA	City:	CHAPEL HILL
NRC Program Code:	NA	State: NC	Zip Code: 27514
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHAPEL HILL
State: NC

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 09/14/2007

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 8500 rad 85 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 66.6 mCi 2464.2 MBq Dose: 12000 rad 120 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 29
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	MICROSPHERES	Radionuclide or Voltage (kVp/MeV):	Y-90		
Manufacturer:	MDS NORDION, INC.	Activity:	0.0473 Ci	1.7501	GBq
Model Number:	THERASPHERE				
Serial Number:	AGGREGATE				

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	MDS NORDION, INC.	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
NC070048	10/11/2007		DCH	AGREEMENT STATE EVENT REPORT
LTR071116	11/20/2007		DCH	AGREEMENT STATE LETTER
NC070048A	12/10/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070612

Last Updated: 12/01/2008

Narrative:

Carilion Health System reported that a female patient, receiving a [redacted] treatment for a breast lesion using an HDR unit [redacted] serial #VS381) with a 225.7 GBq (6.1 Ci) Ir-192 source, received approximately 2,000 cGy (rad) more dose to tissue adjacent to the source than prescribed. The prescribed dose was 340 cGy (rad). There was a 0.5 cm3 site within the treatment volume that received greater than 2500 cGy (rad) and a 1.0 cm3 site that received in excess of 2000 cGy (rad). There was also a radiation exposure of 680 cGy (rad) to an unintended area. The treatment consisted of placing a catheter into the treatment site, inflating a balloon with between 35 and 75 ml saline, and positioning the Ir-192 source inside the catheter into the center volume of the saline balloon. On 8/31/2006, a catheter was inserted and saline was introduced through one of two catheter connections to inflate the balloon. The patient was taken to the HDR unit where the technologist inadvertently connected the HDR unit to the saline instead of the HDR connector. That resulted in draining the saline balloon into the HDR unit. The technologist recognized that the HDR unit was improperly connected, broke the connection, and reconnected to the proper port. When the prescribed 416 second treatment was commenced, the HDR automatically shutdown and retracted the source. During an NRC inspection conducted on 7/26/2007, it was noted that since the saline balloon had been drained, tissue in a 0.5 cm3 volume adjacent to the source received a significantly higher dose than prescribed. Carilion Health informed the prescribing physician and the patient. Corrective actions included revising setup procedures requiring that the catheter not be connected to the HDR unit until after the CT scans are completed and providing training to all personnel on the revised procedure.

Event Date: 08/31/2006 **Discovery Date:** 07/26/2007 **Report Date:** 10/03/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	45-25395-01	Name:	CARILION HEALTH SYSTEM
NRC Docket Number:	03034470	City:	ROANOKE
NRC Program Code:	02230	State: VA	Zip Code: 24033
Respons ble NRC Region:	1		

Site of Event:

Site Name: ROANOKE
State: VA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 2500 rad 25 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6100 mCi 225700 MBq Dose: 340 rad 3.4 Gy

% Dose Exceeds Prescribed: 635
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 680 rad 6.8 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): IR-192
Manufacturer: NR Activity: 6.1 Ci 225.7 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: VS381

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43685	10/09/2007		DCH	EVENT NOTIFICATION
LTR071228	01/03/2008		DCH	NRC LETTER
LTR080129	01/29/2008		DCH	NRC LETTER
LTR080129A	01/29/2008		DCH	NRC LETTER

ML080420222	12/01/2008	RLS	LICENSEE REPORT

Item Number: 070577

Last Updated: 10/10/2007

Narrative:

The University of Iowa reported that a patient received 200 cGy (rad) during a fractionated teletherapy treatment on 2/1/2005 targeting the bone marrow, instead of the prescribed dose of 100 cGy (rad). The incident occurred during the first fraction to the patient and was due to an improperly calculated dose delivery time. The teletherapy machine [redacted] contained a Co-60 source [redacted] serial #T-1316) with an activity of 37.83 TBq (1022.5 Ci). Prior to the second scheduled treatment, a different therapist questioned the long treatment time and notified the medical physicist. The physicist checked the calculations, discovered the error, and cancelled the second treatment. The patient was notified of the incident on 2/1/2005. The licensee is no longer in possession of the teletherapy unit; the Co-60 source was removed on 11/6/2005.

Event Date: 02/01/2005 **Discovery Date:** 02/01/2005 **Report Date:** 02/01/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	IA-37-1-52-AAB	Name:	UNIVERSITY OF IOWA
NRC Docket Number:	NA	City:	IOWA CITY
NRC Program Code:	NA	State: IA	Zip Code: 52242
Respons ble NRC Region:	3		

Site of Event:

Site Name: IOWA CITY
State: IA

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

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: 02/01/2005

Given:
Therapeutic Procedure: TELETHERAPY
Organ: BONE MARROW
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: 200 rad 2 Gy

Intended:
Therapeutic Procedure: TELETHERAPY
Organ: BONE MARROW
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 1022500 mCi 37832500 MBq Dose: 100 rad 1 Gy

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE TELETHERAPY Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: [redacted] Activity: 1022.5 Ci 37832.5 GBq
Model Number: [redacted]
Serial Number: 1-1316

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: TELETHERAPY UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43639	09/18/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IA070003	10/10/2007		DCH	AGREEMENT STATE EVENT REPORT
LTR071010	10/10/2007		DCH	AGREEMENT STATE LETTER

Item Number: 070574

Last Updated: 10/25/2007

Narrative:

The Indiana University Medical Center reported that a 70-year-old male patient received 1.76 GBq (47.7 mCi) of Y-90 labeled microspheres (MDS Nordion TheraSpheres) during treatment for liver cancer on 9/10/2007, instead of the prescribed 2.38 GBq (64.3 mCi). After the microspheres were infused into the patient, the catheters (a microcatheter and a guide catheter) were removed from the patient and deposited in a disposal container along with the original dosage vial and other contaminated items. A radiation survey of the disposal container was compared to the receipt survey for the dosage vial to determine the percentage of the dosage delivered. These measurements indicated that the patient received an underdose of 25.8%. An investigation determined that essentially all of the residual activity resided in the catheters. It was determined that there was a kink in the microcatheter approximately 11 inches from the proximal end. Surveys showed that microspheres collected in the area of the kink. The dose to the patient was approximately 9,000 cGy (rad) instead of the prescribed 12,000 cGy (rad). This dose is within the recommended treatment range, so there should be no deleterious effect to the patient. The patient was notified of this event on 9/11/2007. To prevent recurrence, the licensee will visually verify the integrity of catheters prior to use. Any noted kinks or other imperfections will result in replacement of the catheter.

Event Date: 09/10/2007 **Discovery Date:** 09/10/2007 **Report Date:** 09/11/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-02752-03	Name:	INDIANA UNIVERSITY MEDICAL CENTER
NRC Docket Number:	03001609	City:	INDIANAPOLIS
NRC Program Code:	02110	State: IN	Zip Code: 46202
Respons ble NRC Region:	3		

Site of Event:

Site Name: INDIANAPOLIS
State: IN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR FAILED PART

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 09/11/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 90 rad 0.9 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 64.3 mCi 2379.1 MBq Dose: 120 rad 1.2 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 25.8
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: MDS NORDION, INC. Activity: 0.0477 Ci 1.7649 GBq
Model Number: THERASPHERE
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MDS NORDION, INC. Serial Number: NR

Device Number: 2
Device Name: CATHETER Model Number: NR
Manufacturer: NR Serial Number: NA

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43630	09/17/2007		DCH	EVENT NOTIFICATION
ML072710186	10/08/2007		RLS	LICENSEE REPORT
LTR071016	10/24/2007		DCH	NRC LETTER
ML072890679	10/25/2007		RLS	INSPECTION REPORT
ML072890679	10/25/2007		RLS	NRC LETTER

Item Number: 070547

Last Updated: 05/15/2008

Narrative:

Physician Reliance (dba Texas Oncology at Klabzuba) reported that a patient being treated with a [redacted] high dose rate afterloader [redacted] serial #329) received 2,500 cGy (rad) during the first of five fractions instead of the prescribed dose of 500 cGy (rad). The incident invo ved an Ir-192 source [redacted] serial #02-01-0993-001-071607-09968-83) with an activity of 260.6 GBq (7.043 Ci). The patient was prescribed to receive five fractions with 500 cGy (rad) per fraction. Prior to the treatment, the patient had undergone a right upper lobectomy and the right upper bronchial stump received the dose. The incident was discovered following an independent physicist's review of the treatment plan. The incident occurred as a result human error, with the absolute percent isodose line being chosen for the treatment plan instead of the relative percent line entered into the treatment planning system. The treatment planning system then normalized the calculations to the incorrect isodose line and the resulting treatment. The oncologist signed and approved the plan and the RSO performed a second calculation check on the plan. The calculation error was identified by an independent physicist prior to administration of the second fraction. Corrective actions included procedure modifications (requiring a second check by physics staff for prescription and treatment, retaining a check list in each treatment file that staff are required to review prior to treatment, adding the prescription dose to the check spreadsheet, adding a second calculation point to the plan, etc.) and providing personnel training.

Event Date: 08/22/2007 **Discovery Date:** 08/29/2007 **Report Date:** 08/29/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TX-L05545	Name:	PHYSICIAN RELIANCE
NRC Docket Number:	NA	City:	FORT WORTH
NRC Program Code:	NA	State: TX	Zip Code: 76104
Respons ble NRC Region:	4		

Site of Event:

Site Name: FORT WORTH
State: TX

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BRONCHUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 2500 rad 25 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BRONCHUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 7042.82 mCi 260584.34 MBq Dose: 500 rad 5 Gy

% Dose Exceeds Prescribed: 400
% 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): IR-192
Manufacturer: [redacted] Activity: 7.043 Ci 260.591 GBq
Model Number: NR
Serial Number: 02-01-0993-001-07160

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 329

Reporting Requirements:
MD2
Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43606	09/04/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
TX-I-8439	09/04/2007		DCH	AGREEMENT STATE EVENT REPORT
TX-I-8439A	09/04/2007		DCH	AGREEMENT STATE EVENT REPORT
TX-I-8439B	09/04/2007		DCH	AGREEMENT STATE EVENT REPORT
TX-I-8439C	09/25/2007		DCH	AGREEMENT STATE EVENT REPORT
LTR071115	11/20/2007		DCH	AGREEMENT STATE LETTER
LTR080123	01/24/2008		DCH	AGREEMENT STATE LETTER
LTR080314	03/18/2008		DCH	AGREEMENT STATE LETTER
AS 07-06	05/15/2008		RLS	ABNORMAL OCCURRENCE NUMBER
ML081300424	05/15/2008		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 070471

Last Updated: 09/05/2007

Narrative:

The licensee reported that a patient only received 1,030 cGy (rad) during three fractionated HDR brachytherapy treatments instead of the prescribed 1,500 cGy (rad). The treatments were administered on 7/10, 7/17, and 7/24/2007. The HDR unit [redacted] serial #31558) was manufactured by [redacted] and contained an Ir-192 source with an activity of 281.2 GBq (7.6 Ci). Following the third fraction, the licensee determined that the 500 cGy (rad) isodose line was at the surface of the cylinder, rather than 5 mm from the cylinder. Therefore, the patient only received 1,030 cGy (rad) instead of the dose prescr bed in the written directive. On 7/31/2007, the physician revised the written directive and gave the patient a fourth treatment, which put the total dose at 2,000 cGy (rad). Corrective actions taken by the licensee included revising their procedures to require dual verification that the cylinder and isodose lines match with the written directive. In addition, all future treatment plans will be reviewed and approved by the physician prior to treatment.

Event Date: 07/10/2007 **Discovery Date:** 07/24/2007 **Report Date:** 07/24/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	24-01143-06	Name:	LESTER E. COX MEDICAL CENTER
NRC Docket Number:	03009784	City:	SPRINGFIELD
NRC Program Code:	02230	State: MO	Zip Code: 65802
Respons ble NRC Region:	3		

Site of Event:

Site Name: SPRINGFIELD
State: MO

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

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: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 1030 rad 10.3 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 7600 mCi 281200 MBq Dose: 1500 rad 15 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 31.3
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 7.6 Ci 281.2 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31558

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43516	07/30/2007		DCH	EVENT NOTIFICATION
LTR070806	08/08/2007		DCH	NRC LETTER
ML072290544	08/23/2007		RLS	INSPECTION REPORT
ML072290544	08/23/2007		RLS	NOTICE OF VIOLATION
ML072290544	08/23/2007		RLS	NRC LETTER
ML072290472	09/05/2007		RLS	LICENSEE REPORT

Item Number: 070439

Last Updated: 09/06/2007

Narrative:

The licensee reported an inadvertent dose to a patient's gallbladder during a Y-90 SIR-Sphere procedure to treat liver carcinoma. The licensee administered 1 GBq (27.3 mCi) to the patient intending to deliver 26.1 Gy (2610 rad) to the carcinoma on the patient's liver. After review of the CT images on 7/12/2007, the physicist believes that 20% of the dose went to the gallbladder. The doctor and patient were notified on 7/12/2007. The licensee will follow up with the patient in future visits to determine if there is gal bladder damage. The Florida Department of Health investigated the incident and found no violations that caused the incident.

Event Date: 07/11/2007 **Discovery Date:** 07/12/2007 **Report Date:** 07/13/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-0031-1	Name:	UNIVERSITY OF FLORIDA SHANDS HOSPITAL
NRC Docket Number:	NA	City:	GAINESVILLE
NRC Program Code:	NA	State: FL	Zip Code: 32611
Respons ble NRC Region:	1		

Site of Event:

Site Name: GAINESVILLE
State: FL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NO CORRECTIVE ACTION TAKEN

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 07/12/2007

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: GALLBLADDER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 522 rad 5.22 Gy

Intended:

A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 07/12/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 2088 rad 20.88 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 27.3 mCi 1010.1 MBq Dose: 2610 rad 26.1 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 20
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: SIRTEX MEDICAL Activity: 0.0273 Ci 1.0101 GBq
Model Number: SIR-SPHERES
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: SIRTEX MEDICAL Serial Number: NR

Reporting Requirements:
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 prescr bed 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:
EN43491	07/19/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL07-109	09/06/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070403

Last Updated: 02/13/2008

Narrative:

Christus Saint Francis Cabrini Hospital Cancer Care Center reported that a patient undergoing a mammosite HDR treatment received a dose that was 41.2% greater than prescribed. The Hospital was using a [redacted] HDR unit [redacted] serial #31710) and an Ir-192 source (serial #D36B-0409) with an activity of 233.1 GBq (6.3 Ci). The treatment was halted and the patient was informed. The patient received an additional 350 cGy/day (rad/day) for four days, resulting in a total additional dose of 1,400 cGy (rad). The total prescr bed dose for the four fractions was 3,400 cGy (rad) and the patient received 4,800 cGy (rad). The cause of the incident was determined to be human error. The treatment plan was incorrectly entered into the computer. Corrective actions taken by the Hospital included the use of hand written QA checklists that must be filled out independently by the technologist, physicist, and attending physician prior to treatment. The Hospital also developed an HDR prescription and dose tracking worksheet that must be filled out by the physician and updated after each treatment. In addition, the Hospital updated the computer software to include typical doses for each HDR treatment plan. If the treatment dose entered into the computer is not within the typical dose range for that treatment type, the software questions the individual entering the data.

Event Date: 06/29/2007 **Discovery Date:** 06/29/2007 **Report Date:** 06/29/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	LA-1121-L01	Name:	CHRISTUS SAINT FRANCIS CABRINI HOSPITAL
NRC Docket Number:	NA	City:	ALEXANDRIA
NRC Program Code:	NA	State: LA	Zip Code: 71301
Respons ble NRC Region:	4		

Site of Event:

Site Name: ALEXANDRIA
State: LA

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

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: 06/29/2007

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 4800 rad 48 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 3400 rad 34 Gy

% Dose Exceeds Prescribed: 41
% 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): IR-192
Manufacturer: NR Activity: 6.3 Ci 233.1 GBq
Model Number: NR
Serial Number: D36B-0409

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31710

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43469	07/09/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LA070017	09/11/2007		DCH	AGREEMENT STATE EVENT REPORT
LTR070913	09/17/2007		DCH	AGREEMENT STATE LETTER
LA070017A	02/13/2008		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070392

Last Updated: 08/19/2009

Narrative:

Providence Medford Medical Center (PMMC) reported that a patient received 17.8% of the prescribed dose during an HDR treatment using a [redacted] vaginal cylinder and tandem. The HDR [redacted] serial #600379) utilized an Ir-192 source [redacted] serial #02-01-0588-001-041907-10089-97) with an activity of 373.29 GBq (10.09 Ci). The patient was prescribed 700 cGy (rad), but only received 125 cGy (rad). The treatment was initiated, but the device computer indicated the source wire positioning was not reproducible (error code 18 – wire drift detected) and the treatment was paused. The QA positioning test was conducted and was within acceptable limits. The treatment was continued, but the device again indicated positioning errors. The treatment was discontinued without being completed. [redacted] was contacted and a field engineer was dispatched the following day. The source and dummy wire transport systems were cleaned and tested. The medical physicists performed several QA tests and certified the HDR was ready for patient treatment. The patient and physician were notified of the incident immediately after the treatment was terminated. PMMC stated that while connecting the [redacted] vaginal cylinder to the HDR with seven separate connecting tubes, bloody fluid was noted on one of the connectors. It was determined that the protective caps covering the tubes were removed in surgery instead of waiting until the patient arrived in the department. In the future, PMMC will leave the protective caps on the applicator as long as possible to reduce or preclude any fluid from entering the closed system.

Event Date: 06/25/2007 **Discovery Date:** 06/25/2007 **Report Date:** 06/26/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OR-91035	Name:	PROVIDENCE MEDFORD MEDICAL CENTER
NRC Docket Number:	NA	City:	MEDFORD
NRC Program Code:	NA	State: OR	Zip Code: NR
Respons ble NRC Region:	4		

Site of Event:

Site Name: MEDFORD
State: OR

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

Event Type:

EQP - EQUIPMENT
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: DEFECTIVE OR FAILED PART

MD2
Cause: DEFECTIVE OR FAILED PART

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	PROCEDURE MODIFIED
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 06/25/2007

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 125 rad 1.25 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 10089 mCi 373293 MBq Dose: 700 rad 7 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 82.2
Effect on Patient:

Source of Radiation:
EQP
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 10.089 Ci 373.293 GBq
Model Number: [redacted]
Serial Number: 02010588001041907

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 10.089 Ci 373.293 GBq
Model Number: [redacted]
Serial Number: 02010588001041907

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 600379

MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 600379

Reporting Requirements:
EQP
Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43445	07/02/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR090312	03/25/2009		DCH	AGREEMENT STATE LETTER
LTR090818	08/19/2009		DCH	AGREEMENT STATE LETTER

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 cal bration 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
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:	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 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

Item Number: 070384

Last Updated: 08/19/2009

Narrative:

Oregon Health Sciences University (OHSU) reported that a patient was prescribed to receive 2.45 GBq (66.2 mCi) of Y-90 TheraSpheres for treatment of the liver, which would result in a delivered dose of approximately 11,000 cGy (rad). Only 1.74 GBq (47 mCi) was received from MDS Nordion and used for the treatment, resulting in approximately 8,000 cGy (rad) delivered to the liver. The cause of the medical event was determined to be an incorrect dose received from the supplier, an error in calculating the corrected dose estimate, and a delay of the administration of the dose. OHSU was concerned not to exceed a lung dose of 1,500 cGy (rad), which was achieved due to the treatment dose at the low end of the optimal range. The physician was notified and will consult the patient to decide if additional treatment is needed. Corrective actions included requiring the physicist to use a calculator in adjusting the dose estimate.

Event Date: 06/18/2007 **Discovery Date:** 06/18/2007 **Report Date:** 06/20/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OR-90013	Name:	OREGON HEALTH & SCIENCE UNIVERSITY
NRC Docket Number:	NA	City:	PORTLAND
NRC Program Code:	NA	State: OR	Zip Code: NR
Respons ble NRC Region:	4		

Site of Event:

Site Name: PORTLAND
State: OR

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

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: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 8000 rad 80 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 66.2 mCi 2449.4 MBq Dose: 11000 rad 110 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 29
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: MDS NORDION, INC. Activity: 0.047 Ci 1.739 GBq
Model Number: THERASPHERE
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MDS NORDION, INC. Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43434	06/26/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR090312	03/25/2009		DCH	AGREEMENT STATE LETTER
LTR090818	08/19/2009		DCH	AGREEMENT STATE LETTER

Item Number: 070350

Last Updated: 09/10/2007

Narrative:

The licensee reported that a patient was prescribed by an authorized user's written directive to receive a Y-90 TheraSphere procedure of 1.05 GBq (28.3 mCi), but only received about 88.8 MBq (2.4 mCi). The patient was prescribed to receive 12,300 cGy (rad) to the tumor, but the RSO estimated that only about 700 cGy (rad) or 6% of the prescribed dose was received. During the procedure, the RSO was monitoring the radiation exposure rate in the room and did not observe the expected rise in the rate as the TheraSpheres enter the catheter and then the patient. The injection was stopped to evaluate the problem. The authorized user and RSO noticed that the blue stopcock was in the wrong position, directing the TheraSpheres into the waste vial and not into the patient. A radiation survey revealed that most of the radioactivity was in the waste vial and very little in the patient. Following the procedure, the activity in the waste vial was measured in a dose calibrator and revealed 0.96 GBq (25.9 mCi). The patient will be scheduled for re-treatment in the next few weeks. The licensee revised their TheraSphere checklist and retrained personnel.

Event Date: 05/31/2007 **Discovery Date:** 05/31/2007 **Report Date:** 05/31/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-079-1281-01	Name:	AURORA SAINT LUKE'S MEDICAL CENTER
NRC Docket Number:	NA	City:	MILWAUKEE
NRC Program Code:	NA	State: WI	Zip Code: NR
Respons ble NRC Region:	3		

Site of Event:

Site Name: MILWAUKEE
State: WI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 05/31/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 700 rad 7 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 28.3 mCi 1047.1 MBq Dose: 12300 rad 123 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 94
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: MDS NORDION, INC. Activity: 0.0283 Ci 1.0471 GBq
Model Number: THERASPHERE
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MDS NORDION, INC. Serial Number: NR

Device Number: 2
Device Name: CATHETER Model Number: NR
Manufacturer: NR Serial Number: NA

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43398	06/06/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI070011	07/09/2007		DCH	AGREEMENT STATE EVENT REPORT
WI070011A	09/10/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070327

Last Updated: 03/31/2009

Narrative:

The licensee reported that they ruptured a Pd-103 seed that contained an activity of 0.11 GBq (2.92 mCi), causing interruption of a medical procedure. The incident occurred while performing a patient implant in room 11 of the operating room. Preliminary evaluation by the licensee indicated that the Mick applicator jammed and failed to advance. Efforts to free the device may have damaged the seed. The patient procedure was stopped after 60 seeds were successfully implanted; the written directive prescr bed 83 seeds. The oncologist stated that the 60 seeds implanted were adequate for successful therapy and that no additional seeds would be implanted. Radiation surveys revealed contamination on the applicator and surrounding absorbent chucks. Contaminated items were controlled and stored in the nuclear medicine department. The Mick applicator was removed from service for decay in storage. Following decay, the licensee with send the applicator to the manufacturer for a full evaluation. Smear tests of adjacent operating room surfaces and floor were negative. The operating room was released at approximately 1900 hours the same day. The licensee notified the manufacturer of the incident and a new Mick applicator was purchased. The INL has requested additional information for this event.

Event Date: 05/24/2007 **Discovery Date:** 05/24/2007 **Report Date:** 05/25/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	MD-31-002-03	Name:	HOLY CROSS HOSPITAL
NRC Docket Number:	NA	City:	SILVER SPRINGS
NRC Program Code:	NA	State: MD	Zip Code: 20910
Respons ble NRC Region:	1		

Site of Event:

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

Event Type:

EQP - EQUIPMENT
LKS - LEAKING SOURCE
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: NOT REPORTED

LKS
Cause: NOT REPORTED

MD2
Cause: NOT REPORTED

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	NOT REPORTED
LKS	
1	NOT REPORTED
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: PD-103 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: PD-103 Activity: 242.4 mCi 8968.8 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 27.7
Effect on Patient:

Source of Radiation:
EQP
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): PD-103
Manufacturer: NR Activity: 0.00292 Ci 0.10804 GBq
Model Number: NR
Serial Number: NR

LKS
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): PD-103
Manufacturer: NR Activity: 0.00292 Ci 0.10804 GBq
Model Number: NR Leak Test Result: NR uCi NR kBq
Serial Number: NR

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): PD-103
Manufacturer: NR Activity: 0.1752 Ci 6.4824 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MICK RADIO-NUCLEAR Serial Number: NR

LKS
Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MICK RADIO-NUCLEAR Serial Number: NR

MD2
Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MICK RADIO-NUCLEAR Serial Number: NR

Reporting Requirements:
EQP
Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

LKS

Reporting Requirement: 35.67(e) - Medical source leak test revealed the presence of 185 Bq (0.005 uCi) or more of removable radioactive material.

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43390	05/31/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MD070006	07/10/2007		DCH	AGREEMENT STATE EVENT REPORT
LTR070814	08/15/2007		DCH	AGREEMENT STATE LETTER
LTR070816	08/16/2007		DCH	AGREEMENT STATE LETTER
LTR090330	03/31/2009		DCH	AGREEMENT STATE LETTER

Item Number: 070315

Last Updated: 07/16/2007

Narrative:

The licensee reported that a patient with metastatic cancer and no thyroid received a therapeutic dose of 0.99 GBq (26.8 mCi) of I-131, instead of the prescribed whole body scan. The doctor prescribed the whole body scan, but the technologist administered the therapy dosage. The doctor and patient were notified of the error. A Florida Department of Health investigation revealed that no violation occurred and that no corrective actions were required.

Event Date: 05/17/2007 **Discovery Date:** 05/17/2007 **Report Date:** 05/21/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-1284-1	Name:	LARGO MEDICAL CENTER
NRC Docket Number:	NA	City:	LARGO
NRC Program Code:	NA	State: FL	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: LARGO
State: FL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NO CORRECTIVE ACTION TAKEN

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed:

Given:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: WHOLE BODY
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: rad Gy

Intended:

Diagnostic Study: WHOLE BODY I-131/THYROID

Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: NR mCi NR MBq

% Dose Exceeds Prescribed: NA
% 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):	I-131		
Manufacturer:	NR	Activity:	0.0268 Ci	0.9916	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:
EN43377	05/29/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL07-081	07/16/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070309

Last Updated: 04/14/2008

Narrative:

Rhode Island Hospital reported that a patient received only about 10% of the prescribed dose to the intended treatment site during HDR brachytherapy treatment. The patient was prescribed to receive 500 cGy (rad) to the vagina. The HDR unit [redacted] serial #31148) used a 297.85 GBq (8.05 Ci) Ir-192 source [redacted] serial #D36B-1574). The cause of the incident was an error in the catheter measurement used in the treatment plan. The dose of 500 cGy (rad) was delivered approximately 55 mm from the intended target area. The error was discovered by the chief radiotherapy physicist during an audit. The catheter was retrieved from waste, re-measured, and the treatment plan was altered to address the problem. Corrective actions included re-measurement of catheters prior to treatment. The patient's physician was informed of the incident; however, the patient was not.

Event Date: 05/10/2007 **Discovery Date:** 05/11/2007 **Report Date:** 05/11/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	RI-7D-051-01	Name:	RHODE ISLAND HOSPITAL
NRC Docket Number:	NA	City:	PROVIDENCE
NRC Program Code:	NA	State: RI	Zip Code: 02903
Respons ble NRC Region:	1		

Site of Event:

Site Name: PROVIDENCE
State: RI

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

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: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 50 rad 0.5 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8050 mCi 297850 MBq Dose: 500 rad 5 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90
Effect on Patient:

Patient Number: 1A
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 500 rad 5 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): IR-192
Manufacturer: [redacted] Activity: 8.05 Ci 297.85 GBq
Model Number: [redacted]
Serial Number: D36B-1574

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31148

Device Number: 2
Device Name: CATHETER Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:
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 prescr bed 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.

References:
Reference Number: Entry Date: Retraction Date: Coder Initials: Reference Type:

RI070001	05/23/2007	DCH	AGREEMENT STATE EVENT REPORT
EN43478	07/13/2007	RLS	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
RI070001A	08/20/2007	DCH	AGREEMENT STATE EVENT REPORT
EN43478A	03/31/2008	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
RI070001B	03/31/2008	DCH	AGREEMENT STATE EVENT REPORT
LTR080409	04/10/2008	DCH	NRC LETTER
RI070001C	04/10/2008	DCH	AGREEMENT STATE EVENT REPORT
LTR080414	04/14/2008	DCH	NRC LETTER

Item Number: 070295

Last Updated: 11/05/2007

Narrative:

Saint Anthony Hospital reported that a patient prescribed to receive 5.55 GBq (150 mCi) of I-131 for thyroid cancer only received one-half of the intended dosage. The intended activity was in two capsules in a single vial. The patient was presented with the vial containing the dosage on 4/27/2007. The patient was believed to have taken the dosage and then the vial and lead container were placed in storage. On 5/9/2007, a nuclear technician discovered a capsule in the vial. The technician reported the discovery to the RSO. The Oklahoma Radiation Management Section investigators interviewed licensee nuclear medicine technicians on 5/10/2007. The patient was notified of the incident. The cause of the incident was determined to be a failure to verify that the entire dosage was administered. The unused capsule was allowed to decay in storage. Corrective actions taken by the licensee included modifying procedures and providing additional training to personnel.

Event Date: 04/27/2007 **Discovery Date:** 05/09/2007 **Report Date:** 05/09/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OK-01428-03	Name:	SAINT ANTHONY HOSPITAL
NRC Docket Number:	NA	City:	OKLAHOMA CITY
NRC Program Code:	NA	State: OK	Zip Code: 73101
Respons ble NRC Region:	4		

Site of Event:

Site Name: OKLAHOMA CITY
State: OK

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

Event Type:

LAS - LOST/ABANDONED/STOLEN
MD2 - MEDICAL EVENT

Event Cause:

LAS
Cause: HUMAN ERROR

MD2
Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
LAS	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - A
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 150 mCi 5550 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 50
Effect on Patient:

Source of Radiation:
LAS
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.075 Ci 2.775 GBq
Model Number: NA
Serial Number: NA

MD2
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.075 Ci 2.775 GBq
Model Number: NA
Serial Number: NA

Reporting Requirements:
LAS
Reporting Requirement: 20.2201(a)(1)(i) - Lost, stolen, or missing licensed material in a quantity greater than or equal to 1,000 times the Appendix C quantities.

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.

Keywords:
LAS
MATERIAL LOST AND FOUND

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43356	05/15/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OK070004	05/15/2007		DCH	AGREEMENT STATE EVENT REPORT
OK070004A	11/05/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070276

Last Updated: 05/15/2008

Narrative:

The Aroostook Medical Center (AMC) reported that a patient received 146 MBq (3.94 mCi) of I-131 for a whole body scan instead of the prescribed 5.6 MBq (150 uCi) for a thyroid uptake scan on 1/16/2007. The event was discovered by a consulting physicist on 3/9/2007. The event occurred after a scheduling person (who does not have a background in nuclear medicine) ordered the wrong scan. AMC calculated that the dose to the patient's thyroid was approximately 5,122 cGy (rad) and the whole body effective dose equivalent was approximately 153.7 cSv (rem). If the prescribed I-131 amount had been administered, the doses would have been 525 cGy (rad) and 0.24 cSv (rem), respectively. The State Radiation Control Program performed an onsite investigation on 5/24/2007. The cause of the event was human error. AMC failed to verify the prescribed dosage and the written directive was not completed. Corrective actions included revising procedures to improve communications with referring physicians and requiring the completion of written directives for I-131 administrations greater than 1.11 MBq (30 uCi). Personnel also received additional training.

Event Date: 01/16/2007 **Discovery Date:** 03/09/2007 **Report Date:** 03/09/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	ME-03803-02	Name:	AROOSTOOK MEDICAL CENTER
NRC Docket Number:	NA	City:	PRESQUE ISLE
NRC Program Code:	NA	State: ME	Zip Code: 04769
Respons ble NRC Region:	1		

Site of Event:

Site Name: PRESQUE ISLE
State: ME

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed:

Given:

Diagnostic Study: THYROID IMAGING

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131

Intended:

Diagnostic Study: THYROID UPTAKE MEASUREMENT

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 0.15 mCi 5.55 MBq

% Dose Exceeds Prescribed: NA

% 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): I-131

Manufacturer: NR Activity: 0.00394 Ci 0.14578 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:
EN43337	05/07/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ME070016	05/07/2007		DCH	AGREEMENT STATE EVENT REPORT
EN43337A	11/05/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ME070016A	11/05/2007		DCH	AGREEMENT STATE EVENT REPORT
AS 07-02	05/15/2008		RLS	ABNORMAL OCCURRENCE NUMBER
ML081300424	05/15/2008		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 070270

Last Updated: 06/12/2007

Narrative:

The University of North Carolina Hospital reported that a patient prescribed to receive 836.2 MBq (22.6 mCi) of Y-90 microspheres only received 595.7 MBq (16.1 mCi), which resulted in a 29% underdose. An MDS Nordion TheraSphere delivery system was being used to deliver the microspheres to the patient on 4/20/2007 when a leak developed in the system. The licensee stated that the leak was caused by personnel error when assembling the administration set. They believe that the catheter was either screwed on too tight or not tight enough. The leak was not related to any manufacturing defect. Several attempts have been made to contact the patient, but the licensee has been unsuccessful. Additional attempts will be made. The patient's referring physician and the authorized user believe that the dose received was sufficient and are not planning a make-up administration. Corrective actions taken by the licensee included reviewing procedures.

Event Date: 04/20/2007 **Discovery Date:** 04/20/2007 **Report Date:** 04/23/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NC-068-0565-1	Name:	UNIVERSITY OF NORTH CAROLINA HOSPITAL
NRC Docket Number:	NA	City:	CHAPEL HILL
NRC Program Code:	NA	State: NC	Zip Code: 27514
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHAPEL HILL
State: NC

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 22.6 mCi 836.2 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 29
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: MDS NORDION, INC. Activity: 0.0161 Ci 0.5957 GBq
Model Number: THERASPHERE
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MDS NORDION, INC. Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43325	05/03/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070503	05/03/2007		DCH	AGREEMENT STATE LETTER
NC070020	05/03/2007		DCH	AGREEMENT STATE EVENT REPORT
NC070020A	06/12/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070263

Last Updated: 05/19/2008

Narrative:

Memorial Mission Hospital (MMH) reported that a 19-year-old female patient received 1,235.8 MBq (33,400 uCi) of I-131 instead of the intended 1.24 MBq (33.4 uCi) for a diagnostic thyroid scan. The incident involved a misdrawn and mislabeled dose from Shertech Pharmacy. The written directive was for 1.11 MBq (30 uCi). Two different nuclear medicine technologists at MMH measured the dosage in the dose calibrator; however, both read the number but missed the units. The calibrator printed the results, which were attached to the dose without review. Additionally, the dosage was placed into a neck phantom for a third check, but those results were not evaluated. The dose was administered on 4/24/2007 and the error was discovered on 4/26/2007. As a result of this event, the patient's thyroid received a dose of 28,728 cGy (rad). The patient and physician were notified. The physician indicated that the patient had a normally functioning thyroid prior to the administration. The patient is expected to be on synthetic thyroid hormone for the remainder of her life. Investigations were performed by the North Carolina Radioactive Materials Branch and the North Carolina Board of Pharmacy on 5/8 and 5/9/2007. Items of noncompliance were issued to MMH, but none were issued to Shertech. Corrective actions taken by MMH included ceasing to purchase radiopharmaceuticals from the radiopharmacy, modified their radiopharmaceutical receipt procedure, and providing additional training to personnel.

Event Date: 04/24/2007 **Discovery Date:** 04/26/2007 **Report Date:** 04/26/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NC-011-0091-6	Name:	MEMORIAL MISSION HOSPITAL
NRC Docket Number:	NA	City:	ASHEVILLE
NRC Program Code:	NA	State: NC	Zip Code: 28801
Respons ble NRC Region:	1		

Site of Event:

Site Name: ASHVILLE
State: NC

Additional Involved Party:

License Number:	NC-011-1203-1	Name:	SHERTECH PHARMACY
NRC Docket Number:	NA	City:	ASHVILLE
NRC Program Code:	NA	State: NC	Zip Code: NR
Respons ble NRC Region:	1		

Other Information:

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 04/26/2007

Given:

Therapeutic Procedure: SODIUM IODIDE - T

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Dose: 28728 rad 287.28 Gy

Intended:

Diagnostic Study: THYROID IMAGING

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 0.0334 mCi 1.2358 MBq

% Dose Exceeds Prescribed: 99900

% 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): I-131

Manufacturer: NR Activity: 0.0339 Ci 1.2543 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:
EN43321	05/02/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070501	05/02/2007		DCH	AGREEMENT STATE LETTER
NC070022	06/12/2007		DCH	AGREEMENT STATE EVENT REPORT
LTR070809	08/13/2007		DCH	NRC LETTER
AS 07-04	05/15/2008		RLS	ABNORMAL OCCURRENCE NUMBER
ML081300424	05/15/2008		RLS	ABNORMAL OCCURRENCE NUMBER
NC070022A	05/19/2008		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070235

Last Updated: 06/05/2007

Narrative:

The licensee reported that a patient undergoing Y-90 therasphere treatment of the liver received 5,440 cGy (rad) to the right lobe instead of the prescr bed 12,000 cGy (rad). The patient received 3.28 GBq (88.65 mCi). The authorized user confirmed the setup was correct when queried during the pre-administration checklist. However, the stopcock was turned so that the dose was directed to the waste vial rather than into the patient delivery catheter. During administration, the interventional radiologist noted liquid in the waste vial tubing and directed the authorized user to stop treatment. The authorized user re-checked the delivery system and corrected the stopcock orientation. The remainder of the dose was delivered to the patient. The patient and referring physician were notified of the incident. Corrective action taken to prevent recurrence included requiring a second individual to check the delivery setup portion in addition to the individual actually delivering the dose. That second check was incorporated into the checklist.

Event Date: 04/18/2007 **Discovery Date:** 04/18/2007 **Report Date:** 04/18/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-06009-01	Name:	COMMUNITY HOSPITALS OF INDIANA
NRC Docket Number:	03001625	City:	INDIANAPOLIS
NRC Program Code:	02230	State: IN	Zip Code: 46219
Respons ble NRC Region:	3		

Site of Event:

Site Name: INDIANAPOLIS
State: IN

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

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: 04/18/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 5440 rad 54.4 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: NR mCi NR MBq Dose: 12000 rad 120 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 55
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES
Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: NR
Activity: 0.08865 Ci 3.28005 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

Device Number: 2
Device Name: CATHETER
Model Number: NR
Manufacturer: NR
Serial Number: NA

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43308	04/20/2007		DCH	EVENT NOTIFICATION
ML071430165	05/31/2007		RLS	INSPECTION REPORT
ML071430165	05/31/2007		RLS	NOTICE OF VIOLATION
ML071430165	05/31/2007		RLS	NRC LETTER
LTR070604	06/05/2007		DCH	NRC LETTER

Item Number: 070215

Last Updated: 05/15/2008

Narrative:

The licensee reported that a 31-year-old female patient with a history of vaginal cancer was prescribed 2,500 cGy (rad) via interstitial brachytherapy to the 50 cGy (rad) isodose line, but received 4,590 cGy (rad). The patient's anterior rectal dose was approximately 7,300 cGy (rad). The licensee used both Cs-137 and Ir-192 for the treatment. The medical physicist developed a treatment plan as directed by the authorized user/radiation oncologist using a commercial treatment planning software application. The licensee used 11 seed ribbons, each containing eight Ir-192 seeds (Best Industries), with each seed contained an activity of 1.855 mgRaEq or 118 MBq (3.19 mCi). A Syed template was used to place the Ir-192 ribbons and the Cs-137 sources were loaded into a tandem applicator. The treatment was initiated on 3/6/2007. The medical physicist performed a manual check of the treatment plan calculations on 3/7/2007 and identified a significant discrepancy. It was noted that the hand calculations indicated a significantly higher dose rate than what was generated by the treatment planning software. After several hours of investigation, it was determined that the original treatment plan was in error. After 27 hours of the intended 50-hour treatment time, the sources were removed from the patient. The primary error was the use of an inappropriate dose rate factor in the treatment planning software. The value used corresponded to the dose rate factor for air Kerma; however, the source strength was entered in milligram radium equivalent. During the physics review, it was determined that acceptance testing of this treatment planning software did not include Ir-192; the acceptance testing covered only Cs-137 and I-125. There was no check of the preplan prior to obtaining the Ir-192 seeds, although there was sufficient time. Neither the physicist nor the radiation oncologist had prepared a treatment using Ir-192 in six years and the physicist had not used this particular treatment planning software for Ir-192. It would have been prudent to have an additional review or outside review. The double check was not performed until the day after the treatment began. Corrective actions taken by the licensee included changing the policy and procedures to require a check of calculations for any single fraction brachytherapy treatment. The radiation oncologist disclosed that the patient is at risk for radiation cystitis, rectal proctitis, and, more importantly, fistula formation between the rectum and the vagina. The patient will be monitored closely over the next year by both her gynecologic oncologist and the radiation oncologist. The patient was treated with broad spectrum antibiotics along with daily treatments in a hyperbaric oxygen chamber. Department of Health staff performed a reactive inspection on 3/21/2007. Licensee staff was interviewed and radiation therapy quality assurance policies, procedures, and patient records were reviewed. The patient's record was sent for review by a radiation oncologist and medical physicist. Their report identified several issues which the Department of Health will follow-up on.

Event Date: 03/06/2007 **Discovery Date:** 03/07/2007 **Report Date:** 03/21/2007

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
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:	Y	Abnormal Occurrence:	Y
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: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 4590 rad 45.9 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 2500 rad 25 Gy

% Dose Exceeds Prescribed: 83.6
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 7300 rad 73 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% 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): IR-192
Manufacturer: BEST INDUSTRIES Activity: 0.2807 Ci 10.3859 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: SEED RIBBON Model Number: NA
Manufacturer: BEST INDUSTRIES Serial Number: AGGREGATE

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
NYS-DOH 07-001	04/11/2007		DCH	AGREEMENT STATE EVENT REPORT
EN43301	04/17/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070425	04/30/2007		DCH	NRC LETTER

LTR070608	06/11/2007	DCH	AGREEMENT STATE LETTER
LTR070626	06/27/2007	DCH	AGREEMENT STATE LETTER
AS 07-03	05/15/2008	RLS	ABNORMAL OCCURRENCE NUMBER
ML081300424	05/15/2008	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 070211

Last Updated: 09/10/2007

Narrative:

The licensee reported that a patient did not receive the prescribed dose scheduled for a single fraction interstitial treatment using a [redacted] HDR remote afterloader [redacted] containing an Ir-192 source [redacted]) with an activity of 230.9 GBq (6.24 Ci). The patient was scheduled to receive 900 cGy (rad) to the vagina. An incorrect applicator length of 100 cm was input into the treatment plan. The actual applicator length was 120 cm. The licensee determined that the source was at least 10 cm from the patient's thigh and calculated an excess dose to the thigh of 50 cGy (rad). No reddening of the skin was observed. The authorized user and patient were notified on 4/4/2007. A State inspector was dispatched to the facility on 4/6/2007. Corrective actions taken by the licensee included providing additional training to personnel and generating new policies and procedures. The authorized user and authorized medical physicist will spot check the length of at least 20% of the applicators after treatment planning and prior to patient treatment. The patient was retreated on 4/12/2007.

Event Date: 04/04/2007 **Discovery Date:** 04/04/2007 **Report Date:** 04/05/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-09-1303-01	Name:	SAINT VINCENT HOSPITAL
NRC Docket Number:	NA	City:	GREEN BAY
NRC Program Code:	NA	State: WI	Zip Code: 54307
Respons ble NRC Region:	3		

Site of Event:

Site Name: GREEN BAY
State: WI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING
2	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 04/04/2007

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6240 mCi 230880 MBq Dose: 900 rad 9 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 04/04/2007

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LEG
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 50 rad 0.5 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LEG
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6240 mCi 230880 MBq Dose: 0 rad 0 Gy

% Dose Exceeds Prescribed: 100
% 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): IR-192
Manufacturer: [redacted] Activity: 6.24 Ci 230.88 GBq
Model Number: [redacted]
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
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 prescr bed 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:

EN43288	04/10/2007	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI070008	05/07/2007	DCH	AGREEMENT STATE EVENT REPORT
WI070008A	07/09/2007	DCH	AGREEMENT STATE EVENT REPORT
WI070008B	09/10/2007	DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070184

Last Updated: 10/17/2007

Narrative:

The Department of Veterans Affairs (VA) reported that a patient received 1.11 GBq (30 mCi) of I-131 instead of the prescribed 0.56 GBq (15 mCi) at the VA Eastern Colorado Health Care System on 5/31/2006. The incident was discovered on 3/28/2007. The clinical intent was for the patient to receive 1.11 GBq (30 mCi), but the written directive listed the prescribed dose of 0.56 GBq (15 mCi). The licensee implemented corrective actions to prevent a recurrence of the incident. The NRC reviewed the incident and determined that it is a reportable medical event. The NRC conducted an evaluation of the licensee's inspection results and issued a closure letter to the licensee.

Event Date: 05/31/2006 **Discovery Date:** 03/28/2007 **Report Date:** 03/29/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: DENVER
State: CO

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NOT REPORTED

Patient Information:

Patient Number: 1

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 15 mCi 555 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 100
% 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):	I-131		
Manufacturer:	NR	Activity:	0.03 Ci	1.11	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:
EN43265	04/02/2007		DCH	EVENT NOTIFICATION
ML072540778	09/19/2007		RLS	NRC LETTER
LTR071017	10/17/2007		DCH	NRC LETTER

Item Number: 070183

Last Updated: 10/06/2010

Narrative:

Kay County Hospital reported that 10 patients received doses 27% higher than prescribed during I-125 prostate seed implant procedures (see medical tables for details). The hospital had changed from ordering I-125 doses in Air-Kerma to mCi. During the time period from 5/3/2006 to 3/27/2007, they used an incorrect dose count, which caused each of the 10 patients to receive doses 27% higher than written directives specified. The error was discovered on 3/28/2007 by a newly hired medical physicist. All patients were informed of the errors on 3/29/2007. The Oklahoma Department of Environmental Quality investigated the incidents. Corrective actions taken included an update to the software used to calculate the dose from the I-125 brachytherapy seeds.

Event Date: 05/03/2006 **Discovery Date:** 03/28/2007 **Report Date:** 03/29/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OK-14046-02	Name:	KAY COUNTY HOSPITAL
NRC Docket Number:	NA	City:	PONCA CITY
NRC Program Code:	NA	State: OK	Zip Code: 74602
Respons ble NRC Region:	4		

Site of Event:

Site Name: PONCA CITY
State: OK

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW EQUIPMENT OBTAINED
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 03/29/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12700 rad 127 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 10
Patient Informed: Y Date Informed: 03/29/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12700 rad 127 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 2
Patient Informed: Y Date Informed: 03/29/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 18415 rad 184.15 Gy

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

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 3
Patient Informed: Y Date Informed: 03/29/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12700 rad 127 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 4
Patient Informed: Y Date Informed: 03/29/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12700 rad 127 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 5
Patient Informed: Y Date Informed: 03/29/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12700 rad 127 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 6
Patient Informed: Y Date Informed: 03/29/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 18415 rad 184.15 Gy

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

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 7
Patient Informed: Y Date Informed: 03/29/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12700 rad 127 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 8
Patient Informed: Y Date Informed: 03/29/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12700 rad 127 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 9
Patient Informed: Y Date Informed: 03/29/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 12700 rad 127 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: 27
% 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): I-125
Manufacturer: CORE ONCOLOGY Activity: 0.0144 Ci 0.5328 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 10
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY Activity: 0.0363 Ci 1.3431 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 2
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY Activity: 0.02825 Ci 1.04525 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 3
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY Activity: 0.017215 Ci 0.636955 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 4
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY Activity: 0.02728 Ci 1.00936 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 5
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY Activity: 0.01612 Ci 0.59644 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 6
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: CORE ONCOLOGY Activity: 0.02825 Ci 1.04525 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Source Number: 7

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125		
Manufacturer:	CORE ONCOLOGY	Activity:	0.03274 Ci	1.21138	GBq
Model Number:	125SL				
Serial Number:	AGGREGATE				

Source Number: 8

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125		
Manufacturer:	CORE ONCOLOGY	Activity:	0.03107 Ci	1.14959	GBq
Model Number:	125SL				
Serial Number:	AGGREGATE				

Source Number: 9

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	I-125		
Manufacturer:	CORE ONCOLOGY	Activity:	0.02314 Ci	0.85618	GBq
Model Number:	125SL				
Serial Number:	AGGREGATE				

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43263	04/02/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OK070003	04/17/2007		DCH	AGREEMENT STATE EVENT REPORT
LTR090421	04/22/2009		DCH	NRC LETTER
LTR101004	10/06/2010		DCH	AGREEMENT STATE LETTER

Item Number: 070181

Last Updated: 02/26/2009

Narrative:

The University of Miami School of Medicine (UM) reported that a patient prescr bed to receive 2.74 GBq (74 mCi) of I-131 during a Bexxar Therapy procedure only received between 0.19 and 0.37 GBq (5 and 10 mCi). The T-connector to the catheter was not fitted tight enough, causing the connector to come loose from the tubing. Some I-131 spilled on the floor. The patient and prescr bing physician were notified of the dosing error. UM plans to conduct another procedure on 3/30/2007. The Florida Department of Health will follow up with UM on the incident. Corrective actions included modifying procedures to require that two individuals verify that the T-connector is tightly connected to each tube before administration begins.

Event Date: 03/28/2007 **Discovery Date:** 03/28/2007 **Report Date:** 03/28/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-1319-1	Name:	UNIVERSITY OF MIAMI SCHOOL OF MEDICINE
NRC Docket Number:	NA	City:	MIAMI
NRC Program Code:	NA	State: FL	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: MIAMI
State: FL

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

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:

Given:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 74 mCi 2738 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 93
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	UNSEALED SOURCE RADIOPHARM	Radionuclide or Voltage (kVp/MeV):	I-131		
Manufacturer:	NR	Activity:	0.005 Ci	0.185	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:
EN43260	04/02/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070611	06/11/2007		DCH	AGREEMENT STATE LETTER
FL07-054	02/26/2009		DCH	AGREEMENT STATE EVENT REPORT
LTR090216	02/26/2009		DCH	AGREEMENT STATE LETTER

Item Number: 070180

Last Updated: 05/24/2007

Narrative:

The licensee (dba California Surgery Center) reported that a patient receiving mammosite treatment with a total prescr bed dose of 3,400 cGy (rad) to be delivered in 10 fractions over the course of five days, only received 1,700 cGy (rad). The treatment was performed using a [redacted] high dose rate brachytherapy unit [redacted] serial #31703) and an Ir-192 source (serial #D36B-0632) with an activity of 151.7 GBq (4.1 Ci). The first five fractions were delivered uneventfully. During the last five fractions, the radiation therapy technologist accidentally imported the wrong treatment plan, resulting in an underdose to the treatment area. The dwell position of the source was actually fully outside of the patient, so the tumor received effectively no dose. The licensee is calculating the skin and whole body dose to the patient. The patient and referring physician were notified and re-treatment was scheduled. The incident was discovered upon review of the patient's chart when the patient returned for a follow-up exam. Corrective actions taken by the licensee included transferring all patient plans from the planning computer to the treatment control computer using a patient and date specific optical disk, verification and documentation of the dwell times and dwell positions for each mammosite fraction in writing by the treating therapist on a patient specific QA sheet prior to each fraction, and providing mandatory additional training to all clinical staff involved in HDR treatments including procedure review and treatment planning review for physics/dosimetry.

Event Date: 03/19/2007 **Discovery Date:** 03/26/2007 **Report Date:** 03/27/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CA-6833-15	Name:	RAVI PATEL, MD, INC.
NRC Docket Number:	NA	City:	BAKERSFIELD
NRC Program Code:	NA	State: CA	Zip Code: 93309
Respons ble NRC Region:	4		

Site of Event:

Site Name: BAKERSFIELD
State: CA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 1700 rad 17 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 4100 mCi 151700 MBq Dose: 3400 rad 34 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 50
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 4.1 Ci 151.7 GBq
Model Number: NR
Serial Number: D36B-0632

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31703

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
CA-XCA1088	04/02/2007		DCH	AGREEMENT STATE EVENT REPORT
EN43258	04/02/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070427	05/02/2007		DCH	AGREEMENT STATE LETTER
LTR070523	05/24/2007		DCH	AGREEMENT STATE LETTER

Item Number: 070157

Last Updated: 07/12/2007

Narrative:

The licensee reported that a patient received a dose that was 20% less than prescribed during a gamma knife treatment. The gamma knife [redacted] was manufacturer by [redacted] and contained 201 Co-60 sources with an activity of between 244.16 and 267.73 TBq (6,599 and 7,236 Ci). The treatment dose was prescribed as “40% of maximum dose equivalent equals 1,100 cGy (rad),” but was calculated as "50% of maximum dose equivalent equals 1,100 cGy (rad)". This event was discovered during a quality review by licensee staff. The Florida Bureau of Radiation Control determined this to be a medical event. Corrective actions taken by the licensee included adding a step to the gamma knife treatment plan for dose verification.

Event Date: 01/23/2007 **Discovery Date:** 03/03/2007 **Report Date:** 03/19/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-3823-2	Name:	DOCTORS HOSPITAL
NRC Docket Number:	NA	City:	CORAL GABLES
NRC Program Code:	NA	State: FL	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: CORAL GABLES
State: FL

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

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: U Date Informed:

Given:

Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: 2200 rad 22 Gy

Intended:

Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 2750 rad 27.5 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 20
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:	7236 Ci	267732	GBq
Model Number:	NR				
Serial Number:	AGGREGATE				

Device/Associated Equipment:

MD2

Device Number: 1

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

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43252	03/21/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070611	06/11/2007		DCH	AGREEMENT STATE LETTER
FL07-046	07/12/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070152

Last Updated: 05/09/2007

Narrative:

The licensee reported that a patient received only 66% of a prescribed administration of 1.11 GBq (30 mCi) of Y-90 Sirtex Medical SIR-Spheres. The delivery catheter developed a leak around the c-line collar of the delivery set during administration. The authorized user unsuccessfully attempted to seal the leak. Leakage was contained within the plexiglas box containing the vial of microspheres. There was minimal contamination outside of the box. The licensee performed Bremsstrahlung measurements of the patient and the plexiglas box. Based on the differences, the administered dose was determined to be 66% of the prescribed dose. The licensee noted that this was the first of a two-part administration of the microspheres and the dose at the next treatment was adjusted to compensate for the difference. The incident was reported to the manufacturer. The problem with this delivery set lot number was known to the licensee. A new lot number was shipped to the licensee. The authorized user suspended these procedures until the new delivery systems were obtained and tested to verify satisfactory flow with no leakage. The device manufacturer traced the leaky units to one operator who had deviated from the normal assembly procedure. Sirtex destroyed the remainder of that lot number (batch #63000) and replaced them with a new, tested lot. Retraining was undertaken by all staff and increased inspections were carried out by Sirtex.

Event Date: 01/31/2007 **Discovery Date:** 01/31/2007 **Report Date:** 02/02/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NC-060-0014-3	Name:	CAROLINAS MEDICAL CENTER
NRC Docket Number:	NA	City:	CHARLOTTE
NRC Program Code:	NA	State: NC	Zip Code: 28203
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHARLOTTE
State: NC

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

Event Type:

EQP - EQUIPMENT
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: DEFECTIVE OR FAILED PART

MD2
Cause: DEFECTIVE OR FAILED PART

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	NEW EQUIPMENT OBTAINED
MD2	
1	NEW EQUIPMENT OBTAINED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 01/31/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 30 mCi 1110 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 34
Effect on Patient:

Source of Radiation:
EQP
Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: SIRTEX MEDICAL Activity: 0.0198 Ci 0.7326 GBq
Model Number: SIR-SPHERES
Serial Number: NA

MD2
Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: SIRTEX MEDICAL Activity: 0.0198 Ci 0.7326 GBq
Model Number: SIR-SPHERES
Serial Number: NA

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: SIRTEX MEDICAL Serial Number: NR

MD2
Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: SIRTEX MEDICAL Serial Number: NR

Reporting Requirements:
EQP
Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
NC070002	03/20/2007		DCH	AGREEMENT STATE EVENT REPORT
EN43336	05/08/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC070002A	05/09/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070137

Last Updated: 04/10/2007

Narrative:

The licensee reported that a patient was administered 2,400 cGy (rad) instead of the prescr bed dose of 3,192 cGy (rad) during a series of fractional treatments using a [redacted] high dose rate afterloader (serial #262T) with an Ir-192 source containing an activity of 261.4 GBq (7.066 Ci). The treatments occurred between 2/13/2007 and 2/20/2007. The patient also received dose to an incorrect site. The treatment plan did not include a correction for the catheter connector type (disposable vs. reusable), resulting in a 1.4 cm source positioning error. The error was identified during the review process following the last dose fraction. The patient was informed of the incident on 3/6/2007. The patient will likely have a skin reaction to the treatment, which is expected to heal with time. Corrective actions taken by the licensee included instituting new procedures and checklists.

Event Date: 02/13/2007 **Discovery Date:** 02/20/2007 **Report Date:** 02/23/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CO-197-02	Name:	CENTURA HEALTH PENRONSE SAINT FRANCIS HOSPITAL
NRC Docket Number:	NA	City:	COLORADO SPRINGS
NRC Program Code:	NA	State: CO	Zip Code: 80907
Respons ble NRC Region:	4		

Site of Event:

Site Name: COLORADO SPRINGS
State: CO

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 03/06/2007

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 2400 rad 24 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 7066 mCi 261442 MBq Dose: 3192 rad 31.92 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 24.8
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 03/06/2007

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: NR rad NR Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): IR-192
Manufacturer: [redacted] Activity: 7.066 Ci 261.442 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: NR
Manufacturer: [redacted] Serial Number: 262T

Reporting Requirements:
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 prescr bed 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:

EN43220	03/09/2007	RLS	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
CO07-M07-01	04/10/2007	DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070121

Last Updated: 10/31/2007

Narrative:

Akron General Medical Center reported that a patient received 680 cGy (rad) per fraction for five fractions of [redacted] therapy instead of the prescr bed 340 cGy (rad) per fraction for 10 fractions on 9/27/2007. However, the total prescribed dose of 3,400 cGy (rad) was administered. The licensee was using a [redacted] HDR [redacted] serial #31472) and an Ir-192 source [redacted] serial #D36A-9791) that contained an activity of 219.78 GBq (5.94 Ci). This event occurred when the physician entered the wrong planning film magnification into the treatment system, which doubled the fractional dose. Although some tissue necrosis at the treatment site is expected with [redacted] therapy, the necrosis may have been exacerbated by the administered dosage scheme. The patient and physician were notified on 9/27/2006. The patient is being followed by her attending physician. The licensee developed an extensive revision to the HDR Program and personnel received additional training. The Ohio Department of Health conducted and inspection during the week of 3/5/2007 to ascertain the licensee's corrective actions and the status of the patient.

Event Date: 09/27/2006 **Discovery Date:** 09/27/2006 **Report Date:** 02/26/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120780000	Name:	AKRON GENERAL MEDICAL CENTER
NRC Docket Number:	NA	City:	AKRON
NRC Program Code:	NA	State: OH	Zip Code: 44307
Respons ble NRC Region:	3		

Site of Event:

Site Name: AKRON
State: OH

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INATTENTION TO DETAIL

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW QUALITY MANAGEMENT PLAN
2	PROCEDURE MODIFIED
3	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 09/27/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 680 rad 6.8 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 5940 mCi 219780 MBq Dose: 340 rad 3.4 Gy

% Dose Exceeds Prescribed: 100
% 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): IR-192
Manufacturer: [redacted] Activity: 5.94 Ci 219.78 GBq
Model Number: [redacted]
Serial Number: D36A-9791

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31472

Reporting Requirements:
MD2
Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43192	03/01/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070711	07/11/2007		DCH	AGREEMENT STATE LETTER
OH070011	10/31/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070092

Last Updated: 06/26/2009

Narrative:

The licensee reported at least six medical events involving patient doses ranging from 21.6 to 36.5% more than prescribed for prostate gland permanent brachytherapy seed implant procedures using I-125. The medical table shows the pre-plan D90 (prescribed) doses and the post-plan D90 (received) doses to the six patients. All six patients were prescribed V100 doses of 14,500 cGy (rad). The patient procedures began on 1/4/2006 and the sixth patient received treatment on 8/14/2006. The medical events were discovered on 2/12/2007. The events occurred when an improper dose rate constant was used in treatment planning. The licensee investigated 28 patient procedures performed over the past year. The Texas Department of Health Services is also investigating the incident. Corrective actions taken by the licensee included password protecting the treatment planning system in order to limit access to source data, developing policies and procedures to address source data changes/corrections, developing policies and procedures to require that source data be reviewed on a regular basis by a physicist, and training dosimetry and physics staff regarding revisions.

Event Date: 01/04/2006 **Discovery Date:** 02/12/2007 **Report Date:** 02/13/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TX-L05805	Name:	CHRISTUS SANTA ROSA SURGERY CENTER
NRC Docket Number:	NA	City:	SAN ANTONIO
NRC Program Code:	NA	State: TX	Zip Code: NR
Respons ble NRC Region:	4		

Site of Event:

Site Name: SAN ANTONIO
State: TX

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Old Cause: INCORRECT DATA USED IN THERAPY DOSE PLANNING

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 19145 rad 191.45 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 24382 rad 243.82 Gy

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 2
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 18574 rad 185.74 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 23595 rad 235.95 Gy

% Dose Exceeds Prescribed: 27
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 3
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 18897 rad 188.97 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 22736 rad 227.36 Gy

% Dose Exceeds Prescribed: 20
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 4
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 17712 rad 177.12 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 24178 rad 241.78 Gy

% Dose Exceeds Prescribed: 37
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 5
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 18876 rad 188.76 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 22954 rad 229.54 Gy

% Dose Exceeds Prescribed: 22
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 6
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 18752 rad 187.52 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 23503 rad 235.03 Gy

% Dose Exceeds Prescribed: 25
% 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): I-125
Manufacturer: NR
Activity: NR Ci NR GBq
Model Number: NR
Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43163	02/19/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
TX-I-8391	02/19/2007		DCH	AGREEMENT STATE EVENT REPORT
LTR070411	04/18/2007		DCH	AGREEMENT STATE LETTER
LTR070425	05/01/2007		DCH	AGREEMENT STATE LETTER
LTR090625	06/26/2009		DCH	AGREEMENT STATE LETTER

Item Number: 070074

Last Updated: 05/15/2008

Narrative:

The University of Virginia Hospital reported that a patient received 770 cGy (rad) to the cervix instead of the prescribed 3,000 cGy (rad). The patient also received doses to unintended locations. A Fletcher-Suit tandem and ovoid applicator containing 6.29 GBq (170 mCi) of Cs-137 was loaded into the patient on 2/2/2007 for a treatment time of 48.5 hours. Upon removal of the device, it was observed that the tandem applicator had been loaded with a plastic radioactive source carrier insert (tandem insert) that was approximately 4 cm shorter than the required 24 cm. This caused the sources in the tandem applicator to be displaced from the intended position, resulting in a lower than intended dose to the treatment site and higher than intended doses to other locations. There were three areas of unintended dose. The rectum area was prescribed 930 cGy (rad) and received 2,472 cGy (rad), the vaginal mucosa area was prescribed 411 cGy (rad) and received 1,484 cGy (rad), and a second vaginal mucosa area was prescr bed 265 cGy (rad) and received 1,414 cGy (rad). The licensee administered external beam treatment to compensate for the underdose. The NRC contracted a medical consultant to review this event. The consultant concluded that no significant adverse impact is expected. Corrective actions included additional training for applicable personnel and procedure modification.

Event Date: 02/02/2007 **Discovery Date:** 02/04/2007 **Report Date:** 02/05/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	45-00034-26	Name:	UNIVERSITY OF VIRGINIA
NRC Docket Number:	03003296	City:	CHARLOTTESVILLE
NRC Program Code:	02110	State: VA	Zip Code: 22903
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHARLOTTESVILLE
State: VA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: NOT REPORTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 770 rad 7.7 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 170 mCi 6290 MBq Dose: 3000 rad 30 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 74
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 2472 rad 24.72 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 170 mCi 6290 MBq Dose: 930 rad 9.3 Gy

% Dose Exceeds Prescribed: 166
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1B
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 1484 rad 14.84 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 170 mCi 6290 MBq Dose: 411 rad 4.11 Gy

% Dose Exceeds Prescribed: 261
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1C
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 1414 rad 14.14 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 170 mCi 6290 MBq Dose: 265 rad 2.65 Gy

% Dose Exceeds Prescribed: 434
% 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: 0.17 Ci 6.29 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: MANUAL AFTERLOADER Model Number: NR
Manufacturer: FLETCHER-SUIT Serial Number: NR

Reporting Requirements:
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 prescr bed 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:
EN43145	02/07/2007		DCH	EVENT NOTIFICATION
ML071280817	05/16/2007		RLS	INSPECTION REPORT
ML071280817	05/16/2007		RLS	NOTICE OF VIOLATION
ML071280817	05/16/2007		RLS	NRC LETTER
LTR070615	06/18/2007		DCH	NRC LETTER
LTR070615A	06/18/2007		DCH	NRC LETTER
ML071300432	02/13/2008		RLS	LICENSEE REPORT
ML071300432	02/13/2008		RLS	REGION REPORT
07-05	05/15/2008		RLS	ABNORMAL OCCURRENCE NUMBER
ML081300424	05/15/2008		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 070060

Last Updated: 04/18/2007

Narrative:

The Florida Agency for Health Care Administration reported that while performing an audit of the licensee, a medical event involving brachytherapy seeds was identified. The procedure involved the implant of 60 I-125 seeds totaling approximately 0.75 GBq (20.39 mCi). A review of preplanning, live planning, and post planning documents was conducted on 6/22/2006 and a wrong site administration was declared by the prescribing radiation oncologist and RSO. Their conclusion was supported by diagnostic films and physics calculations. The referring physician and patient were informed of the incident. The patient has undergone a diagnostic computed tomography exam and follow-up appointment. The medical event was determined reportable. The Florida Department of Health visited the licensee's facility to obtain details of the incident. It was determined that the written transrectal ultrasound-guided treatment plan had not been followed. A new plan was developed and implemented without the assistance of a certified sonographer and without a written change by the authorized user. The prostate was prescribed to receive 11400 cGy (rad) to 98% of its volume, but received only 1000 cGy (rad) to 46% of its volume. The penile bulb was estimated to have received approximately 14400 cGy (rad) to 11% of its volume. Corrective actions taken by the licensee included procedure modifications requiring a qualified ultrasound technologist to be present at all implants to ensure the visualization of the prostate. Also, if the urologist, radiation oncologist, or medical physicist have any questions concerning the location of the prostate and or the placement of the needles, the implant procedure will be stopped until those questions are resolved.

Event Date: 06/13/2006 **Discovery Date:** 06/22/2006 **Report Date:** 01/11/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-3704-1	Name:	SURGICAL CENTER OF CENTRAL FLORIDA
NRC Docket Number:	NA	City:	SEBRING
NRC Program Code:	NA	State: FL	Zip Code: 33870
Respons ble NRC Region:	1		

Site of Event:

Site Name: SEBRING
State: FL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED
Old Cause: NOT REPORTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 1000 rad 10 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 20.39 mCi 754.43 MBq Dose: 11400 rad 114 Gy

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

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PENILE BULB
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 14400 rad 144 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): I-125
Manufacturer: NR Activity: 0.02039 Ci 0.75443 GBq
Model Number: NR
Serial Number: AGGREGATE

Reporting Requirements:
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 prescr bed 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:
EN43112	01/29/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL07-005	03/27/2007		DCH	AGREEMENT STATE EVENT REPORT
LTR070412	04/18/2007		DCH	AGREEMENT STATE LETTER

Item Number: 070025

Last Updated: 05/30/2007

Narrative:

The licensee reported an underdose to a patient's prostate after a Mick applicator malfunctioned during treatment. The patient was scheduled to receive 44 I-125 brachytherapy seeds (Best Medical), each containing an activity of 9.25 MBq (0.25 mCi). However, only 33 seeds had been implanted when the malfunction occurred. The seeds not implanted were accounted for and were placed in storage. The patient was notified of the incident on 1/10/2007. The patient received 11,000 cGy (rad) to the prostate gland. In the future, the operating room team will be more aware of the seed count. The dosimetrist will monitor the seed count and the physicist will not be distracted with interruptions. The Mick applicator was sent to the manufacturer for inspection/repair.

Event Date: 01/09/2007 **Discovery Date:** 01/09/2007 **Report Date:** 01/09/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	SC-0646	Name:	CARE ALLIANCE HEALTH SERVICES ROPER HOSPITAL
NRC Docket Number:	NA	City:	CHARLESTON
NRC Program Code:	NA	State: SC	Zip Code: 29401
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHARLESTON
State: SC

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

Event Type:

EQP - EQUIPMENT
MD2 - MEDICAL EVENT

Event Cause:

EQP
Cause: DEFECTIVE OR FAILED PART
Old Cause: NOT REPORTED

MD2
Cause: DEFECTIVE OR FAILED PART
Old Cause: NOT REPORTED

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	PROCEDURE MODIFIED
2	EQUIPMENT RETURNED TO MANUFACTURER FOR REPAIR OR DISPOSAL
MD2	
1	PROCEDURE MODIFIED
2	EQUIPMENT RETURNED TO MANUFACTURER FOR REPAIR OR DISPOSAL

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 01/10/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 11000 rad 110 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 11 mCi 407 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 25
Effect on Patient:

Source of Radiation:
EQP
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BEST MEDICAL INTER. Activity: 0.00825 Ci 0.30525 GBq
Model Number: NR
Serial Number: AGGREGATE

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BEST MEDICAL INTER. Activity: 0.00825 Ci 0.30525 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MICK RADIO-NUCLEAR Serial Number: NR

MD2
Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: MICK RADIO-NUCLEAR Serial Number: NR

Reporting Requirements:
EQP
Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43087	01/15/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
SC070001	03/01/2007		DCH	AGREEMENT STATE EVENT REPORT
LTR070314	03/19/2007		DCH	AGREEMENT STATE LETTER
LTR070524	05/30/2007		DCH	AGREEMENT STATE LETTER

Item Number: 070024

Last Updated: 05/14/2008

Narrative:

Hackley Hospital reported that an error occurred during a brachytherapy seed implant procedure, resulting in a dose less than prescribed to the intended site and doses greater than prescr bed to unintended sites. The patient was prescr bed a total dose of 12,000 cGy (rad) to the prostate using 41 I-125 seeds, with each seed containing 11.84 MBq (0.32 mCi). The patient moved after seven seeds had been implanted (two of the 14 treatment needles). The procedure was delayed to allow additional anesthesia to take affect. The lineup was checked using ultrasound and the implant procedure was resumed once the urologist, radiation oncologist, and medical physicist were comfortable with the situation. After the procedure was completed, radiographs revealed that 34 of the 41 seeds (needles 3 through 14) were inadvertently deposited approximately 4 cm inferior to the prostate into the penile bulb. As a result, the prostate received a dose of 1,300 cGy (rad). In addition, the penile bulb received approximately 11,000 cGy (rad), and the patient's skin received approximately 240 cGy (rad), more than 50% greater than prescribed. The dose to the penile bulb could result in scarring, fibrosis, erectile dysfunction, and impotency. The patient was notified of the error. This event was caused by the failure to have adequate procedures and a lack of communication. The NRC contracted a medical consultant, who concurred with the hospital's evaluation. Corrective actions included procedure revision, including performing imaging during the treatment rather than only at the end of the treatment.

Event Date: 01/08/2007 **Discovery Date:** 01/08/2007 **Report Date:** 01/08/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-04125-01	Name:	HACKLEY HOSPITAL
NRC Docket Number:	03002044	City:	MUSKEGON
NRC Program Code:	02120	State: MI	Zip Code: 49443
Respons ble NRC Region:	3		

Site of Event:

Site Name: MUSKEGON
State: MI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 01/08/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 1300 rad 13 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 13.12 mCi 485.44 MBq Dose: 12000 rad 120 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 89
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 01/08/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PENILE BULB
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 11000 rad 110 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1B
Patient Informed: Y Date Informed: 01/08/2007

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 240 rad 2.4 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): I-125
Manufacturer: NR
Activity: 0.01312 Ci 0.48544 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

Reporting Requirements:

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 prescr bed 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:
EN43082	01/15/2007		DCH	EVENT NOTIFICATION
ML070820067	04/17/2007		RLS	CONSULTANT REPORT
ML070960426	04/17/2007		RLS	INSPECTION REPORT
ML070960426	04/17/2007		RLS	NRC LETTER
ML070960431	04/17/2007		RLS	ADAMS DOCUMENT PACKAGE
LTR070430	05/02/2007		DCH	NRC LETTER
LTR070625	06/25/2007		DCH	NRC LETTER
ML071730448	07/09/2007		RLS	NOTICE OF VIOLATION
ML071730448	07/09/2007		RLS	NRC LETTER
ML071290394	08/23/2007		RLS	LICENSEE REPORT
ML071340044	08/23/2007		RLS	LICENSEE REPORT
07-03	05/14/2008		RLS	ABNORMAL OCCURRENCE NUMBER
ML081300424	05/14/2008		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 070015

Last Updated: 02/01/2007

Narrative:

The licensee reported that a dose delivered to part of the target organ exceeded the prescribed dose by more than 50% during the first of four high dose rate (HDR) brachytherapy fractions. The licensee was using a [redacted] HDR [redacted] and an Ir-192 source with an activity of 370 GBq (10 Ci). The patient was prescr bed to receive four HDR brachytherapy fractions to a 7 cm length of the vaginal mucosa of 500 cGy (rad) each. About halfway through the first treatment fraction, it was determined that the inferior 3 cm of the treatment length received 756 cGy (rad). The medical physicist had entered 1,220 cGy (rad) into the HDR treatment planning computer instead of 500 cGy (rad). The physicist also entered 1,220 cGy (rad) on his HDR dosimetry check. He then completed the HDR dosimetry check, not realizing the incorrect dosage was entered on the checklist. Standard protocol is to check the treatment dose on the prescription plan, but that did not occur. The authorized user reviewed the treatment plan and isodose distribution curves and approved the plan for a dose of 1,220 cGy (rad) instead of 500 cGy (rad), which was stated on the written directive. As the patient was treated, the medical physicist gathered the pertinent medical documents for the patient file and noticed that the authorized user's checklist (physician's HDR dosimetry checklist) had 500 cGy (rad) for the prescribed dose. The medical physicist immediately terminated treatment. The patient received 756 cGy (rad) instead of the planned 500 cGy (rad), 51% over the prescr bed dose. The patient received the prescribed total dose during the four fractions. The Wisconsin Department of Health and Family Services dispatched a team on 1/8/2007 for investigation. The patient was notified of the incident on 12/27/2006. Corrective actions taken by the licensee included modifying existing procedures and writing new policies and procedures.

Event Date: 12/27/2006 **Discovery Date:** 12/27/2006 **Report Date:** 12/27/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-025-1323-01	Name:	UNIVERSITY OF WISCONSIN
NRC Docket Number:	NA	City:	MADISON
NRC Program Code:	NA	State: WI	Zip Code: 53792
Respons ble NRC Region:	3		

Site of Event:

Site Name: MADISON
State: WI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INCORRECT DATA ENTERED INTO CONTROLLER

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 12/27/2006

Given:

Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR

Organ: VAGINA

Radiopharmaceutical: NA

Radionuclide: IR-192 Dose: 756 rad 7.56 Gy

Intended:

Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR

Organ: VAGINA

Radiopharmaceutical: NA

Radionuclide: IR-192 Activity: 10000 mCi 370000 MBq Dose: 500 rad 5 Gy

% Dose Exceeds Prescribed: 51

% 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): IR-192

Manufacturer: NR Activity: 10 Ci 370 GBq

Model Number: NR

Serial Number: NR

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]

Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:

MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43074	01/10/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR070110	01/10/2007		DCH	AGREEMENT STATE LETTER
WI070002	02/01/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 070014

Last Updated: 05/15/2008

Narrative:

Saint James Hospital & Health Center reported that a 75-year-old female patient received a high dose rate (HDR) treatment to the wrong site. The [redacted] HDR unit [redacted]) contained a 370 GBq (10 Ci) Ir-192 source [redacted] serial #020113680011120061 01). A series of fractions were conducted on 11/29, 12/6, 12/13, and 12/20/2006. A portion of the patient's inner thighs were treated instead of the intended cancerous target. The delivered dose to the skin was 2,000 cGy (rad) and the dose to the intended site was zero. The medical physicist stated that the error had been identified as part of a chart audit that was conducted prior to performing the next similar treatment of a subsequent patient. Computerized dosimetry planning records showed that the prescribed treatment was to occur with an automated source travel distance of 120 cm. The actual data point used during treatment was a travel distance of only 100 cm. The authorized radiation oncologist confirmed reddening of the skin on both inner thighs of approximately 3 cm2. HDR treatments have been rescheduled. The cause was determined to be human error, not equipment malfunction. An investigation by Illinois Department of Health also determined that Saint James Hospital failed to ensure that both an authorized user and an authorized medical physicist were present for the treatments and that the treatment plan did not receive the routine review during any of the subsequent treatment fractions to ensure the prescribed dose was being administered. The NRC had a medical consultant investigate the incident. The consultant found that personnel required additional operational training and that safety controls were missing. Corrective actions taken included procedural modifications to assure catheter lengths are verified prior to treatment, providing additional training to personnel, and generating new procedures.

Event Date: 11/29/2006 **Discovery Date:** 01/04/2007 **Report Date:** 01/04/2007

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	IL-01289-01	Name:	SAINT JAMES HOSPITAL & HEALTH CENTER
NRC Docket Number:	NA	City:	OLYMPIA FIELDS
NRC Program Code:	NA	State: IL	Zip Code: 60411
Respons ble NRC Region:	3		

Site of Event:

Site Name: OLYMPIA FIELDS
State: IL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INCORRECT DATA ENTERED INTO CONTROLLER

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 01/04/2007

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LEG
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 2000 rad 20 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 01/04/2007

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 10000 mCi 370000 MBq Dose: 2000 rad 20 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 10 Ci 370 GBq
Model Number: [redacted]
Serial Number: 02011368001112006101

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
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 prescr bed 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:

EN43078	01/09/2007	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IL070001	02/12/2007	DCH	AGREEMENT STATE EVENT REPORT
IL070001A	04/23/2007	DCH	AGREEMENT STATE EVENT REPORT
LTR070416	04/23/2007	DCH	AGREEMENT STATE LETTER
IL070001B	05/24/2007	DCH	AGREEMENT STATE EVENT REPORT
IL070001C	01/21/2008	DCH	AGREEMENT STATE EVENT REPORT
AS 07-01	05/15/2008	RLS	ABNORMAL OCCURRENCE NUMBER
ML081300424	05/15/2008	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 060760

Last Updated: 12/10/2007

Narrative:

During an NRC inspection at Cooper Health System on 12/18/2006, it was determined that a patient received a dose of 137 cGy (rad) to the intended site instead of the prescribed 600 cGy (rad) during HDR treatment for cervical carcinoma. The [redacted] HDR unit [redacted] serial #31469) used a 236.99 GBq (6.405 Ci) Ir-192 source. The patient was prescribed five fractions at 600 cGy (rad) per fraction, for a total dose of 3,000 cGy (Rad). This was prescr bed as a ring and tandem treatment to be performed using a 4-cm tandem. During the second of five fractions, the reference source position for the tandem applicators was entered incorrectly into the treatment console (the source position for the ring applicator was entered correctly). Consequently, the tandem source was displaced by 18 cm from the intended dwell position and was outside the patient's body during this fraction. An extra fraction was added to the patient's treatment plan, which resulted in a total dose of 3,137 cGy (rad) and was within 20% of the total prescribed treatment. The maximum dose to unintended tissue was approximately 47 cGy (rad). The incident was reviewed by the NRC Medical Review Committee and was determined to be a reportable medical event. Corrective actions included procedure modification, personnel training, and increased program oversight.

Event Date: 11/09/2006 **Discovery Date:** 12/18/2006 **Report Date:** 12/18/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	29-08285-01	Name:	COOPER HEALTH SYSTEM
NRC Docket Number:	03002512	City:	CAMDEN
NRC Program Code:	02110	State: NJ	Zip Code: 08103
Respons ble NRC Region:	1		

Site of Event:

Site Name: CAMDEN
State: NJ

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INCORRECT DATA ENTERED INTO CONTROLLER

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	PERSONNEL RECEIVE IMPROVED SUPERVISION

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 137 rad 1.37 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6405 mCi 236985 MBq Dose: 600 rad 6 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 77.2
Effect on Patient:

Source of Radiation:
MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 6.405 Ci 236.985 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31469

Reporting Requirements:
MD2
Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43057	12/21/2006		DCH	EVENT NOTIFICATION
ML071420244	06/18/2007		RLS	INSPECTION REPORT
ML071420244	06/18/2007		RLS	NRC LETTER
ML071590326	06/18/2007		RLS	NOTICE OF VIOLATION
ML071590326	06/18/2007		RLS	NRC LETTER
LTR070831	09/05/2007		DCH	NRC LETTER
ML070160135	12/10/2007		RLS	LICENSEE REPORT
ML070160135	12/10/2007		RLS	REGION REPORT

Item Number: 060748

Last Updated: 05/14/2008

Narrative:

Kennedy Memorial Hospitals reported that a patient was prescribed a brachytherapy treatment of 14,500 cGy (rad) to the prostate gland for prostate cancer, but instead received a dose of 14,500 cGy (rad) to an unintended treatment site. The patient was implanted with 104 I-125 brachytherapy seeds on 10/25/2006. The total activity of the implanted seeds was 1.57 GBq (42.4 mCi). A post-implant CT scan performed on 12/8/2006 indicated that the seeds were misplaced approximately 1.5 cm inferior to the intended position. The patient and the prescribing physician were notified of the incident. Calculations showed the D90 value (the minimum dose received by 90% of the prostate volume) to be 6% of the prescribed dose or 800 cGy (rad) versus the prescribed dose of 14,500 cGy (rad). Also, an unintended tissue volume of 76.7 cc received 100% of the prescribed prostate dose. The patient required further treatment of the prostate gland, which was performed using a linear accelerator. This event was caused by the failure to accurately identify the position of the prostate. Corrective actions included having a radiologist review the volume study during implant procedure, filling the Foley catheter balloon with contrast to better identify the prostate base, and using fluoroscopy to confirm needle depth before depositing the seeds and fluoroscopic confirmation of seed position intermittently during the procedure. A medical consultant was contracted by the NRC to review the incident. It was concluded that no significant adverse effect was expected.

Event Date: 10/25/2006 **Discovery Date:** 12/08/2006 **Report Date:** 12/08/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	29-15459-01	Name:	KENNEDY MEMORIAL HOSPITALS
NRC Docket Number:	03009149	City:	TURNERSVILLE
NRC Program Code:	02120	State: NJ	Zip Code: 08012
Respons ble NRC Region:	1		

Site of Event:

Site Name: TURNERSVILLE
State: NJ

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: FAILURE TO VERIFY TREATMENT SITE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 12/08/2006

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: NR
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 14500 rad 145 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 12/08/2006

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 800 rad 8 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 42.4 mCi 1568.8 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 94
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: BARD BRACHYTHERAPY Activity: 0.0424 Ci 1.5688 GBq
Model Number: NR
Serial Number: AGGREGATE

Reporting Requirements:
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 prescr bed 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:
EN43039	12/12/2006		DCH	EVENT NOTIFICATION
ML070440431	02/26/2007		RLS	INSPECTION REPORT
ML070440431	02/26/2007		RLS	NRC LETTER
ML071000445	05/31/2007		DCH	CONSULTANT REPORT
ML071000445	05/31/2007		DCH	LICENSEE REPORT
ML071000445	05/31/2007		DCH	REGION REPORT

LTR070828	09/05/2007	DCH	NRC LETTER
07-04	05/14/2008	RLS	ABNORMAL OCCURRENCE NUMBER
ML081300424	05/14/2008	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 060742

Last Updated: 01/31/2007

Narrative:

The licensee reported that a prostate gland seed implant procedure was not performed properly, resulting in a total shift of seeds from the intended treatment site. The dose to the intended site was 40% less than prescr bed. The seeds (UROCOR model 125SL, batch 1B060245J) used for the implant procedure contained I-125 with a total activity of 725.2 MBq (19.6 mCi). The patient was notified at the time of the treatment. The licensee stated that the cause of the incident was human error. An Ohio Bureau of Radiation inspector performed an inspection on 12/12/2006 and determined that the incident occurred due to difficulty in visualizing the superior portion of the prostate gland. The licensee has instituted a policy to have both the urologist and the radiation oncologist agree on visualization of the superior portion of the prostate prior to implantation. The incident was reviewed by the NRC Medical Review Committee and determined to be a reportable medical event.

Event Date: 12/05/2006 **Discovery Date:** 12/05/2006 **Report Date:** 12/06/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02200310002	Name:	UROLOGY CENTER
NRC Docket Number:	NA	City:	CINCINNATI
NRC Program Code:	NA	State: OH	Zip Code: 45212
Respons ble NRC Region:	3		

Site of Event:

Site Name: CINCINNATI
State: OH

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: FAILURE TO VERIFY TREATMENT SITE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 12/05/2006

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 11000 rad 110 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 15400 rad 154 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 40
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: UROCOR Activity: 0.0196 Ci 0.7252 GBq
Model Number: 125SL
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43034	12/11/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OH2006-100	12/19/2006		DCH	AGREEMENT STATE EVENT REPORT
OH2006-100A	01/31/2007		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 060716

Last Updated: 05/15/2008

Narrative:

University of Washington Harborview Gamma Knife reported that a patient prescribed to receive 18 Gy (1,800 rad) during a gamma knife treatment actually received 28 Gy (2,800 rad). The gamma knife [redacted] contained 267.7 TBq (7,236 Ci) of Co-60. The cause of the incident was determined to be human error. The prescribing physician, apparently in a hurry to leave for the day, had prescribed 18 Gy (1,800 rad). The physician then entered the prescribed value into the computer treatment plan rather than having the medical physicist do it as is the usual procedure. The physician erroneously entered 28 Gy (2,800 rad). The patient and referring physician were notified of the incident. Corrective actions included a verification process to ensure the prescribed treatment value is transferred from the treatment planning computer to the gamma knife computer prior to patient therapy. A treatment plan signed by the treating oncologist, physicist, and neurosurgeon is now required. In addition, the treating oncologist and physicist will verify and initial the prescribed dose and isodose.

Event Date: 11/16/2006 **Discovery Date:** 11/16/2006 **Report Date:** 11/22/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WA-WN-M0219-1	Name:	UNIVERSITY OF WASHINGTON HARBORVIEW GAMMA KNIFE
NRC Docket Number:	NA	City:	SEATTLE
NRC Program Code:	NA	State: WA	Zip Code: NR
Respons ble NRC Region:	4		

Site of Event:

Site Name: SEATTLE
State: WA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Old Cause: INCORRECT DATA ENTERED INTO CONTROLLER

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: 2800 rad 28 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 7236000 mCi 267732000 MBq Dose: 1800 rad 18 Gy

% Dose Exceeds Prescribed: 56
% Dose is Less Than Prescribed: NA
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: 7236 Ci 267732 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

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

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN43008	11/28/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WA-06-066	11/28/2006		DCH	AGREEMENT STATE EVENT REPORT
WA-06-066A	12/12/2006		DCH	AGREEMENT STATE EVENT REPORT
WA-06-066B	12/20/2006		DCH	AGREEMENT STATE EVENT REPORT
AS 07-05	05/15/2008		RLS	ABNORMAL OCCURRENCE NUMBER
ML081300424	05/15/2008		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 060659

Last Updated: 05/14/2008

Narrative:

Saint Luke's Hospital of Kansas City reported a medical event involving a 67-year-old female patient that received a high dose rate afterloader [redacted], serial #600389) breast therapy [redacted] treatment. At the time of the event, the HDR contained approximately 144.3 GBq (3.9 Ci) of Ir-192. While the physicist was verifying the source positions and dwell times prior to treatment number eight of ten, it was noted that the first (most distal) source position was different from the previous treatments. A subsequent investigation revealed that the usable catheter length entered into the treatment planning computer was 93 cm rather than the correct value of 95 cm. This error in catheter length was used for the first seven treatments beginning on 10/23/2006, which resulted in an unplanned dose to tissue proximal to the mammosite balloon. The patient was prescribed to receive 340 cGy/fraction (rad/fraction) to the specified site, or 2,380 cGy (rad) for the first seven fractions, but received only 700 to 1,000 cGy (rad) to the specified site. The incorrect site received 10,000 cGy (rad). If the fractions would have been administered correctly, that site would have received 2,450 cGy (rad). The hospital believes that a typographical error occurred in entering the usable catheter length. The referring physician and patient were notified of the incident and the remaining treatment fractions were cancelled. Corrective actions included training and procedure revisions that require verification of treatment parameters. The NRC contracted a medical consultant to review this event, who determined that the patient will likely experience breast atrophy and fat necrosis in the overexposed region.

Event Date: 10/23/2006 **Discovery Date:** 10/26/2006 **Report Date:** 10/27/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	24-00889-01	Name:	SAINT LUKES HOSPITAL OF KANSAS CITY
NRC Docket Number:	03002286	City:	KANSAS CITY
NRC Program Code:	02110	State: MO	Zip Code: 64111
Respons ble NRC Region:	3		

Site of Event:

Site Name: KANSAS CITY
State: MO

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: COMPUTER TREATMENT PLANNING SOFTWARE ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 10/27/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 10000 rad 100 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 3900 mCi 144300 MBq Dose: 2450 rad 24.5 Gy

% Dose Exceeds Prescribed: 308
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 10/27/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 700 rad 7 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 3900 mCi 144300 MBq Dose: 2380 rad 23.8 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 71
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 3.9 Ci 144.3 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 600389

Reporting Requirements:
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 prescr bed 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:
EN42941	10/30/2006		DCH	EVENT NOTIFICATION

LTR061031	11/06/2006	DCH	NRC LETTER
LTR061106	11/07/2006	DCH	NRC LETTER
ML063060100	11/15/2006	RLS	NRC LETTER
LTR061218	12/19/2006	DCH	NRC LETTER
ML063630381	01/04/2007	RLS	ADAMS DOCUMENT PACKAGE
ML063630404	01/04/2007	RLS	CONSULTANT REPORT
LTR070108	01/08/2007	RLS	NRC LETTER
ML063630396	01/08/2007	RLS	INSPECTION REPORT
ML063630396	01/08/2007	RLS	NRC LETTER
ML070780288	03/23/2007	RLS	NOTICE OF VIOLATION
ML070780288	03/23/2007	RLS	NRC LETTER
ML070370211	08/23/2007	RLS	LICENSEE REPORT
07-02	05/14/2008	RLS	ABNORMAL OCCURRENCE NUMBER
ML081300424	05/14/2008	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 060607

Last Updated: 11/16/2006

Narrative:

The licensee reported that a patient with Graves's disease was administered 0.39 GBq (10.65 mCi) of I-131 instead of the prescribed 0.37 MBq (10 uCi). The physician inadvertently wrote the prescription for 0.37 MBq (10 uCi), although the normal dosage for such a treatment is 0.37 GBq (10 mCi). The technologist noted the scheduled procedure was a therapeutic treatment for Graves disease and ordered the customary 0.37 GBq (10 mCi) I-131 capsule without consulting the written directive. On 6/28/2006, the technologist assayed the I-131 capsule at 0.39 GBq (10.65 mCi) prior to administration. The physician was present at the assay and signed the written directive. The assayed dose was subsequently administered to the patient, in violation with the incorrect prescribed dose of 0.37 MBq (10 uCi). This error was discovered by a consultant on 9/25/2006 during a routine quarterly audit. Corrective actions included staff re-training on the importance of following written directives.

Event Date: 06/28/2006 **Discovery Date:** 09/25/2006 **Report Date:** 09/25/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-18892-01	Name:	WEST BRANCH REGIONAL MEDICAL CENTER
NRC Docket Number:	03017321	City:	WEST BRANCH
NRC Program Code:	02120	State: MI	Zip Code: 48661
Respons ble NRC Region:	3		

Site of Event:

Site Name: WEST BRANCH
State: MI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED
Old Cause: PROCEDURE NOT FOLLOWED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 09/27/2006

Given:

Therapeutic Procedure: SODIUM IODIDE - T

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - T

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 0.01 mCi 0.37 MBq Dose: rad Gy

% Dose Exceeds Prescribed: 106400

% 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): I-131

Manufacturer: NR Activity: 0.01065 Ci 0.39405 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:
EN42859	10/02/2006		DCH	EVENT NOTIFICATION
LTR061108	11/16/2006		RLS	NRC LETTER
ML063100650	11/16/2006		RLS	INSPECTION REPORT
ML063100650	11/16/2006		RLS	NOTICE OF VIOLATION
ML063100650	11/16/2006		RLS	NRC LETTER

Item Number: 060605

Last Updated: 09/13/2007

Narrative:

The licensee (dba Sewickley Valley Hospital) reported that a patient was administered 1.32 GBq (35.6 mCi) of I-131 instead of the prescr bed dose of 3.7 GBq (100 mCi). A technician removed a vial of I-131 therapy capsules and measured the activity in the dose calibrator. The dose was administered to the patient by emptying the contents of the vial into the patient's hand. Only one I-131 capsule came out of the vial instead of two, which agreed with the information on the packing slip but disagreed with handwritten information on the lead pig. The vial was placed back into the shipping container and returned to the pharmacy. On 9/26/2006, the pharmacy notified the licensee that they had returned a capsule with an activity of 2.6 GBq (70.4 mCi). The licensee notified the referring physician and contacted the patient to administer the rest of the prescribed dose. Licensee corrective actions include instituting changes to their procedures requiring the vial be visually inspected and checked in the dose calibrator following patient administration. This event was discovered while investigating a similar event (see NMED Item 060404).

Event Date: 09/01/2006 **Discovery Date:** 09/26/2006 **Report Date:** 09/26/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	37-11562-01	Name:	HERITAGE VALLEY HEALTH SYSTEM
NRC Docket Number:	03003143	City:	BEAVER
NRC Program Code:	02230	State: PA	Zip Code: 15009
Respons ble NRC Region:	1		

Site of Event:

Site Name: SEWICKLEY
State: PA

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

Event Type:

LAS - LOST/ABANDONED/STOLEN
MD2 - MEDICAL EVENT

Event Cause:

LAS
Cause: MANAGEMENT DEFICIENCY
Old Cause: LOSS OF ADMINISTRATIVE CONTROL

MD2
Cause: HUMAN ERROR
Old Cause: FAILURE TO VERIFY THAT THE ENTIRE DOSE WAS ADMINISTERED

Corrective Actions Information:

Action Number:	Corrective Action:
LAS	
1	PROCEDURE MODIFIED
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 100 mCi 3700 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 65
Effect on Patient:

Source of Radiation:
LAS
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.0704 Ci 2.6048 GBq
Model Number: NA
Serial Number: NA

MD2
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.0356 Ci 1.3172 GBq
Model Number: NA
Serial Number: NA

Source Number: 2
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.0704 Ci 2.6048 GBq
Model Number: NA
Serial Number: NA

Device/Associated Equipment:
LAS
Device Number: 1
Device Name: CONTAINER, SHIPPING Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:
LAS
Reporting Requirement: 20.2201(a)(1)(i) - Lost, stolen, or missing licensed material in a quantity greater than or equal to 1,000 times the Appendix C quantities.

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.

Keywords:
LAS
MATERIAL LOST AND FOUND

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42863	09/28/2006		DCH	EVENT NOTIFICATION
ML062980012	11/02/2006		RLS	NOTICE OF VIOLATION
ML062980012	11/02/2006		RLS	NRC LETTER

ML063190389	09/13/2007	RLS	LICENSEE REPORT

Item Number: 060604

Last Updated: 09/13/2007

Narrative:

The licensee (dba Sewickley Valley Hospital) reported that a patient was administered 0.196 GBq (5.3 mCi) of I-131 instead of the prescr bed dose of 0.93 GBq (25 mCi). A technician removed a vial of I-131 therapy capsules and measured the activity in the dose calibrator. The dose was administered to the patient by emptying the contents of the vial into the patient's hand. Only one I-131 capsule came out of the vial instead of two, which agreed with the information on the packing slip but disagreed with handwritten information on the lead pig. The vial was placed back into the shipping container and returned to the pharmacy. On 9/25/2006, the pharmacy notified the licensee that they had returned a capsule with an activity of 0.766 GBq (20.7 mCi). The licensee notified the referring physician and contacted the patient to administer the rest of the prescribed dose. Licensee corrective actions include instituting changes to their procedures requiring the vial be visually inspected and checked in the dose calibrator following patient administration. While investigating this event, the licensee discovered a similar event (see NMED Item 060405).

Event Date: 09/21/2006 **Discovery Date:** 09/25/2006 **Report Date:** 09/26/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	37-11562-01	Name:	HERITAGE VALLEY HEALTH SYSTEM
NRC Docket Number:	03003143	City:	BEAVER
NRC Program Code:	02230	State: PA	Zip Code: 15009
Respons ble NRC Region:	1		

Site of Event:

Site Name: SEWICKLEY
State: PA

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

Event Type:

LAS - LOST/ABANDONED/STOLEN
MD2 - MEDICAL EVENT

Event Cause:

LAS
Cause: MANAGEMENT DEFICIENCY
Old Cause: LOSS OF ADMINISTRATIVE CONTROL

MD2
Cause: HUMAN ERROR
Old Cause: FAILURE TO VERIFY THAT THE ENTIRE DOSE WAS ADMINISTERED

Corrective Actions Information:

Action Number:	Corrective Action:
LAS	
1	PROCEDURE MODIFIED
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 25 mCi 925 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 80
Effect on Patient:

Source of Radiation:
LAS
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.0207 Ci 0.7659 GBq
Model Number: NA
Serial Number: NA

MD2
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.0053 Ci 0.1961 GBq
Model Number: NA
Serial Number: NA

Source Number: 2
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.0207 Ci 0.7659 GBq
Model Number: NA
Serial Number: NA

Device/Associated Equipment:
LAS
Device Number: 1
Device Name: CONTAINER, SHIPPING Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:
LAS
Reporting Requirement: 20.2201(a)(1)(i) - Lost, stolen, or missing licensed material in a quantity greater than or equal to 1,000 times the Appendix C quantities.

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.

Keywords:
LAS
MATERIAL LOST AND FOUND

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42862	09/28/2006		DCH	EVENT NOTIFICATION
ML062980012	11/02/2006		RLS	NOTICE OF VIOLATION
ML062980012	11/02/2006		RLS	NRC LETTER

ML063190389	09/13/2007	RLS	LICENSEE REPORT

Item Number: 060603

Last Updated: 01/23/2007

Narrative:

The licensee reported that a patient was administered a therapeutic dose of Sm-153 Quadramet for palliative treatment of metastatic bone pain that was 100% more than prescribed. The patient was prescr bed 2.74 GBq (74 mCi) of Sm-153, but received 5.48 GBq (148 mCi). The licensee ordered the Sm-153 dosage from Bristol Myers Squibb Medical Imaging and Cytogen Corporation (BMS). The dose was ordered per vendor dosage recommendation for a patient weight of 164 pounds. At the time of order, BMS verbally instructed the licensee that two vials would be required to meet the dosage needed. Two vials were received by the licensee. The Oncology nurse drew up and completely emptied both Quadramet vials into a 10 ml syringe. The Radiation Oncologist and Oncology nurse noted only 5 ml in the syringe. That was contradictory to the vials labeled as containing 3 ml each. The Oncology team proceeded with the administration although they were not comfortable with the syringe contents. Following the administration, the physician contacted BMS to discuss the dosage. A member of the BMS staff stated that each vial contained 2.44 GBq (66 mCi) at the time of administration. Calculations based on the activity reported on the vial labels indicated that each vial contained an activity of 2.74 GBq (74 mCi) at the time of administration. Corrective actions included discontinued use of the radionuclide distr butor and procedure modification to assure dosage for future administrations.

Event Date: 09/22/2006 **Discovery Date:** 09/22/2006 **Report Date:** 09/22/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	KY-202-053-20	Name:	PIKEVILLE MEDICAL CENTER
NRC Docket Number:	NA	City:	PIKEVILLE
NRC Program Code:	NA	State: KY	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: PIKEVILLE
State: KY

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Old Cause: RADIOPHARMACEUTICAL OR DOSE ORDER MISUNDERSTOOD

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Activity: 74 mCi 2738 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 100
% 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): SM-153
Manufacturer: BRISTOL-MYERS SQUIBB Activity: 0.148 Ci 5.476 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:
EN42856	09/28/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR061115	11/16/2006		DCH	AGREEMENT STATE LETTER
LTR070123	01/23/2007		RLS	AGREEMENT STATE LETTER

Item Number: 060596

Last Updated: 12/10/2007

Narrative:

The Pennsylvania Hospital reported that an elderly female patient received a dose to an incorrect location in the brain during a gamma knife treatment of a single large metastatic lesion. The prescribed dose was 1,500 cGy (rad) to a volume of approximately 5.5 cc during a series of nine treatment shots. The gamma knife unit [redacted], serial #4341) was manufactured by [redacted] and contained a total of 192.07 TBq (5191 Ci) of Co-60. After the patient was framed and imaged for the treatment, measurements indicated that there would be a collision between the anterior left post and the gamma knife helmet. The neurosurgeon decided that it would be in the best interest of the patient to remove the anterior left post and pin rather than having to re-frame and re-image the patient. The three remaining pins were checked to confirm that they remained firmly attached to the patient. Partway through the first of nine treatment shots, the patient became very agitated and her body was observed to shift. However, head movements are not observable when patients are in the treatment position. The hospital completed the first shot and then paused the treatment to further sedate the patient. Upon approaching the patient, personnel found that she had worked loose of the remaining pins. If the patient's head had not shifted position, the patient would have received a dose of 600 cGy (rad) to a volume of approximately 0.6 cc during the first shot. However, it was not poss ble to determine the exact time of the patient's head movement or the exact position to which the patient's head moved. On 5/26/2006, the patient was successfully treated using a 4-pin technique. The hospital believed that the incident was caused by patient intervention. However, an NRC medical consultant concluded that inadequate tightening of the three remaining pins was a factor in the event. The consultant also concluded that this event is unlikely to be of significant consequence to the patient. Corrective actions included procedure modification to address patient monitoring and reacting to patient movement.

Event Date: 05/19/2006 **Discovery Date:** 05/19/2006 **Report Date:** 09/20/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	37-06864-06	Name:	PENNSYLVANIA HOSPITAL
NRC Docket Number:	03015163	City:	PHILADELPHIA
NRC Program Code:	02120	State: PA	Zip Code: 19107
Respons ble NRC Region:	1		

Site of Event:

Site Name: PHILADELPHIA
State: PA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: FAILURE TO VERIFY TREATMENT SITE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 05/19/2006

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: NR rad NR 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: Y Date Informed: 05/19/2006

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 5191000 mCi 192067000 MBq Dose: NR rad NR 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: 5191 Ci 192067 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: GAMMA KNIFE UNIT
Model Number: [redacted]
Manufacturer: [redacted]
Serial Number: 4341

Reporting Requirements:
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 prescr bed 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:
EN42850	09/26/2006		DCH	EVENT NOTIFICATION

LTR061226	01/03/2007	DCH	NRC LETTER
ML070090528	01/18/2007	RLS	INSPECTION REPORT
ML070090528	01/18/2007	RLS	NRC LETTER
ML062920284	12/10/2007	RLS	LICENSEE REPORT
ML062920284	12/10/2007	RLS	REGION REPORT
ML063050211	12/10/2007	RLS	NRC LETTER
ML063050681	12/10/2007	RLS	LICENSEE REPORT

Item Number: 060551

Last Updated: 11/09/2006

Narrative:

The licensee reported that two patients only received 10% of their prescribed doses during mammosite treatments of ten fractions using a [redacted] remote brachytherapy afterloader HDR unit [redacted] serial #VS60037) and an Ir-192 source [redacted] serial #02-01-0699-001-062106-10250-03) containing an activity of 377.4 GBq (10.2 Ci). The two patients were prescribed to rece ve 340 cGy (rad) per fraction for a total dose of 3,400 cGy (rad), but instead received 34 cGy (rad) per fraction for a total dose of 340 cGy (rad). Patient procedures started for one patient on 7/28/2006 and started for the second patient on 8/22/2006. It was determined that the treatment planning software, [redacted], had a known issue with regard to fractionated doses. A [redacted] bulletin had been generated in March 2003 and alerted customers to the appropriate method for data entry for fractionated doses. However, the licensee did not acquire their equipment until August 2005 and, although their treatment planning software had been updated to a newer version, the same issue remained. According to the authorized user and medical physicist, there was no training provided on the aspect of use of the software when they had attended the manufacturer's training. Both patients have been notified of the incident and are considering options for additional treatment. Corrective actions taken by the licensee included modifying procedures to require a second method to confirm appropriate treatment time that is independent from the treatment planning software and providing additional training to personnel.

Event Date: 07/28/2006 **Discovery Date:** 08/29/2006 **Report Date:** 08/29/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	IL-01207-01	Name:	RUSH-COPLEY MEDICAL CENTER
NRC Docket Number:	NA	City:	AURORA
NRC Program Code:	NA	State: IL	Zip Code: 60505
Respons ble NRC Region:	3		

Site of Event:

Site Name: AURORA
State: IL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: INADEQUATE TRAINING
Old Cause: INADEQUATE TRAINING

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 08/28/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 340 rad 3.4 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 10200 mCi 377400 MBq Dose: 3400 rad 34 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90
Effect on Patient:

Patient Number: 2
Patient Informed: Y Date Informed: 08/28/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 340 rad 3.4 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 10200 mCi 377400 MBq Dose: 3400 rad 34 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 90
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 10.2 Ci 377.4 GBq
Model Number: [redacted]
Serial Number: 02010699001062106

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: VS60037

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42811	09/05/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IL060046	09/28/2006		DCH	AGREEMENT STATE EVENT REPORT
IL060046A	11/09/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 060540

Last Updated: 05/09/2007

Narrative:

The licensee reported that a patient prescribed to receive 0.56 GBq (15 mCi) of I-131 was administered 1.08 GBq (29.3 mCi), resulting in 95.3% greater activity than intended. Two patients were scheduled to receive radioactive treatments for hyperthyroidism at the same time. One was to receive 0.56 GBq (15 mCi) and the other was to receive 1.07 GBq (29 mCi). The first patient was administered the second patient's prescr bed dosage, resulting in the patient receiving a higher dose than intended The error was identified by the licensee before administering I-131 to the second patient. This event resulted in a thyroid dose of 106,600 cGy (rad). No negative health effects from this event are expected. During a routine inspection on 7/11/2006, the licensee explained to a Utah Division of Radiation Control (DRC) inspector that a misadministration had occurred. On 7/17/2006, the licensee sent a letter to the DRC indicating that a medical event had occurred. Corrective actions included procedure modifications to improve patient identity verification and not scheduling patients with similar exams in concurrent time slots.

Event Date: 06/19/2006 **Discovery Date:** 06/19/2006 **Report Date:** 07/11/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	UT2900147	Name:	MCKAY DEE HOSPITAL
NRC Docket Number:	NA	City:	OGDEN
NRC Program Code:	NA	State: UT	Zip Code: 84403
Respons ble NRC Region:	4		

Site of Event:

Site Name: OGDEN
State: UT

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: WRONG PATIENT SELECTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	IMPROVED PATIENT IDENTIFICATION VERIFICATION
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 06/19/2006

Given:

Therapeutic Procedure: SODIUM IODIDE - T

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Dose: 106600 rad 1066 Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - T

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 15 mCi 555 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 95.3

% 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): I-131

Manufacturer: NR Activity: 0.0293 Ci 1.0841 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:
UT060002	08/28/2006		DCH	AGREEMENT STATE EVENT REPORT
EN42748	03/14/2007		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
AS 06-03	05/09/2007		RLS	ABNORMAL OCCURRENCE NUMBER
ML071080195	05/09/2007		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 060515

Last Updated: 10/24/2006

Narrative:

The licensee reported that a patient received dose to the wrong site during the third of three fractional doses from a [redacted] HDR afterloader [redacted] and Ir-192 source. The first two fractions had been delivered properly. When the third fraction was delivered, the medical physicist inadvertently selected the wrong delivery tube. There were two delivery tubes available depending upon the treatment plan. The longer tube was incorrectly selected for this fraction and the source remained outside the patient for the entire fraction. The preliminary estimate of the highest dose in this configuration was approximately 100 to 125 cGy (rad) to the perineum, which was not the intended treatment site, and which would have received less than 50 cGy (rad) with the intended configuration. The patient was notified. The patient was rescheduled and returned for the final treatment on 8/17/2006. The final treatment was adjusted for the under dosing from the previous treatment. Corrective actions taken by the licensee included using several program cards for repeat patients so that each treatment does not have to be recalculated during each visit, the physicist and physician will re-verify all treatment information after the physicist prints out the treatment plan that is programmed on the card (the physician will sign or initial the printout before the treatment is started), and the physicians and physicists will be trained on that procedural change.

Event Date: 08/09/2006 **Discovery Date:** 08/10/2006 **Report Date:** 08/11/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CA-3693-56	Name:	NORTH OAKS RADIATION CENTER
NRC Docket Number:	NA	City:	THOUSAND OAKS
NRC Program Code:	NA	State: CA	Zip Code: 91360
Respons ble NRC Region:	4		

Site of Event:

Site Name: THOUSAND OAKS
State: CA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: AFTERLOADER/APPLICATOR PLACED IN WRONG LOCATION

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 08/10/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: PERINEUM
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 125 rad 1.25 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: PERINEUM
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 50 rad 0.5 Gy

% Dose Exceeds Prescribed: 150
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 08/10/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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:
CA-XCA969	08/17/2006		DCH	AGREEMENT STATE EVENT REPORT

EN42768	08/17/2006	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR061002	10/03/2006	DCH	AGREEMENT STATE LETTER
LTR061019	10/24/2006	DCH	AGREEMENT STATE LETTER

Item Number: 060480

Last Updated: 05/09/2007

Narrative:

The licensee reported that an 18-year-old male patient received an administration of 74 MBq (2 mCi) of I-131 instead of the prescribed dose of 0.19 MBq (5 uCi). A 0.19 MBq (5 uCi) Na-I thyroid uptake diagnostic study was ordered by an endocrinologist at the facility. However, instead of 0.19 MBq (5 uCi), the doctor ordered 74 MBq (2 mCi). The nuclear technologist did not question the request and the dose was drawn and administered to the patient. When the authorized user came in to do the imaging on 7/25/2006, he noted the error. It appears the authorized user was not directly involved in ordering the study. The licensee estimated a whole body dose of 1.89 cSv (rem) and a dose to the thyroid of 4,140 cSv (rem), based on 59.2% uptake. Using the same assumptions, the intended dose of 0.19 MBq (5 uCi) would have given the patient a thyroid dose of 10.4 cSv (rem). The RSO reported that a physician had determined that the patient was suffering from Graves Disease. As a result, the doctor prescribed an additional 629 to 740 MBq (17 to 20 mCi) of I-131 for treatment in the near future. The Illinois Emergency Management Agency performed an onsite investigation to determine how the event occurred and to review the licensee's corrective actions. The cause of the incident was determined to be the lack of a written directive and miscommunication between the physician and nuclear medicine technologist. Corrective actions included instituting additional procedures, implementing improved personnel supervision, and providing additional training to personnel. The Illinois Emergency Management Agency concurred with the licensee's dose estimates.

Event Date: 07/24/2006 **Discovery Date:** 07/25/2006 **Report Date:** 07/26/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	IL-01165-01	Name:	CHILDREN'S MEMORIAL MEDICAL CENTER
NRC Docket Number:	NA	City:	CHICAGO
NRC Program Code:	NA	State: IL	Zip Code: 60614
Respons ble NRC Region:	3		

Site of Event:

Site Name: CHICAGO
State: IL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: WRONG DIAGNOSTIC STUDY OR THERAPY REQUESTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVE IMPROVED SUPERVISION
2	PROCEDURE MODIFIED
3	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 07/28/2006

Given:

Therapeutic Procedure: SODIUM IODIDE - T

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Dose: 4140 rad 41.4 Gy

Intended:

Diagnostic Study: THYROID IMAGING

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 0.005 mCi 0.185 MBq

% Dose Exceeds Prescribed: 39707

% 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): I-131

Manufacturer: NR Activity: 0.002 Ci 0.074 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:
EN42736	08/01/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IL060036	09/27/2006		DCH	AGREEMENT STATE EVENT REPORT
LTR061005	10/05/2006		DCH	NRC LETTER
IL060036A	11/09/2006		DCH	AGREEMENT STATE EVENT REPORT
AS 06-05	05/09/2007		RLS	ABNORMAL OCCURRENCE NUMBER
ML071080195	05/09/2007		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 060475

Last Updated: 10/16/2006

Narrative:

The licensee reported that a patient prescribed to receive a prostate seed implant procedure received seeds with 27% higher activity than intended. The licensee stated that the seed implant plans are specified in air kerma units on their computer planning system. However, the ordering of seeds is specified in mCi. When the seeds for this patient were ordered, the activity was not changed to mCi. The patient was prescribed to receive 111 I-125 seeds, each with an activity of 14.58 MBq (0.394 mCi). The patient was implanted with seeds that had an activity of approximately 18.5 MBq (0.5 mCi), each. The physician, patient, and the State of Ohio were notified of the incident on 7/13/2006. The State Agency inspected the licensee's facility on 7/18/2006. Corrective actions taken by the licensee included observing compliance to newly established procedures through periodic inspections.

Event Date: 07/10/2006 **Discovery Date:** 07/12/2006 **Report Date:** 07/13/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OH-02120780000	Name:	AKRON GENERAL MEDICAL CENTER
NRC Docket Number:	NA	City:	AKRON
NRC Program Code:	NA	State: OH	Zip Code: NR
Respons ble NRC Region:	3		

Site of Event:

Site Name: AKRON
State: OH

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: SOURCES SELECTED WITH INCORRECT ACTIVITY

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	IMPROVE RADIOACTIVE MATERIAL LABELING AND HANDLING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 07/13/2006

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 43.73 mCi 1618.01 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 27
% 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): I-125
Manufacturer: NR Activity: 0.0555 Ci 2.0535 GBq
Model Number: NR
Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42729	07/31/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR061016	10/16/2006		DCH	AGREEMENT STATE LETTER

Item Number: 060469

Last Updated: 10/26/2006

Narrative:

The licensee (dba Florida Hospital Ormond Beach) reported that five patients (over a three-month period) did not receive any of their prescribed doses during high dose rate brachytherapy [redacted]) vaginal treatments using an Ir-192 source with an activity of 296 GBq (8 Ci). The delivery tube was 18.5 cm too long, resulting in the source being outside of the patients. The treatments should have delivered 500 cGy (500 rad) per fraction. A typical patient gets 3-5 fractions. Skin doses to the patients were determined to be between 500 and 9600 cGy (rad). The medical physicist discovered the mistakes after observing a treatment. Two different types of applicators are used; one has a longer tube than the other. The tubes were mixed up, which resulted in the incidents. The licensee determined which patients were affected by using the films recorded for each treatment. The physicians and the patients have been notified. Corrective actions taken by the licensee included taking the longer transfer tube out of the clinic, providing staff with training on proper service tubes and applicators, implementing applicable procedures, and having photographs on line for proper patient setup.

Event Date: 07/21/2006 **Discovery Date:** 07/21/2006 **Report Date:** 07/21/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-2897-1	Name:	ADVENTIST HEALTH SYSTEMS/SUNBELT, INC.
NRC Docket Number:	NA	City:	ALTAMONTE SPRINGS
NRC Program Code:	NA	State: FL	Zip Code: 32701
Respons ble NRC Region:	1		

Site of Event:

Site Name: ORMOND BEACH
State: FL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: ERROR IN EQUIPMENT SELECTION

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8000 mCi 296000 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: NR rad NR Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 2
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8000 mCi 296000 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Patient Number: 2A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: NR rad NR Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 3
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8000 mCi 296000 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Patient Number: 3A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: NR rad NR Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 4
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8000 mCi 296000 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Patient Number: 4A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: NR rad NR Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 5
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 0 rad 0 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 8000 mCi 296000 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Patient Number: 5A

Patient Informed: Y Date Informed:

Given:

Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR

Organ: SKIN

Radiopharmaceutical: NA

Radionuclide: IR-192 Dose: NR rad NR Gy

Intended:

A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100

% 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): IR-192

Manufacturer: NR Activity: 8 Ci 296 GBq

Model Number: NR

Serial Number: NR

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]

Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:

MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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:
EN42721	07/26/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR061016	10/17/2006		DCH	NRC LETTER
FL06-098	10/26/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 060461

Last Updated: 01/29/2007

Narrative:

The licensee reported that a patient was administered a dose using a [redacted] high dose rate brachytherapy afterloader [redacted] serial #600386) and a 257.15 GBq (6.95 Ci) Ir-192 source to treat a lung tumor. During the administration, the catheter was about 20 cm short of the planned location for the dose. An unintended dose of less than 100 cGy (rad) was administered to the patient's vocal chord area. The patient was prescribed to receive 500 cGy (rad) to the lung tumor. The licensee notified the patient. A licensee physician examined the patient and determined that there was no erythema. The licensee reported that a human error, not a device error, resulted in the medial event. The State of Maryland investigated the incident on 7/19/2006 and concluded that no exact root cause could be identified; however, patient intervention appeared to be the most likely contributing factor. The patient was notified of the incident. Corrective actions included changes to the licensee's procedure mandating a nurse remain with the patient during the therapy time-out process performed by the physician, physicist, therapist, and dosimetrist. Also, the physician will return inside the treatment vault and measure the yellow flag from the patient's nose to insure that the catheter placement is unchanged prior to treatment.

Event Date: 06/21/2006 **Discovery Date:** 07/03/2006 **Report Date:** 07/17/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	MD-03-001-06	Name:	ANNE ARUNDEL COUNTY MEDICAL CENTER
NRC Docket Number:	NA	City:	ANNAPOLIS
NRC Program Code:	NA	State: MD	Zip Code: 21401
Respons ble NRC Region:	1		

Site of Event:

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: AFTERLOADER/APPLICATOR PLACED IN WRONG LOCATION

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 07/13/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LARYNX
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 100 rad 1 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 07/13/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LUNG
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LUNG
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 500 rad 5 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): IR-192
Manufacturer: NR Activity: 6.95 Ci 257.15 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 600386

Reporting Requirements:
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 prescr bed 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:

EN42707	07/24/2006	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
MD070001	01/29/2007	DCH	AGREEMENT STATE EVENT REPORT

Item Number: 060452

Last Updated: 07/17/2006

Narrative:

The licensee reported that a patient presented to the Nuclear Medicine Department for a 3.7 GBq (100 mCi) therapeutic dose of I-131 was given a 0.15 GBq (4 mCi) diagnostic dose. It was determined that the written prescription for the correct dose was not included with the printed order sent from the Scheduling Department. The patient and attending physician were notified of the incident. Future doses will be verified via written orders from the physician by either fax or phone. The radiologist in attendance in the Nuclear Medicine Department will review the diagnosis and prescription.

Event Date: 01/03/2006 **Discovery Date:** 01/03/2006 **Report Date:** 01/04/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TN-R-19111-93	Name:	CENTENNIAL MEDICAL CENTER
NRC Docket Number:	NA	City:	NASHVILLE
NRC Program Code:	NA	State: TN	Zip Code: 37203
Respons ble NRC Region:	1		

Site of Event:

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE
Old Cause: INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 01/04/2006

Given:

Diagnostic Study: THYROID IMAGING

Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131

Intended:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 100 mCi 3700 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 96
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	UNSEALED SOURCE RADIOPHARM	Radionuclide or Voltage (kVp/MeV):	I-131	
Manufacturer:	NR	Activity:	0.004 Ci	0.148 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:
TN06020	07/17/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 060430

Last Updated: 01/08/2007

Narrative:

The licensee reported that a female patient who was prescribed to receive 0.555 MBq (15 uCi) of I-131 for a thyroid uptake study was actually administered 199.8 MBq (5.4 mCi) of I-131. The patient's thyroid received a dose pf approximately 700 cSv (rem) rather than the prescribed 20 cSv (rem). This event occurred when a new technologist failed to followed procedures and mistakenly assumed that the patient had been previously diagnosed and came for a treatment dose. This event was discovered the same day. The authorized user does not anticipate any adverse effects to the patient because she was confirmed to be hyperthyroid and would have been prescribed the administered dose. The patient and the referring physician were informed of the actual dose given. Corrective actions included revising procedures and policies for administering I-131 doses, providing training to the nuclear medicine staff, and requiring dual verification of the dose preparation, assay, and patient identification for all I-131 procedures.

Event Date: 06/28/2006 **Discovery Date:** 06/28/2006 **Report Date:** 07/03/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	24-15159-01	Name:	SAINT JOSEPH HEALTH CENTER
NRC Docket Number:	03008664	City:	SAINT CHARLES
NRC Program Code:	02240	State: MO	Zip Code: 63301
Respons ble NRC Region:	3		

Site of Event:

Site Name: SAINT CHARLES
State: MO

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED
Old Cause: PROCEDURE NOT FOLLOWED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 06/29/2006

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: 700 rad 7 Gy

Intended:
Diagnostic Study: THYROID UPTAKE MEASUREMENT

Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 0.015 mCi 0.555 MBq

% Dose Exceeds Prescribed: 3400
% 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): I-131
Manufacturer: NR Activity: 0.0054 Ci 0.1998 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:
EN42683	07/05/2006		DCH	EVENT NOTIFICATION
ML062300259	09/19/2006		RLS	INSPECTION REPORT
ML062300259	09/19/2006		RLS	NRC LETTER
ML062410488	09/19/2006		RLS	LICENSEE REPORT
LTR060915	09/25/2006		DCH	NRC LETTER
ML062580406	09/25/2006		RLS	LICENSEE REPORT
ML062960224	11/01/2006		RLS	NOTICE OF VIOLATION
ML062960224	11/01/2006		RLS	NRC LETTER
ML063610512	01/08/2007		RLS	INSPECTION REPORT

Item Number: 060376

Last Updated: 06/24/2008

Narrative:

The licensee reported an administration that was 68% less than prescribed during one of a series of brachytherapy doses to a patient. The patient received 116 cGy (rad) instead of the prescribed 360 cGy (rad). This was the first use of the new HDR modality [redacted] treatment equipment. An Ir-192 source [redacted] with an activity of 222 GBq (6 Ci) was used. The QC on the instrument was performed prior to the patient treatment. The treatment plan was sent from the dosimetry computer to the HDR control computer. The computer, or personnel, chose the plan used from the QC. The computer interpreted the plan to mean that a particular amount of dose had already been given. Inspection of computer records revealed that the exposure had been stopped during treatment. The licensee informed the patient of the dose discrepancy. Corrective actions taken by the licensee included performing the QC activity in a way that can't be confused with the therapy. The State of Oklahoma is sending an inspector to the site. The INL has requested additional information for this event.

Event Date: 06/05/2006 **Discovery Date:** 06/06/2006 **Report Date:** 06/06/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OK-07018-02	Name:	MERCY HEALTH CENTER
NRC Docket Number:	NA	City:	OKLAHOMA CITY
NRC Program Code:	NA	State: OK	Zip Code: NR
Respons ble NRC Region:	4		

Site of Event:

Site Name: OKLAHOMA CITY
State: OK

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: NOT REPORTED
Old Cause: NOT REPORTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW QUALITY MANAGEMENT PLAN

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 06/06/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 116 rad 1.16 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6000 mCi 222000 MBq Dose: 360 rad 3.6 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 68
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 6 Ci 222 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42620	06/12/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080624	06/24/2008		DCH	AGREEMENT STATE LETTER

Item Number: 060319

Last Updated: 05/09/2007

Narrative:

The licensee (dba Bozeman Deaconess Hospital) reported that a patient received only 6% of the prescribed dose during a prostate seed implant procedure. The patient was prescribed to receive a dose of 14,500 cGy (rad) to the prostate using 82 I-125 seeds with a total activity of 1.12 GBq (30.3 mCi). Imaging confirmed that only 10 seeds were implanted in the correct location of the prostate, resulting in a dose of 860 cGy (rad) to the prescribed treatment site. Of the remaining seeds, three seeds were recovered by the urologist and 69 seeds were implanted in the soft tissues of the penile bulb and the base of the penis. The licensee estimated that the radiation dose to the unintended site was 13,000 cGy (rad). The patient and his physician were informed of the event and were advised of the possible side effects. This event was caused by human error as the licensee did not verify that the sources were positioned in the proper location in the prostate. The urologist misidentified the anatomy visualized under the ultrasound guidance procedure and mistook the penile bu b and base of the penis to be the prostate. The inexperience of the urologist was a contributing factor. Corrective actions included additional training and procedural modifications to include performing a fluoroscopic examination early in the procedure to ensure that the seeds are placed in the prostate. The NRC contracted a medical consultant to review this event.

Event Date: 05/09/2006 **Discovery Date:** 05/10/2006 **Report Date:** 05/10/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	25-10994-04	Name:	BOZEMAN DEACONESS FOUNDATION
NRC Docket Number:	03033305	City:	BOZEMAN
NRC Program Code:	02120	State: MT	Zip Code: 59715
Respons ble NRC Region:	4		

Site of Event:

Site Name: BOZEMAN
State: MT

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: FAILURE TO VERIFY TREATMENT SITE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: URETHRA
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 13000 rad 130 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 860 rad 8.6 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 30.3 mCi 1121.1 MBq Dose: 14500 rad 145 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 94
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: 0.0303 Ci 1.1211 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

Reporting Requirements:
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 prescr bed 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:
EN42566	05/11/2006		DCH	EVENT NOTIFICATION

ML061350216	05/16/2006	DCH	PRELIMINARY NOTIFICATION
PN406006	05/16/2006	DCH	PRELIMINARY NOTIFICATION
LTR060920	09/25/2006	DCH	NRC LETTER
ML062890418	10/30/2006	RLS	INSPECTION REPORT
ML062890418	10/30/2006	RLS	NOTICE OF VIOLATION
ML062890418	10/30/2006	RLS	NRC LETTER
06-02	05/09/2007	RLS	ABNORMAL OCCURRENCE NUMBER
ML071080195	05/09/2007	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 060317

Last Updated: 05/09/2007

Narrative:

The licensee reported that an 80-year-old female patient received less than 30% of the prescr be dose during a [redacted] brachytherapy procedure using a [redacted] high dose rate afterloader [redacted] serial #31662) and a 240.5 GBq (6.5 Ci) Ir-192 source. The patient received a total dose of 3,400 cGy (rad) to the intended site during 10 treatments. The source stopped 6 cm short of the intended position because an incorrect number was entered into the computer. An unintended area of approximately 2 cm received 10,000 cGy (rad), which was three times the prescribed dose. The treatment was given twice a day for five days, from 3/31 to 4/7/2006. The patient visited the attending physician for follow-up on 5/2/2006. The physician discovered that the patient's skin was abnormally red. He contacted the medical physicist, who investigated and discovered the computer input error. The physician, patient, and patient's family were notified of the incident. The patient was treated for erythema. Corrective actions taken by the licensee included developing HDR administration procedures that require that personnel verify indexer values prior to treatment. The authorized user will be required to identify the distance needed. Personnel will receive additional training on those procedures. The State of Florida is tracking the incident as number FL06-062.

Event Date: 03/31/2006 **Discovery Date:** 05/02/2006 **Report Date:** 05/05/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-2667-1	Name:	21ST CENTURY ONCOLOGY
NRC Docket Number:	NA	City:	CORAL SPRINGS
NRC Program Code:	NA	State: FL	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: CORAL SPRINGS
State: FL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: COMPUTER TREATMENT PLANNING SOFTWARE ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 3400 rad 34 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6500 mCi 240500 MBq Dose: 11333 rad 113.33 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 70
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 10000 rad 100 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6500 mCi 240500 MBq Dose: 3333 rad 33.33 Gy

% Dose Exceeds Prescribed: 200
% 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): IR-192
Manufacturer: NR Activity: 6.5 Ci 240.5 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31662

Reporting Requirements:
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 prescr bed 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:

EN42556	05/10/2006	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR060510	05/10/2006	DCH	AGREEMENT STATE LETTER
LTR060713	07/31/2006	DCH	NRC LETTER
LTR060816	08/17/2006	DCH	AGREEMENT STATE LETTER
AS 06-02	05/09/2007	RLS	ABNORMAL OCCURRENCE NUMBER
ML071080195	05/09/2007	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 060280

Last Updated: 05/09/2007

Narrative:

The licensee reported that 84 I-125 seeds (Oncura, model Oncoseed 6711), with an average activity of 8.103 MBq (0.219 mCi), were implanted approximately 4 cm inferior to their intended position during a prostate implant procedure. The post-implant dose calculation determined that a dose of 10,800 cGy (rad), which was consistent with the prescribed dose, had been delivered to the incorrect area. The root cause was determined to be two-fold. First was the inability prior to implant to place a Foley catheter to fill the bladder allowing a clear definition of the base of the prostate gland. Second was the human error in clear delineation of the prostate gland and alignment of the template prior to seed implant. The patient will require further treatment of the prostate gland via re-implantation in order to deliver the appropriate dose. The licensee implemented a new policy for inexperienced urologists that requires placement of the Foley catheter prior to implanting seeds to ensure clear definition of the base of the prostate and urethra.

Event Date: 03/28/2006 **Discovery Date:** 04/21/2006 **Report Date:** 04/21/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	AR-654-BP-1208	Name:	CENTRAL ARKANSAS RADIATION THERAPY INSTITUTE
NRC Docket Number:	NA	City:	LITTLE ROCK
NRC Program Code:	NA	State: AR	Zip Code: 72205
Respons ble NRC Region:	4		

Site of Event:

Site Name: LITTLE ROCK
State: AR

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: FAILURE TO VERIFY TREATMENT SITE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 04/21/2006

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PERI-PROSTATIC TISSUE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 10800 rad 108 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 04/21/2006

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 18.4 mCi 680.8 MBq Dose: 10800 rad 108 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 100
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125
Manufacturer: ONCURA Activity: 0.0184 Ci 0.6808 GBq
Model Number: 6711
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
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 prescr bed 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:

EN42523	04/27/2006	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
AR-04-06-01	06/05/2006	DCH	AGREEMENT STATE EVENT REPORT
AR-04-06-01A	09/19/2006	DCH	AGREEMENT STATE EVENT REPORT
AS 06-04	05/09/2007	RLS	ABNORMAL OCCURRENCE NUMBER
ML071080195	05/09/2007	RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 060265

Last Updated: 01/02/2007

Narrative:

The licensee reported that two female patients received fractionated brachytherapy doses that were approximately 110% greater than prescribed. The treatments involved the insertion of a 162.8 GBq (4.4 Ci) Ir-192 source into the cervical area using a high dose rate afterloader [redacted] serial #32194). Each patient was to receive a total dose of 3,000 cGy (rad) distributed over six fractions of 500 cGy (rad) each. During the first fraction, patient #1 received 1,041 cGy (rad) on 4/11/2006, and patient #2 received 1,058 cGy (rad) on 4/18/2006. The attending physician altered the remaining fractions to 350 cGy (rad). The cause of this event was human error in that the physicist did not enter the correct x-ray film magnification factor into the computer before administering the dose to each patient. This caused the computer to use the default value for the film magnification and calculate a treatment time that was approximately twice as high as intended. The referring physician discussed the error with each patient when they came in for follow-up treatments on 4/21/2006. Corrective actions included performing measurements of certain digitized prescription points, instituting a checklist to include confirmation that the magnification factors were input into the system, and creating a spreadsheet so that the data can be checked independently. A medical consultant contracted to review the incidents concluded that no adverse effects were expected.

Event Date: 04/11/2006 **Discovery Date:** 04/18/2006 **Report Date:** 04/19/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	47-01458-01	Name:	UNITED HOSPITAL CENTER
NRC Docket Number:	03003375	City:	CLARKSBURG
NRC Program Code:	02230	State: WV	Zip Code: 26301
Respons ble NRC Region:	1		

Site of Event:

Site Name: CLARKSBURG
State: WV

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INCORRECT DATA ENTERED INTO CONTROLLER

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 04/21/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 1041 rad 10.41 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 4400 mCi 162800 MBq Dose: 500 rad 5 Gy

% Dose Exceeds Prescribed: 108
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 2
Patient Informed: Y Date Informed: 04/21/2006

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 1058 rad 10.58 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 4400 mCi 162800 MBq Dose: 500 rad 5 Gy

% Dose Exceeds Prescribed: 112
% 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): IR-192
Manufacturer: NR Activity: 4.4 Ci 162.8 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 32194

Reporting Requirements:
MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42511	04/20/2006		DCH	EVENT NOTIFICATION
LTR060705	07/06/2006		DCH	NRC LETTER
ML062190307	08/11/2006		RLS	LICENSEE REPORT
ML062190307	08/11/2006		RLS	REGION REPORT

ML062190309	08/11/2006	RLS	CONSULTANT REPORT
ML063480211	01/02/2007	RLS	INSPECTION REPORT
ML063480211	01/02/2007	RLS	NOTICE OF VIOLATION
ML063480211	01/02/2007	RLS	NRC LETTER

Item Number: 060235

Last Updated: 08/23/2007

Narrative:

The licensee reported that a terminally ill lung cancer patient received a [redacted] high dose rate (HDR) remote afterloader [redacted] serial #31417) treatment to the incorrect site. The treatment involved an Ir-192 source with an activity of 265.7 GBq (7.18 Ci). During treatment simulation and planning, the licensee failed to attach a metal interface connector to the end of a catheter used to position non-radioactive "dummy" sources inside of the patient. However, during the treatment, the connector was used to attach the catheter to the HDR unit. The connector effectively added a 7 mm distance between the source and the end of the catheter. Therefore, the treatment resulted in the source, and the associated radiation dose contour, being placed 7 mm higher than specified in the treatment plan and written directive. The licensee identified the error immediately after the treatment and notified the physician, but failed to perform an adequate evaluation to determine if the event was reportable. This event resulted in the airway above the lung receiving a dose of 500 cGy (rad) rather than the prescribed dose of 200 cGy (rad). The treatment area of the lung received a dose of 200 cGy (rad) rather than the prescribed dose of 500 cGy (rad). This treatment was performed to relieve the patient's symptoms rather than cure the illness. The patient succumbed to the illness approximately two weeks later. This event was caused by deficient procedures. Corrective actions included procedure modification.

Event Date: 11/08/2005 **Discovery Date:** 04/04/2006 **Report Date:** 04/05/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-06009-01	Name:	COMMUNITY HOSPITALS OF INDIANA
NRC Docket Number:	03001625	City:	INDIANAPOLIS
NRC Program Code:	02230	State: IN	Zip Code: 46219
Respons ble NRC Region:	3		

Site of Event:

Site Name: INDIANAPOLIS
State: IN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE
Old Cause: INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: TRACHEA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 500 rad 5 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: TRACHEA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 7180 mCi 265660 MBq Dose: 200 rad 2 Gy

% Dose Exceeds Prescribed: 150
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LUNG
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 200 rad 2 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LUNG
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 7180 mCi 265660 MBq Dose: 500 rad 5 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 60
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: NR Activity: 7.18 Ci 265.66 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31417

Reporting Requirements:
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 prescr bed 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:
EN42474	04/06/2006		DCH	EVENT NOTIFICATION

LTR060510	05/15/2006	RLS	NRC LETTER
ML061080272	05/31/2006	RLS	LICENSEE REPORT
ML061420469	05/31/2006	RLS	NRC LETTER
ML061390091	06/12/2006	RLS	LICENSEE REPORT
ML061930015	07/31/2006	RLS	NOTICE OF VIOLATION
ML061930015	07/31/2006	RLS	NRC LETTER
LTR061011	10/11/2006	DCH	NRC LETTER
ML061430346	08/23/2007	RLS	LICENSEE REPORT

Item Number: 060219

Last Updated: 08/23/2007

Narrative:

The licensee reported that a patient received a dose of 1,203 cGy (rad) instead of the prescr bed dose of 2,500 cGy (rad) during a gynecological administration using a [redacted] manual low dose rate brachytherapy device with Cs-137 sources. The event was discovered during a review of patient records as a result of a previous medical event (see NMED Item 060216). Both the referring physician and patient were informed. The event was caused by the use of a source carrier that was too short for the applicator, resulting in the sources not being positioned properly in the patient. Patient follow up indicated no recurrence of the initial medical condition and no observable negative effects to the patient from this event. To prevent recurrence, the licensee removed the short source carriers from service, ordered a new set of source carriers and applicators, and modified procedures.

Event Date: 01/17/2005 **Discovery Date:** 04/03/2006 **Report Date:** 04/03/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-02752-03	Name:	INDIANA UNIVERSITY MEDICAL CENTER
NRC Docket Number:	03001609	City:	INDIANAPOLIS
NRC Program Code:	02110	State: IN	Zip Code: 46202
Respons ble NRC Region:	3		

Site of Event:

Site Name: INDIANAPOLIS
State: IN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INATTENTION TO DETAIL

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW EQUIPMENT OBTAINED
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 1203 rad 12.03 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: NR mCi NR MBq Dose: 2500 rad 25 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 52
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: NR Ci NR GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42469	04/04/2006		DCH	EVENT NOTIFICATION
ML061070500	05/03/2006		RLS	LICENSEE REPORT
LTR060510	05/16/2006		RLS	NRC LETTER
ML061250047	05/16/2006		RLS	INSPECTION REPORT
ML061250047	05/16/2006		RLS	NRC LETTER
ML061570465	06/21/2006		RLS	LICENSEE REPORT
ML061920472	07/31/2006		RLS	NOTICE OF VIOLATION
ML061920472	07/31/2006		RLS	NRC LETTER
LTR061011	10/11/2006		DCH	NRC LETTER
ML062900553	10/30/2006		RLS	INSPECTION REPORT
ML061580400	08/23/2007		RLS	LICENSEE REPORT

Item Number: 060216

Last Updated: 08/23/2007

Narrative:

The licensee reported that a patient received a dose of 612 cGy (rad) instead of the prescribed dose of 1600 cGy (rad) during a gynecological administration using a [redacted] manual low dose rate brachytherapy device with Cs-137 sources. The device used a hinged source carrier to properly position the sources within the applicator. After the administration, it was noted that the source carrier was too short for the applicator. As a result, the sources were not positioned properly in the patient. Reviews of the x-ray taken to verify placement during the exam confirmed that a different dose distribution was given to the patient than intended. The event occurred because the licensee did not perform a direct physical comparison of the source carrier and applicator prior to the procedure. Based on a follow-up examination, no significant impact to the patient is expected and the licensee decided not to inform the patient of the event. The licensee reviewed all of the treatments that had been conducted with the brachytherapy device and identified six additional treatments that involved similar incorrect source positioning due to the use of source carriers that were too short for the applicator; however, only one of the additional six treatments resulted in a medical event (see NMED Item 060219). To prevent recurrence, the licensee removed the short source carriers from service, ordered a new set of source carriers and applicators, and modified procedures.

Event Date: 03/15/2006 **Discovery Date:** 03/29/2006 **Report Date:** 03/30/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-02752-03	Name:	INDIANA UNIVERSITY MEDICAL CENTER
NRC Docket Number:	03001609	City:	INDIANAPOLIS
NRC Program Code:	02110	State: IN	Zip Code: 46202
Respons ble NRC Region:	3		

Site of Event:

Site Name: INDIANAPOLIS
State: IN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INATTENTION TO DETAIL

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW EQUIPMENT OBTAINED
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 612 rad 6.12 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: NR mCi NR MBq Dose: 1600 rad 16 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 62
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: NR Ci NR GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42453	04/03/2006		DCH	EVENT NOTIFICATION
ML060930528	04/04/2006		DCH	PRELIMINARY NOTIFICATION
PN306008	04/04/2006		DCH	PRELIMINARY NOTIFICATION
ML061070500	05/03/2006		RLS	LICENSEE REPORT
LTR060510	05/16/2006		RLS	NRC LETTER
ML061250047	05/16/2006		RLS	INSPECTION REPORT
ML061250047	05/16/2006		RLS	NRC LETTER
ML061570465	06/21/2006		RLS	LICENSEE REPORT
ML061920472	07/31/2006		RLS	NOTICE OF VIOLATION
ML061920472	07/31/2006		RLS	NRC LETTER
ML062900553	10/30/2006		RLS	INSPECTION REPORT
ML061580400	08/23/2007		RLS	LICENSEE REPORT

Item Number: 060167

Last Updated: 05/11/2006

Narrative:

The licensee reported that a patient received 28% more dose than prescribed from an I-125 prostate seed implant. The patient received a total dose of 12,850 cGy (rad) instead of the prescr bed 10,000 cGy (rad). The licensee ordered the seeds with an activity of 0.4 air-kerma units per seed. However, the seeds (BARD Brachytherapy, model STM 1251) were received with an activity of 14.8 MBq (0.4 mCi), each, or a total activity of 0.96 GBq (26 mCi). The difference in activity units was not detected until after the surgery was complete. The referring urologist and the patient have been notified of the dose discrepancy. Corrective actions taken by the licensee included introducing a new form to be used during permanent implant preparation. The form will be used to record seed activity, including units, used in treatment planning and listed on the shipping form as well as the seed activity observed at the time of implant.

Event Date: 03/01/2006 **Discovery Date:** 03/06/2006 **Report Date:** 03/06/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	OK-14046-02	Name:	VIA CHRISTI REGIONAL MEDICAL CENTER
NRC Docket Number:	NA	City:	PONCA CITY
NRC Program Code:	NA	State: OK	Zip Code: 74602
Respons ble NRC Region:	4		

Site of Event:

Site Name: PONCA CITY
State: OK

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: SOURCES SELECTED WITH INCORRECT ACTIVITY

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Dose: 12850 rad 128.5 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: PROSTATE

Radiopharmaceutical: NA

Radionuclide: I-125 Activity: NR mCi NR MBq Dose: 10000 rad 100 Gy

% Dose Exceeds Prescribed: 28

% 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): I-125

Manufacturer: BARD BRACHYTHERAPY Activity: 0.026 Ci 0.962 GBq

Model Number: STM 1251

Serial Number: AGGREGATE

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42388	03/09/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
OK060004	05/11/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 060078

Last Updated: 12/18/2006

Narrative:

The licensee reported that a patient received less than the prescr bed dose of Y-90 microspheres during treatment for liver cancer. The nuclear medicine physician delivered the microspheres to the patient; however, after the treatment was presumed finished, he noted that some of the fluid remained in the vial. The retention fluid for the microspheres had become backed up from the site of injection (hepatic artery) and some spillage at the surface occurred, which was absorbed with gauze. The patient was prescribed to receive 0.41 GBq (11 mCi), but there was 0.17 GBq (4.5 mCi) left in the vial. The licensed medical physicist is evaluating the incident to assess the dose delivered to the patient. Corrective actions taken by the licensee included retraining of staff on the use of the Sirtex microsphere delivery system, using a thicker septum and plastic vial, and modifying procedures. The manufacturer has improved the design of the delivery system so that future events of overfilling will be much less likely to lead to leakage outside the delivery vial. Also, a thicker septum and a plastic vial are now included as part of the improvement.

Event Date: 01/10/2006 **Discovery Date:** 01/10/2006 **Report Date:** 01/20/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TX-L00650	Name:	MEMORIAL HERMANN HOSPITAL
NRC Docket Number:	NA	City:	HOUSTON
NRC Program Code:	NA	State: TX	Zip Code: 77030
Respons ble NRC Region:	4		

Site of Event:

Site Name: HOUSTON
State: TX

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: FAILURE TO VERIFY THAT THE ENTIRE DOSE WAS ADMINISTERED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	ENGINEERING CHANGE TO SYSTEM

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 01/10/2006

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 11 mCi 407 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 41
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: SIRTEX MEDICAL Activity: 0.0065 Ci 0.2405 GBq
Model Number: SIR-SPHERES
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: SIR-SPHERES
Manufacturer: SIRTEX MEDICAL Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
TX060001	02/02/2006		DCH	AGREEMENT STATE EVENT REPORT
TX060001A	03/07/2006		DCH	AGREEMENT STATE EVENT REPORT
TX060001B	03/21/2006		DCH	AGREEMENT STATE EVENT REPORT
TX060001C	09/21/2006		DCH	AGREEMENT STATE EVENT REPORT
TX060001D	10/03/2006		DCH	AGREEMENT STATE EVENT REPORT
TX060001E	12/18/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 060049

Last Updated: 03/13/2006

Narrative:

The licensee reported that a patient received 6,474 cGy (rad) instead of the prescribed 4,338 cGy (rad) during a manual brachytherapy treatment. The authorized user's written directive called for a temporary implant tandem and ovoid using Cs-137 sources to deliver the dose over 68 hours. The applicator (Fletcher-Suit-Delclos, model 640 M) was to be loaded with 1.89 GBq (51.1 mCi) in the right ovoid, 1.89 GBq (51.1 mCi) in the left ovoid, and 1.45 GBq (39.2 mCi), 1.89 GBq (51.1 mCi), and 1.45 GBq (39.2 mCi) in the tandem. The medical dosimetrist loaded the tandem and ovoid incorrectly. The applicator was loaded with 1.89 GBq (51.1 mCi) in the right ovoid, 1.89 GBq (51.1 mCi) in the left ovoid, and 1.45 GBq (39.2 mCi), 3.21 GBq (86.8 mCi), and 3.21 GBq (86.8 mCi) in the tandem. The error resulted in a delivered dose 49.2% greater than prescribed. The 1.45 GBq (39.2 mCi) source (model 6502) was manufactured by 3M, the 1.89 GBq (51.1 mCi) sources (model 6503) were manufactured by 3M, and the 3.21 GBq (86.8 mCi) source (model CDC.T1, serial #GG 899 and GG 909) was manufactured by AEA Technology. The patient was notified of the incident on 1/20/2006. The licensee conducted follow-up investigations. Corrective actions taken by the licensee included writing a new procedure.

Event Date: 01/17/2006 **Discovery Date:** 01/18/2006 **Report Date:** 01/18/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	NC-060-0014-3	Name:	CAROLINAS MEDICAL CENTER
NRC Docket Number:	NA	City:	CHARLOTTE
NRC Program Code:	NA	State: NC	Zip Code: 28203
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHARLOTTE
State: NC

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: SOURCES SELECTED WITH INCORRECT ACTIVITY

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 01/20/2006

Given:
Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 6474 rad 64.74 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 243.6 mCi 9013.2 MBq Dose: 4338 rad 43.38 Gy

% Dose Exceeds Prescribed: 49.2
% 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: 3M CO. Activity: 0.0511 Ci 1.8907 GBq
Model Number: 6503
Serial Number: NR

Source Number: 2
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: 3M CO. Activity: 0.0511 Ci 1.8907 GBq
Model Number: 6503
Serial Number: NR

Source Number: 3
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: 3M CO. Activity: 0.0392 Ci 1.4504 GBq
Model Number: 6502
Serial Number: NR

Source Number: 4
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: AEA TECHNOLOGIES Activity: 0.0868 Ci 3.2116 GBq
Model Number: CDC.T1
Serial Number: GG 899

Source Number: 5
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: AEA TECHNOLOGIES Activity: 0.0868 Ci 3.2116 GBq
Model Number: CDC.T1
Serial Number: GG 909

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: 640 M
Manufacturer: DELCLOS Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:
Reference Number: Entry Date: Retraction Date: Coder Initials: Reference Type:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42270	01/23/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
NC060004	02/15/2006		DCH	AGREEMENT STATE EVENT REPORT
NC060004A	03/13/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 060047

Last Updated: 04/12/2006

Narrative:

The licensee reported that a patient prescribed to receive an I-131 therapy dose of 5.6 GBq (150 mCi) in two capsules was only administered one capsule containing 2.99 GBq (80.85 mCi). The patient was given a vial containing two capsules, upended the vial into his mouth, and took several sips of water. The technologist placed the vial into the lead pig and capped it. It was later determined that the vial still contained one capsule. The patient was notified of the incident. As a result, the patient received approximately 64,000 cGy (rad) to the remnants of the thyroid base. Corrective actions taken by the licensee included procedure modifications involving visually inspecting and assaying the vial to document that the entire dose was given, modifying the therapy dose worksheet to include a line that states the entire dose was given and ingested by the patient (signed or initialed by the administering technologist), requiring the technologist to ask the patient how many capsules were swallowed, and requiring the technologist to verify the number of capsules ingested against the prescription number.

Event Date: 01/10/2006 **Discovery Date:** 01/17/2006 **Report Date:** 01/17/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	GA-0677-1	Name:	PROMINA GWINETT HEALTH SYSTEM
NRC Docket Number:	NA	City:	LAWRENCEVILLE
NRC Program Code:	NA	State: GA	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: ATLANTA
State: GA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Old Cause: FAILURE TO VERIFY THAT THE ENTIRE DOSE WAS ADMINISTERED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: SODIUM IODIDE - A
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: 64000 rad 640 Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - A
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 150 mCi 5550 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 46.1
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.08085 Ci 2.99145 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:
EN42265	01/23/2006		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
GA-2006-03I	02/21/2006		DCH	AGREEMENT STATE EVENT REPORT
LTR060411	04/12/2006		DCH	AGREEMENT STATE LETTER

Item Number: 060046

Last Updated: 07/25/2006

Narrative:

The licensee reported problems with an HDR brachytherapy treatment using a [redacted] HDR unit [redacted], serial #VS331) and an Ir-192 source with an activity of 0.26 TBq (7.059 Ci). The patient was prescribed to receive a dose of 750 cGy (rad) in a single fraction to a distance 1.0 cm beyond the active dwell positions in the right lung. The patient instead received 750 cGy (rad) to a distance of 15 cm from the active dwell positions in the right lung. A catheter was inserted in the right bronchus on 11/22/2005 for the treatment. The catheter was marked at the entrance of the nostril and taped to the nose and face. The patient was then taken to CT for the treatment planning. The treatment plan was developed and approved. The patient was treated in a linear accelerator vault. Prior to treatment, a dummy wire was placed into the catheter and a megavoltage portal image was taken to confirm placement of the catheter. The radiation oncologist believed that he had verified the catheter placement from the portal image. The catheter was connected to the HDR unit and the treatment was performed. At the conclusion of the treatment, the prescribing physician and nurse entered the treatment room to remove the catheter from the patient. At that time, it was discovered that the catheter was not fully inserted into the patient's lung. The mark that was put on the catheter during the planning was 15 cm outside of the nose. Apparently the catheter had become loose from the tape. The patient was informed on 11/22/2005. External beam therapy will be used to treat the patient. Two modifications have been made to the licensee's endobronchial HDR procedure to prevent recurrence.

Event Date: 11/22/2005 **Discovery Date:** 11/22/2005 **Report Date:** 11/22/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	LA-2651-L01	Name:	MARY BIRD PERKINS CANCER CENTER
NRC Docket Number:	NA	City:	BATON ROUGE
NRC Program Code:	NA	State: LA	Zip Code: 70809
Respons ble NRC Region:	4		

Site of Event:

Site Name: BATON ROUGE
State: LA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE
Old Cause: AFTERLOADER/APPLICATOR PLACED IN WRONG LOCATION

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 11/22/2005

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: THORAX
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 750 rad 7.5 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: Y Date Informed: 11/22/2005

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LUNG
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LUNG
Radiopharmaceutical: NA
Radionuclide: NR Activity: 7059 mCi 261183 MBq Dose: 750 rad 7.5 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): IR-192
Manufacturer: NR Activity: 7.059 Ci 261.183 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: VS331

Reporting Requirements:
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 prescr bed 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:

EN42263	01/23/2006	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR060215	02/20/2006	DCH	AGREEMENT STATE LETTER
LA050009	07/25/2006	DCH	AGREEMENT STATE EVENT REPORT

Item Number: 060044

Last Updated: 02/23/2006

Narrative:

The licensee reported that a patient received a dose that was 67% less than prescribed while being treated with a high dose rate afterloading brachytherapy system using an Ir-192 source. During the first of three treatments to the pelvic region, the patient received a dose of 233 cGy (rad) rather than the prescribed dose of 700 cGy (rad). The treatment plan specified three fractionated doses of 700 cGy (rad) for a total of 2,100 cGy (rad). The patient ended up receiving four treatments and the fourth fraction was 467 cGy (rad). The licensee stated that no HDR treatments will occur until the manual dose calculations check has been performed. The INL has requested additional information for this event.

Event Date: 01/12/2006 **Discovery Date:** 01/12/2006 **Report Date:** 01/13/2006

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	SC-0646	Name:	CARE ALLIANCE HEALTH SERVICES ROPER HOSPITAL
NRC Docket Number:	NA	City:	CHARLESTON
NRC Program Code:	NA	State: SC	Zip Code: 29401
Respons ble NRC Region:	1		

Site of Event:

Site Name: CHARLESTON
State: SC

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INCORRECT DATA USED IN THERAPY DOSE PLANNING

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 01/13/2006

Given:

Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: PELVIS
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 233 rad 2.33 Gy

Intended:

Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: PELVIS
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 700 rad 7 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 67
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	IR-192
Manufacturer:	NR	Activity:	NR Ci NR GBq
Model Number:	NR		
Serial Number:	NR		

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	REMOTE AFTERLOADER HDR	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42256	01/18/2006		RLS	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
SC060004	02/23/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 050818

Last Updated: 03/28/2006

Narrative:

The licensee reported that a patient, being treated for cervical cancer with a manual brachytherapy afterloader (Best Industries, model 640RB) using Cs-137 sealed sources (3M Company), received an average dose of 5,430 cGy (rad) to the intended site instead of the planned 4,000 cGy (rad). Four sealed Cs-137 sources with a total activity of 6.59 GBq (178 mCi) were inserted into the patient. A transposition error was made in the digitization of the patient's lateral film used to construct the applicator's position and thus the positions of the radiation sources relative to the locations of the dose calculation points. Therefore, the digital locations used for mapping and treatment planning of points "right A" and "left A" relative to the sources were incorrectly determined. The calculated points used in the treatment planning were located in a region of lower dose rate within the tumor than the true anatomical "A points" at which the prescription should have been defined. As a result, the prescription/final treatment plan used incorrect lower dose rate points and called for the use of an erroneously high source loading. Based on a retrospective analysis, instead of the calculated average dose rate of 54.5 cGy/hour (rad/hour) for the erroneous "A points", the actual delivered average dose rate to the true "A points" was 74 cGy/hour (rad/hour). The dose to other points, namely rectum and bladder, were calculated correctly because their location did not involve the digitization step in which the transposition error occurred. Only the tumor dose was in excess of the intended dose. The event occurred because of a misunderstanding concerning use of the new treatment planning system (TPS) that was being introduced into the clinic. The error was discovered in December 2005 when investigating why positions of calculated points sometimes appeared unusual. The licensee reviewed all the patients whose dosimetry plans were determined with the new TPS since treatments were first initiated. Three total patients were identified. The magnitude of the effect was found to also depend upon the orientation of the applicator in the patient. Only this patient had those adverse complications, which resulted in a medical event. Corrective actions taken by the licensee included modifying procedures and providing additional training to personnel.

Event Date: 09/12/2005 **Discovery Date:** 12/14/2005 **Report Date:** 12/14/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	IL-01678-02	Name:	UNIVERSITY OF CHICAGO HOSPITAL
NRC Docket Number:	NA	City:	CHICAGO
NRC Program Code:	NA	State: IL	Zip Code: 60637
Respons ble NRC Region:	3		

Site of Event:

Site Name: CHICAGO
State: IL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: INATTENTION TO DETAIL
Old Cause: INATTENTION TO DETAIL

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 5430 rad 54.3 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 178 mCi 6586 MBq Dose: 4000 rad 40 Gy

% Dose Exceeds Prescribed: 36
% 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: 3M CO. Activity: 0.0517 Ci 1.9129 GBq
Model Number: 6505
Serial Number: 00500

Source Number: 2
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: 3M CO. Activity: 0.0517 Ci 1.9129 GBq
Model Number: 6505
Serial Number: 00507

Source Number: 3
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: 3M CO. Activity: 0.0336 Ci 1.2432 GBq
Model Number: 6D6C
Serial Number: 0373

Source Number: 4
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: 3M CO. Activity: 0.0404 Ci 1.4948 GBq
Model Number: 6D6C
Serial Number: 0087

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: MANUAL AFTERLOADER Model Number: 640RB
Manufacturer: BEST INDUSTRIES Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42207	12/20/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
IL050073	02/22/2006		DCH	AGREEMENT STATE EVENT REPORT
IL050073A	03/28/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 050808

Last Updated: 06/05/2007

Narrative:

The licensee reported that a patient was only administered two of three I-131 capsules. The three capsules were transported to the licensee in two small pigs. After the administration, one of the capsules was discovered in a pig, indicating that the patient only received two of the capsules. The patient was prescribed to receive 7.96 GBq (215 mCi), but only received 5.62 GBq (152 mCi). The patient was notified of the event on 12/15/2005. On 12/16/2005 she spoke with the doctor and refused to take her third therapy capsule. Corrective actions taken by the licensee included requiring the authorized user to administer the dosage instead of the technician, requiring the authorized user's signature indicating that the required dosage was administered, verification of the number of pills that make up a dosage, and performing a post administration assay of the containers to ensure that a pill is not still in the container.

Event Date: 12/09/2005 **Discovery Date:** 12/13/2005 **Report Date:** 12/13/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	45-09207-01	Name:	LEWIS-GALE MEDICAL CENTER
NRC Docket Number:	03003333	City:	SALEM
NRC Program Code:	02230	State: VA	Zip Code: 24153
Respons ble NRC Region:	1		

Site of Event:

Site Name: SALEM
State: VA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Old Cause: FAILURE TO VERIFY THAT THE ENTIRE DOSE WAS ADMINISTERED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 12/15/2005

Given:
Therapeutic Procedure: SODIUM IODIDE - A
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - A
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 215 mCi 7955 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 29.3
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.152 Ci 5.624 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:
EN42202	12/14/2005		DCH	EVENT NOTIFICATION
LTR060214	02/16/2006		DCH	NRC LETTER
ML060340528	06/05/2007		DCH	LICENSEE REPORT
ML060340528	06/05/2007		DCH	REGION REPORT

Item Number: 050778

Last Updated: 08/09/2006

Narrative:

The licensee reported that a female patient undergoing HDR brachytherapy treatment for cervical cancer received 259 cGy (rad) instead of the prescribed 600 cGy (rad) during the third of five fractions. The treatment involved the use of a [redacted] HDR unit [redacted], serial #31123) with a 260.74 GBq (7.047 Ci) Ir-192 source [redacted] serial #D36A-8119). Each fraction was scheduled to deliver 600 cGy (rad) to the intended treatment site for a total delivered dose of 3000 cGy (rad). The treatment for the third fraction was delivered based on a dose calculation performed to a depth of one centimeter rather than to the prescribed depth of two centimeters. This event was discovered while preparing for the fourth fraction. The licensee determined that this event would not result in any adverse health effects for the patient. The licensee had developed written procedures to ensure that doses are administered in accordance with the treatment plan. However, the staff involved with HDR treatments were not aware of these procedures and were not using them. The licensee was required to examine all of its previous treatments for similar errors. Corrective actions included procedure modification and personnel training.

Event Date: 11/22/2005 **Discovery Date:** 11/29/2005 **Report Date:** 11/29/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	52-11832-02	Name:	HOSPITAL ANDRES GRILLASCA, INC.
NRC Docket Number:	03034175	City:	PONCE
NRC Program Code:	02230	State: PR	Zip Code: 00733
Respons ble NRC Region:	1		

Site of Event:

Site Name: PONCE
State: PR

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: MANAGEMENT DEFICIENCY
Old Cause: QUALITY MANAGEMENT INADEQUATE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 11/30/2005

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 259 rad 2.59 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 7047 mCi 260739 MBq Dose: 600 rad 6 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 57
Effect on Patient:

Source of Radiation:
MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 7.047 Ci 260.739 GBq
Model Number: [redacted]
Serial Number: D36A-8119

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 31123

Reporting Requirements:
MD2
Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42174	11/30/2005		DCH	EVENT NOTIFICATION
ML053400023	12/19/2005		RLS	CONFIRMATORY ACTION LETTER
ML053420668	12/19/2005		RLS	CONFIRMATORY ACTION LETTER
LTR060210	02/13/2006		DCH	NRC LETTER
ML061440433	06/05/2006		RLS	LICENSEE REPORT
ML061460183	06/05/2006		RLS	NRC LETTER
LTR060607	06/13/2006		DCH	NRC LETTER
ML061600393	06/20/2006		RLS	INSPECTION REPORT
ML061600393	06/20/2006		RLS	NRC LETTER
ML060680061	08/09/2006		RLS	CONFIRMATORY ACTION LETTER
ML062020414	08/09/2006		RLS	NRC LETTER

Item Number: 050676

Last Updated: 01/02/2006

Narrative:

The licensee reported that a patient receiving I-131 therapy was administered only one of two prescribed capsules. Consequently, only 3.44 GBq (93 mCi) of an ordered 5.55 GBq (150 mCi) was delivered to the patient. The referring endocrinologist was notified and determined that the patient had received an adequate amount for the therapy. The patient will be monitored closely and, if necessary, will receive additional therapy after six months. The technologist involved in the event was also responsible for a previous medical event and resigned immediately following the discovery of the second event. The licensee provided in-service training to the remaining staff on the importance of dose verification. The capsule that was not administered was found in the lead container while preparing for a subsequent procedure for another patient.

Event Date: 09/15/2005 **Discovery Date:** 09/29/2005 **Report Date:** 09/29/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	GA-1039-1	Name:	SOUTHERN REGIONAL MEDICAL CENTER
NRC Docket Number:	NA	City:	RIVERDALE
NRC Program Code:	NA	State: GA	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: RIVERDALE
State: GA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INATTENTION TO DETAIL

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL TERMINATED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 10/03/2005

Given:

Therapeutic Procedure: SODIUM IODIDE - A

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - A

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 150 mCi 5550 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 38

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131

Manufacturer: NR Activity: 0.093 Ci 3.441 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:
EN42036	10/07/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
GA-05-029I	11/04/2005		DCH	AGREEMENT STATE EVENT REPORT
GA-05-029IA	11/04/2005		DCH	AGREEMENT STATE EVENT REPORT
GA-05-029IB	11/29/2005		DCH	AGREEMENT STATE EVENT REPORT
GA-05-029C	01/02/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 050671

Last Updated: 10/18/2010

Narrative:

The Department of Veterans Affairs (VA) reported the improper positioning of I-125 brachytherapy seeds during a prostate implant procedure performed on 10/3/2005. The prescribed prostate dose was 16,000 cGy (rad) using 90 I-125 seeds, each containing an activity of 14 MBq (0.38 mCi). After all 90 seeds were implanted, 47 seeds were recovered from the patient's bladder. Of the remaining 43 seeds, 11 were outside of the designated treatment site. The written directive was revised by the authorized user prior to the completion of the procedure to document the actual number of seeds implanted into the prostate. The dose to the prostate was 4,000 cGy (rad). The dose to the rectum, bladder wall, and peri-prostatic tissue was 6,600, 18,400, and 21,500 cGy (rad), respectively. The VHA National Health Physics Program (NHPP) performed an announced reactive site inspection of the radiation safety program to evaluate the circumstances of the potential medical event. No violations were identified. The NHPP issued a report on 10/19/2005 and concluded that a medical event did not occur because the authorized user revised the written directive before the procedure was completed. The VA retracted the event on 2/3/2006, based on discussions with the NRC Region III Office. However, a subsequent review associated with NMED Item 080296 determined that this was a reportable medical event. This medical event was caused by multiple programmatic deficiencies, including the failure to follow procedures, inadequate training, human error on the part of the physician inserting the needles, and inadequate procedures to ensure that the administered dose was in accordance with the written directives. Corrective actions include procedure modification, personnel training, and replacing several key personnel involved in the procedures.

Event Date: 10/03/2005 **Discovery Date:** 10/03/2005 **Report Date:** 10/05/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: PHILADELPHIA
State: PA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: MANAGEMENT DEFICIENCY
Old Cause: NOT REPORTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING
3	PERSONNEL TERMINATED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 4000 rad 40 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 34.2 mCi 1265.4 MBq Dose: 16000 rad 160 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 75
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: BLADDER
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 18400 rad 184 Gy

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

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

Patient Number: 1B
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PERI-PROSTATIC TISSUE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: 21500 rad 215 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PERI-PROSTATIC TISSUE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: NR mCi NR MBq Dose: NR rad NR Gy

% 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): I-125
Manufacturer: NR
Activity: 0.0342 Ci 1.2654 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

Reporting Requirements:

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 prescr bed 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:
EN42038	10/06/2005	02/03/2006	DCH	EVENT NOTIFICATION
LTR060331	04/03/2006		DCH	NRC LETTER
LTR061023	10/24/2006		DCH	NRC LETTER
ML090900382	04/06/2009		RLS	INSPECTION REPORT
ML090900382	04/06/2009		RLS	NRC LETTER
ML052970407	05/18/2009		RLS	LICENSEE REPORT
ML082900902	05/18/2009		RLS	LICENSEE REPORT
08-02	06/09/2009		RLS	ABNORMAL OCCURRENCE NUMBER
ML091540747	06/09/2009		RLS	ABNORMAL OCCURRENCE NUMBER
ML091750854	06/26/2009		RLS	OTHER
ML091940392	08/03/2009		RLS	OTHER
ML093080147	11/30/2009		RLS	LICENSEE REPORT
ML093210599	11/30/2009		RLS	INSPECTION REPORT
ML093210599	11/30/2009		RLS	NRC LETTER
ML093210611	11/30/2009		RLS	NRC NEWS ANNOUNCEMENT
ML093220187	11/30/2009		RLS	ADAMS DOCUMENT PACKAGE
ML093440822	12/14/2009		RLS	NRC NEWS ANNOUNCEMENT
ML093490877	12/16/2009		RLS	ENFORCEMENT CONFERENCE
ML093490891	12/16/2009		RLS	ENFORCEMENT CONFERENCE
ML093570466	01/07/2010		RLS	NRC LETTER
ML093580162	01/07/2010		RLS	NRC LETTER
ML100060316	01/07/2010		RLS	ENFORCEMENT CONFERENCE
ML100150326	01/22/2010		RLS	LICENSEE REPORT
ML100190247	01/22/2010		RLS	LICENSEE REPORT
ML100331994	02/25/2010		RLS	LICENSEE REPORT
ML100710692	03/22/2010		RLS	NOTICE OF VIOLATION
ML100710692	03/22/2010		RLS	NRC LETTER
ML100760426	03/22/2010		RLS	NRC NEWS ANNOUNCEMENT
ML100820091	04/06/2010		RLS	OTHER
ML101030828	04/19/2010		RLS	LICENSEE REPORT
ML100700572	05/04/2010		RLS	NOTIFICATION OF SIGNIFICANT ENFORCEMENT ACTION
ML101440380	05/26/2010		RLS	INSPECTION REPORT
ML101440380	05/26/2010		RLS	NRC LETTER
ML093451474	06/02/2010		RLS	LICENSEE REPORT
ML102810376	10/18/2010		RLS	INSPECTION REPORT
ML102810376	10/18/2010		RLS	NRC LETTER

Item Number: 050640

Last Updated: 12/22/2005

Narrative:

The licensee reported that they found I-125 contamination during the post-operative clean-up of an I-125 prostate seed implant. The licensee was not sure if there was a leaking seed implanted into the patient. None of the seeds remaining after the procedure were leaking. A thyroid scan performed on the patient on 9/22/2005 showed that there had been an uptake. Potassium iodide was administered to the patient. The seeds (model ProstaSeed I125-SL) were distr buted by Mantor Brachytherapy and the applicator (model 200TP, serial #05012P) was manufactured by MICK. Each seed contained an activity of 5.29 MBq (143 uCi). The licensee indicated that during the final phase of the procedure, the operation physician found that several seeds in the last cartridge were lodged in the applicator. The physician pushed the plunger to free the seeds. After the implant, the post procedure survey revealed radioactive contamination on the MICK applicator, in the water used to wash it, and on the linens and table. The seeds had been leak tested on 8/12/2005 and surveyed prior to implant and showed no signs of removable contamination. Therefore, it is assumed that one or more sees were damaged and began leaking during the implant. Although slight force was used to dislodge the jammed seeds, the licensee judged that it was not enough force to break the normal seed welds and suspects that a seed had a weak or missing weld. A radiograph of the implant indicates the presence of one broken seed. Corrective actions taken by the licensee included rechecking source alignment in cartridges before implant procedures and rearranging the seeds if there is sign of seed jamming during the procedure. The latest dose assessment supplied by the licensee projects a CDE to the patient's thyroid of 333.3 cSv (rem).

Event Date: 09/20/2005 **Discovery Date:** 09/20/2005 **Report Date:** 09/21/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	AL-0600	Name:	BAPTIST MEDICAL CENTER PRINCETON
NRC Docket Number:	NA	City:	BIRMINGHAM
NRC Program Code:	NA	State: AL	Zip Code: 35211
Respons ble NRC Region:	1		

Site of Event:

Site Name: BIRMINGHAM
State: AL

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

Event Type:

EQP - EQUIPMENT
LKS - LEAKING SOURCE
MD2 - MEDICAL EVENT
RLM - RADIOACTIVE MATERIAL REL.

Event Cause:

EQP
Cause: DEFECTIVE OR FAILED PART
Old Cause: DEFECTIVE OR FAILED PARTS
LKS
Cause: DEFECTIVE OR FAILED PART
Old Cause: DEFECTIVE OR FAILED PARTS
MD2
Cause: DEFECTIVE OR FAILED PART
Old Cause: DEFECTIVE OR FAILED PARTS
RLM
Cause: DEFECTIVE OR FAILED PART
Old Cause: DEFECTIVE OR FAILED PARTS

Corrective Actions Information:

Action Number:	Corrective Action:
EQP	
1	PROCEDURE MODIFIED
LKS	

1 PROCEDURE MODIFIED

MD2

1 PROCEDURE MODIFIED

RLM

1 PROCEDURE MODIFIED

Release of Material or Contamination Information:

Type or Release or Contamination:	Activity: Ci	Activity: GBq	Radionuclide:	Effect of Release or Contamination:
SURFACE	NR	NR	I-125	

Patient Information:

Patient Number: 1

Patient Informed: U Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL IMPLANT

Organ: THYROID

Radiopharmaceutical: NA

Radionuclide: I-125 Dose: 333.3 rad 3.333 Gy

Intended:

A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100

% Dose is Less Than Prescribed: NA

Effect on Patient:

Source of Radiation:

EQP

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: UROCOR Activity: 0.000143 Ci 0.005291 GBq

Model Number: PROSTASEED I125-SL

Serial Number: AGGREGATE

LKS

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: UROCOR Activity: 0.000143 Ci 0.005291 GBq

Model Number: PROSTASEED I125-SL Leak Test Result: NR uCi NR kBq

Serial Number: AGGREGATE

MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: UROCOR Activity: 0.000143 Ci 0.005291 GBq

Model Number: PROSTASEED I125-SL

Serial Number: AGGREGATE

RLM

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): I-125

Manufacturer: UROCOR Activity: 0.000143 Ci 0.005291 GBq

Model Number: PROSTASEED I125-SL

Serial Number: AGGREGATE

Device/Associated Equipment:

EQP

Device Number: **1**

Device Name:	APPLICATOR	Model Number:	200-TP
Manufacturer:	MICK RADIO-NUCLEAR	Serial Number:	05012P

LKS

Device Number: **1**

Device Name:	APPLICATOR	Model Number:	200-TP
Manufacturer:	MICK RADIO-NUCLEAR	Serial Number:	05012P

MD2

Device Number: **1**

Device Name:	APPLICATOR	Model Number:	200-TP
Manufacturer:	MICK RADIO-NUCLEAR	Serial Number:	05012P

RLM

Device Number: **1**

Device Name:	APPLICATOR	Model Number:	200-TP
Manufacturer:	MICK RADIO-NUCLEAR	Serial Number:	05012P

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.

LKS

Reporting Requirement: 35.67(e) - Medical source leak test revealed the presence of 185 Bq (0.005 uCi) or more of removable radioactive material.

MD2

Reporting Requirement: 35.3045(a)(2)(v) - Leaking sealed source that results in a dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to the skin.

RLM

Reporting Requirement: 30.50(b)(1)(iii) - old - (SUPERSEDED) UNPLANNED CONTAMINATION EVENT THAT HAS ACCESS TO THE AREA RESTRICTED FOR A REASON OTHER THAN TO ALLOW ISOTOPES WITH A HALF-LIFE LESS THAN 24 HOURS TO DECAY PRIOR TO DECONTAMINATION.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN42016	09/29/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
AL050048	10/26/2005		DCH	AGREEMENT STATE EVENT REPORT
LTR051220	12/22/2005		DCH	AGREEMENT STATE LETTER

Item Number: 050635

Last Updated: 05/10/2006

Narrative:

The licensee reported that a patient was prescribed 3.7 GBq (100 mCi) I-131 for thyroid therapy post thyroidectomy. The patient received verbal and written directives, completed and signed an informed request and consent, and was sent to a restricted area to receive a single capsule. The patient exh bited difficulty swallowing and remained in the laboratory for 30 minutes attempting to swallow the capsule. The capsule was vomited from the mouth, almost entirely undissolved, and the capsule was never ingested. Immediate protective actions were taken by the CNMT. The CNMT did not spend time analyzing the content of the sputum/vomitus that was regurgitated back into the cup. The patient was released and rescheduled for a future administration. The incident did not constitute a dose to an unintended area (the mouth). The sputum/vomitus was considered patient waste and disposed in the sanitary sewer system. The cup was bagged, crushed, surveyed, and placed in shielded storage. The laboratory floor showed a small amount of contamination and two pairs of shoes were contaminated. The floor was cleaned and the shoes were confiscated. Contaminated items were placed in storage for decay. There was no release above SRPAR limits for contamination, effluent, or sanitary water. The patient was scheduled for imaging to confirm administration and diagnostic purposes, but would not return to the facility. Therefore, the licensee could not determine the amount of I-131 administered (if any). The licensee will consider having patients, who have difficulty swallowing, take a placebo capsule to ensure they can swallow.

Event Date: 02/22/2005 **Discovery Date:** 02/22/2005 **Report Date:** 03/23/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TN-R-01029-G97	Name:	METHODIST HOSPITAL OF OAK RIDGE
NRC Docket Number:	NA	City:	OAK RIDGE
NRC Program Code:	NA	State: TN	Zip Code: 37830
Respons ble NRC Region:	1		

Site of Event:

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: PATIENT OTHER

Old Cause: PATIENT BECAME NAUSEOUS OR INCONTINENT AFTER A SODIUM IODIDE THERAPY DOSE WAS ADMINISTERED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 02/22/2005

Given:

Therapeutic Procedure: SODIUM IODIDE - A

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - A

Organ: THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 100 mCi 3700 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA

% Dose is Less Than Prescribed: 100

Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131

Manufacturer: NR Activity: 0.1 Ci 3.7 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:
TN05038	09/28/2005		DCH	AGREEMENT STATE EVENT REPORT
TN05038A	05/10/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 050560

Last Updated: 01/16/2006

Narrative:

The licensee reported that a patient received 1,451 cGy (rad) during the first of two fractions instead of the intended 550 cGy (rad) during vaginal cancer treatment. The patient was prescribed to receive 1,100 cGy (rad) in two fractions during remote high dose rate afterloader treatment [550 cGy (rad) per fraction]. The licensee used a [redacted] HDR remote afterloader [redacted] and an Ir-192 source [redacted] serial #02-01-0695-0054-063005-10374-05) with an activity of 249.8 GBq (6.75 Ci). The first fraction was oriented interior 4.5 cm, resulting in a dose 164% greater than intended. The dose was delivered to the correct site of the vaginal cuff. The medical physicist discovered the error in the brachytherapy vision software. When digitizing the calculation point of the coronal plane, the sagittal plane viewing plane was in an incorrect position, which resulted in the calculation point being entered incorrectly. There was no other medical physicist to second check the plan at the time due to personnel shortage issues. The second fraction was not administered and the patient is not returning for further treatment. The radiation dose to the surrounding organs remained within normal tissue tolerance. The vital organs, such as the bladder, received 526 cGy (rad) and the lower part of the vaginal canal received 150 cGy (rad). Corrective actions taken by the licensee included implementing a policy that requires the medical physicist to have the plan second checked by another HDR trained physicist.

Event Date: 08/15/2005 **Discovery Date:** 08/15/2005 **Report Date:** 08/16/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	TX-L00384-004	Name:	UNIVERSITY OF TEXAS SOUTHWESTERN MEDICAL CENTER
NRC Docket Number:	NA	City:	DALLAS
NRC Program Code:	NA	State: TX	Zip Code: 75390
Respons ble NRC Region:	4		

Site of Event:

Site Name: DALLAS
State: TX

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: AFTERLOADER/APPLICATOR PLACED IN WRONG LOCATION

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 1451 rad 14.51 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 550 rad 5.5 Gy

% Dose Exceeds Prescribed: 164
% 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): IR-192
Manufacturer: [redacted] Activity: 6.75 Ci 249.75 GBq
Model Number: [redacted]
Serial Number: 02-01-0695-0054-0630

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
MD2
Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN41932	08/23/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
TX-I-8253	08/23/2005		DCH	AGREEMENT STATE EVENT REPORT
EN42091	11/02/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
TX-I-8253A	11/02/2005		DCH	AGREEMENT STATE EVENT REPORT
LTR051201	12/05/2005		DCH	AGREEMENT STATE LETTER
LTR060109	01/13/2006		DCH	LICENSEE REPORT
LTR060111	01/13/2006		DCH	AGREEMENT STATE LETTER
LTR060116	01/16/2006		DCH	NRC LETTER

Item Number: 050551

Last Updated: 08/07/2007

Narrative:

The licensee reported that a female patient received only two of the scheduled five gamma knife treatments to a glioblastoma lesion. This resulted in the patient receiving 900 cGy (rad) instead of the prescribed 1,200 cGy (rad). Prior to the third treatment, the shielding jaws on the [redacted] gamma knife [redacted] were unable to open completely and the gamma knife was removed from service. The patient had inadvertently knocked off the metal clip that holds a microphone to the patient couch and it fell into the unit's shielding jaws. Because of this, the microswitches inside the unit would not allow the shielding jaws to open completely. Consequently, the patient did not receive the final three prescr bed treatments at that time. The licensee requested repairs on the gamma knife unit from an authorized service representative, which were completed later that day. The configuration of the microphone was changed so that there is no metal clip involved (now a [redacted] strip is used). The remainder of the treatment dose was administered on 8/25/2005. This treatment interruption was not expected to have any deleterious effect on the projected outcome of the treatment.

Event Date: 08/18/2005 **Discovery Date:** 08/18/2005 **Report Date:** 08/18/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	37-11866-04	Name:	LANCASTER GENERAL HOSPITAL
NRC Docket Number:	03035003	City:	LANCASTER
NRC Program Code:	02310	State: PA	Zip Code: 17603
Respons ble NRC Region:	1		

Site of Event:

Site Name: LANCASTER
State: PA

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

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	REPAIRS MADE WITHOUT ENGINEERING CHANGE TO SYSTEM
MD2	
1	REPAIRS MADE WITHOUT ENGINEERING CHANGE TO SYSTEM

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 08/18/2005

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: 900 rad 9 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 1200 rad 12 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 25
Effect on Patient:

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

MD2
Source Number: 1
Source/Radioactive Material: SEALED SOURCE GAMMA KNIFE Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
EQP
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

MD2
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: NR

Reporting Requirements:
EQP
Reporting Requirement: 30.50(b)(2) - Equipment is disabled or fails to function as designed.

MD2
Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN41928	08/22/2005		DCH	EVENT NOTIFICATION
EN41937	08/23/2005		DCH	EVENT NOTIFICATION
ML052520190	09/22/2005		RLS	LICENSEE REPORT
ML052520190	09/22/2005		RLS	REGION REPORT
ML052870031	10/18/2005		RLS	NRC LETTER
ML053000253	11/09/2005		RLS	LICENSEE REPORT
LTR060330	04/05/2006		RLS	OTHER

ML052380226	08/07/2007	RLS	EVENT NOTIFICATION

Item Number: 050550

Last Updated: 05/17/2006

Narrative:

The licensee reported that a male patient received an overdose to an unintended site and an underdose to the intended site during a palliative treatment for metastatic disease. The treatment used a [redacted] HDR brachytherapy unit [redacted] serial #31062) with an Ir-192 source [redacted] serial #D36A-7277) containing an activity of 252 GBq (6.81 Ci). The patient was prescribed to receive three palliative fractions to the left bronchus using a special catheter separately placed, imaged, and digitized for each fraction occurring approximately a week apart. The intended dose for each fraction was 700 cGy (rad). The first fraction was delivered as prescribed. During the second fraction, the catheter was in a slightly different location within the left bronchus than in the first fraction. A reference distance of 995 mm was specified at the first digitized treatment position. The reference distance should have been 965 mm at the first digitized treatment position. A 3 cm length of the left bronchus received 640 to 1,860 cGy (rad) more at 0.5 cm depth than would have been received from planned proximity to the source. That same 3 cm length received 254 to 662 cGy (rad) more at 1 cm depth than would have been received from the planned proximity. A 3-cm length of the 4 cm region intended for treatment received up to 600 cGy (rad) less than the intended dose. The patient and referring physician were notified on 8/11/2005. The physician decided not to alter the patient's treatment plan for the third fraction or attempt to compensate for the lack of dose at the proximal end of the intended region. The cause of the event was determined to be insufficient time to insure adequate preparation and verification for a non-typical HDR treatment. Corrective actions taken by the licensee included adding a question addressing the reference distance to the second check of the procedure.

Event Date: 08/04/2005 **Discovery Date:** 08/04/2005 **Report Date:** 08/10/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	UT1800001	Name:	UNIVERSITY OF UTAH
NRC Docket Number:	NA	City:	SALT LAKE CITY
NRC Program Code:	NA	State: UT	Zip Code: 84112
Respons ble NRC Region:	4		

Site of Event:

Site Name: SALT LAKE CITY
State: UT

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: COMPUTER TREATMENT PLANNING SOFTWARE ERROR

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 08/11/2005

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BRONCHUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 2560 rad 25.6 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BRONCHUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6810 mCi 251970 MBq Dose: 700 rad 7 Gy

% Dose Exceeds Prescribed: 166
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 08/11/2005

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BRONCHUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 1362 rad 13.62 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BRONCHUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6810 mCi 251970 MBq Dose: 700 rad 7 Gy

% Dose Exceeds Prescribed: 95
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1B
Patient Informed: Y Date Informed: 08/11/2005

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BRONCHUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 100 rad 1 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BRONCHUS
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 6810 mCi 251970 MBq Dose: 700 rad 7 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 86
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1

Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY

Radionuclide or Voltage (kVp/MeV): IR-192

Manufacturer: [redacted]

Activity: 6.81 Ci 251.97 GBq

Model Number: [redacted]

Serial Number: D36A-7277

Device/Associated Equipment:

MD2

Device Number: 1

Device Name: REMOTE AFTERLOADER HDR

Model Number: [redacted]

Manufacturer: [redacted]

Serial Number: 31062

Reporting Requirements:

MD2

Reporting Requirement: 35.3045(a)(1)(iii) - Fractionated dose delivered that differs from the prescr bed dose for a single fraction by 50% 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:
EN41925	08/22/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
UT050006	09/07/2005		DCH	AGREEMENT STATE EVENT REPORT
AS 05-05	05/17/2006		RLS	ABNORMAL OCCURRENCE NUMBER
ML061170171	05/17/2006		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 050529

Last Updated: 05/30/2006

Narrative:

The licensee reported that a patient received 50% less dose than prescribed to two of seven lesions during a gamma knife treatment. The [redacted] gamma knife unit [redacted] contained several Co-60 sources [redacted] with a combined activity of 259 TBq (7,000 Ci). The patient was prescribed 1,500 cGy (rad) per lesion, but only received 750 cGy (rad) to two lesions. The event was discovered on 8/3/2005 during an internal audit of treatments. An investigation did not identify a problem with the gamma knife or the dose programs involved in planning. The cause of the event was determined to be personnel lack of knowledge concerning the treatment planning software and communication difficulties between the physicist and neurologist. Corrective actions taken by the licensee included additional education in treatment planning and reinforcement of the necessity of communications between personnel.

Event Date: 07/18/2005 **Discovery Date:** 08/03/2005 **Report Date:** 08/03/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	RI-7A-051-02	Name:	RHODE ISLAND HOSPITAL
NRC Docket Number:	NA	City:	PROVIDENCE
NRC Program Code:	NA	State: RI	Zip Code: 02902
Respons ble NRC Region:	1		

Site of Event:

Site Name: PROVIDENCE
State: RI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INCORRECT DATA USED IN THERAPY DOSE PLANNING

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 08/05/2005

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: 750 rad 7.5 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 7000000 mCi 259000000 MBq Dose: 1500 rad 15 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 50
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: [redacted] Activity: 7000 Ci 259000 GBq
Model Number: [redacted]
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

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

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN41905	08/12/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR050811	08/12/2005		DCH	NRC LETTER
RI050003	08/12/2005		DCH	AGREEMENT STATE EVENT REPORT
LTR050822	09/06/2005		DCH	AGREEMENT STATE LETTER
RI050003A	09/06/2005		DCH	AGREEMENT STATE EVENT REPORT
RI050003B	05/30/2006		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 050503

Last Updated: 06/05/2007

Narrative:

The licensee reported that a patient received less dose than prescribed during a SIR-sphere treatment for liver cancer. SIR-sphere treatments utilize radioactive microspheres that contain Y-90. The first of two scheduled treatments prescribed 0.46 GBq (12.4 mCi) of Y-90. Due to difficulty in determining how much of the Y-90 remained in the vial and the injection catheter, the licensee determined that only 0.25 GBq (6.8 mCi) was administered in the first treatment. Therefore, the fraction of Y-90 administered differs from the prescribed dose by 45%. The patient will be given a second treatment that takes into consideration the actual amount administered on the first treatment. The NRC determined that the event involved separate treatments, not two fractions of a treatment. Corrective actions taken by the licensee included developing and implementing new procedures for the administration of Y-90 to ensure that the amount administered was between -5% and +15% of the prescribed amount. Training on the revised procedures was provided to all personnel involved in the treatments.

Event Date: 07/26/2005 **Discovery Date:** 07/26/2005 **Report Date:** 07/29/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	37-07939-01	Name:	SAINT LUKES HOSPITAL
NRC Docket Number:	03003100	City:	BETHLEHEM
NRC Program Code:	02230	State: PA	Zip Code: 18015
Respons ble NRC Region:	1		

Site of Event:

Site Name: BETHLEHEM
State: PA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR

Old Cause: FAILURE TO VERIFY THAT THE ENTIRE DOSE WAS ADMINISTERED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: rad Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 12.4 mCi 458.8 MBq Dose: rad Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 45
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: SIRTEX MEDICAL Activity: 0.0068 Ci 0.2516 GBq
Model Number: SIR-SPHERES
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: SIR-SPHERES
Manufacturer: SIRTEX MEDICAL Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN41880	08/01/2005		DCH	EVENT NOTIFICATION
LTR050811	08/11/2005		DCH	NRC LETTER
ML052770266	10/17/2005		RLS	NRC LETTER
LTR060227	03/01/2006		DCH	NRC LETTER
ML060530157	03/14/2006		RLS	NOTICE OF VIOLATION
ML060530157	03/14/2006		RLS	NRC LETTER
ML061150556	06/05/2007		DCH	LICENSEE REPORT
ML061150556	06/05/2007		DCH	REGION REPORT

Item Number: 050492

Last Updated: 09/25/2007

Narrative:

The licensee reported that a patient was administered 2.44 GBq (66 mCi) of Sm-153 instead of the intended 3.96 GBq (107 mCi) dose for bone pain therapy. The patient received a calculated exposure of 26.4 cSv (rem) to the whole body, 16,498 cGy (rad) to the bony surfaces, and 3,753 cGy (rad) to the bone marrow (assuming a quality factor of 10). The event was discovered when a medical technologist questioned the dose with a supervisor. The technologist checked the dose cal brator correction factor for the assay of Sm-153 and discovered that it was incorrect. This event occurred because the staff did not know the proper dose calibrator setting for Sm-153, it had been nearly a year since the previous Sm-153 case, procedures for therapy dose tolerances were not followed, and supervising personnel were not notified prior to the administration. The prescribing physician notified the patient's doctor, who contacted the patient. Corrective actions taken by the licensee included retraining personnel and adding a check on their administration sheet that requires the technologist to check the instrument calibration setting. The licensee also verified and posted the proper dose calibrator setting for SM-153 more prominently and modified their Quality Management Program.

Event Date: 07/22/2005 **Discovery Date:** 07/26/2005 **Report Date:** 07/26/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	45-01589-01	Name:	VALLEY HEALTH SYSTEM
NRC Docket Number:	03003308	City:	WINCHESTER
NRC Program Code:	02220	State: VA	Zip Code: 22601
Respons ble NRC Region:	1		

Site of Event:

Site Name: WINCHESTER
State: VA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED
Old Cause: DOSE CALIBRATOR SET IMPROPERLY

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: N Date Informed:

Given:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Dose: 16498 rad 164.98 Gy

Intended:
Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE
Radiopharmaceutical: EDTMP/QUADRAMET
Radionuclide: SM-153 Activity: 107 mCi 3959 MBq Dose: 26747 rad 267.47 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 38
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): SM-153
Manufacturer: NR Activity: 0.066 Ci 2.442 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:
EN41872	07/27/2005		DCH	EVENT NOTIFICATION
ML053480191	01/03/2006		RLS	NOTICE OF VIOLATION
ML053480191	01/03/2006		RLS	NRC LETTER
ML060120378	02/16/2006		RLS	LICENSEE REPORT
ML060390080	02/16/2006		RLS	OTHER
ML060390686	02/16/2006		RLS	LICENSEE REPORT
ML060100308	09/25/2007		RLS	LICENSEE REPORT

Item Number: 050451

Last Updated: 10/10/2005

Narrative:

The licensee reported that a dose was delivered to an unintended site during a bile duct carcinoma brachytherapy procedure using 22 Ir-192 sources totaling 1.99 GBq (53.9 mCi) in a seed ribbon. The ribbon was routed through the nasal gastric system to the treatment site and would remain for the 35.1 hour treatment time. A radiograph was taken of the source placement in the bile duct before releasing the patient to a hospital room. The bile duct procedure prescribed a treatment dose of 2000 cGy (rad) at 1 cm during a 35 hour treatment. The radiograph verified that the sources were in the prescribed location. On 7/7/2005, a verification image was taken and revealed that the sources had moved approximately 5 cm toward the gastrointestinal tract. The location of the sources was outside of the intended site and some of the sources were located in the duodenum of the small intestine. The authorized user decided to terminate treatment after 25 hours and attempted to remove the ribbon and guide catheter through the nasal cavity. The source ribbon would not move with reasonable force being applied. The authorized user waited for the gastroenterologist's help. The source r bbon was removed from the patient and the sources placed in a lead pig at 1715 CDT on 7/7/2005. Dose estimates revealed 490 cGy (rad) to the the liver/unintended site. The Wisconsin DHFS investigated the incident on 7/11/2005. The licensee failed to obtain the correct catheter (more flex ble) with a lead marker, the nursing staff was not specifically trained on the procedure, the follow-up radiograph (ordered for 7/7/2005 at 0600 CDT) was placed in the wrong day's request tray, the authorized user's orders for the follow-up radiograph was not interpreted by the radiologist as to be read STAT, and there was no procedure/policy requiring the radiologist to take action to immediately notify the ordering physician of findings. Also, the bedside radiograph taken on 7/7/2005 was of poor quality and a second radiograph should have been ordered to better image the sources. Corrective actions taken by the licensee included revising procedures, changing the written directive form, and refining staff education.

Event Date: 07/06/2005 **Discovery Date:** 07/07/2005 **Report Date:** 07/08/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-073-1342-01	Name:	ASPIRUS - WAUSAU HOSPITAL
NRC Docket Number:	NA	City:	WAUSAU
NRC Program Code:	NA	State: WI	Zip Code: 54401
Respons ble NRC Region:	3		

Site of Event:

Site Name: WAUSAU
State: WI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE
Old Cause: INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 07/08/2005

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 490 rad 4.9 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed: 07/08/2005

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: GALLBLADDER
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 1430 rad 14.3 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: GALLBLADDER
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: 53.9 mCi 1994.3 MBq Dose: 2000 rad 20 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 29
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: BEST INDUSTRIES Activity: 0.0539 Ci 1.9943 GBq
Model Number: NR
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: SEED RIBBON Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:
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 prescr bed 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:

EN41827	07/13/2005	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR050711	07/13/2005	DCH	NRC LETTER
WI050015	09/08/2005	DCH	AGREEMENT STATE EVENT REPORT
LTR051010	10/10/2005	DCH	AGREEMENT STATE LETTER

Item Number: 050394

Last Updated: 08/17/2005

Narrative:

The licensee reported that a hyperthyroid patient received one of the intended two sodium iodide I-131 capsules sent by the radiopharmacy. The patient received 0.38 GBq (10.2 mCi) in one capsule instead of the prescribed 0.76 GBq (20.6 mCi) in two capsules. This was approximately 49% of the prescribed dosage. Both capsules were received in one plastic vial. The entire vial was assayed, but the technologist failed to notice that there were two capsules in the vial because a desiccant blocked the view of the second capsule and prevented it from leaving the vial. The licensee stated that normally hyperthyroid therapy doses are received in one capsule. Therefore, the technologist was not expecting a second capsule. The radiopharmacy discovered the second capsule in the returned package on 6/10/2005. They called the licensee, the prescribing physician requested that the patient receive the second capsule, and the patient returned on 6/10/2005 and received the second capsule. The second capsule assayed at 0.36 GBq (9.74 mCi) at the time of administration. The patient received a total dosage of 0.74 GBq (19.94 mCi). To prevent a recurrence, the licensee will assay all applicable capsule vials after the patient has received their dosage, but before the patient leaves the facility. This event was retracted by the licensee based on a re-reading of Part 35 and a conversation with the NRC Region III. However, the NRC Medical Team evaluated the event and determined that it did indeed meet Part 35 reporting requirements.

Event Date: 06/09/2005 **Discovery Date:** 06/10/2005 **Report Date:** 06/10/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-01430-01	Name:	EDWARD W. SPARROW HOSPITAL
NRC Docket Number:	03002009	City:	LANSING
NRC Program Code:	02230	State: MI	Zip Code: 48909
Respons ble NRC Region:	3		

Site of Event:

Site Name: LANSING
State: MI

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

Event Type:

LAS - LOST/ABANDONED/STOLEN
MD2 - MEDICAL EVENT

Event Cause:

LAS
Cause: INATTENTION TO DETAIL
Old Cause: LOSS OF ADMINISTRATIVE CONTROL

MD2
Cause: INATTENTION TO DETAIL
Old Cause: INATTENTION TO DETAIL

Corrective Actions Information:

Action Number:	Corrective Action:
LAS	
1	PROCEDURE MODIFIED
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 06/10/2005

Given:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 20.6 mCi 762.2 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 51
Effect on Patient:

Source of Radiation:
LAS
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.0104 Ci 0.3848 GBq
Model Number: NA
Serial Number: NA

MD2
Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.0102 Ci 0.3774 GBq
Model Number: NA
Serial Number: NA

Reporting Requirements:
LAS
Reporting Requirement: 20.2201(a)(1)(i) - Lost, stolen, or missing licensed material in a quantity greater than or equal to 1,000 times the Appendix C quantities.

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.

Keywords:
LAS
MATERIAL LOST AND FOUND

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN41763	06/13/2005		DCH	EVENT NOTIFICATION
LTR050615	06/15/2005		DCH	NRC LETTER
LTR050816	08/17/2005		DCH	NRC LETTER

Item Number: 050392

Last Updated: 02/13/2007

Narrative:

The licensee reported that a patient received 75% of the prescribed 2 GBq (54 mCi) of Y-90 Siraspheres (microspheres) for liver treatment. Backpressure from the liver catheter popped the tubing off the three-way stopcock and approximately 25% of the material was spilled before the tubing could be re-attached. A lower flow-rate was used and no further problems were encountered. The patient received 3,957 cGy (rad) to the liver. The spill was contained within the case around the stopcock. It was determined that a 3F catheter was used instead of a 4F catheter (inattention to detail). Corrective actions taken by the licensee included no longer using a 3F catheter and using an extension tubing equivalent to the catheter size. The licensee will also confirm the integrity and flow of all valves and compression fittings prior to the start of procedures. The Florida Department of Health continues to investigate this event.

Event Date: 05/25/2005 **Discovery Date:** 05/25/2005 **Report Date:** 06/01/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	FL-0031-1	Name:	UNIVERSITY OF FLORIDA SHANDS HOSPITAL
NRC Docket Number:	NA	City:	GAINESVILLE
NRC Program Code:	NA	State: FL	Zip Code: 32611
Respons ble NRC Region:	1		

Site of Event:

Site Name: GAINESVILLE
State: FL

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: INATTENTION TO DETAIL
Old Cause: INATTENTION TO DETAIL

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Dose: 3957 rad 39.57 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: LIVER
Radiopharmaceutical: NA
Radionuclide: Y-90 Activity: 54 mCi 1998 MBq Dose: 5276 rad 52.76 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 25
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: MICROSPHERES Radionuclide or Voltage (kVp/MeV): Y-90
Manufacturer: SIRTEX MEDICAL Activity: 0.054 Ci 1.998 GBq
Model Number: SIR-SPHERES
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: SIR-SPHERES
Manufacturer: SIRTEX MEDICAL Serial Number: NR

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN41756	06/13/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
FL05-086	06/27/2005		DCH	AGREEMENT STATE EVENT REPORT
LTR050822	08/23/2005		DCH	AGREEMENT STATE LETTER
LTR070213	02/13/2007		DCH	AGREEMENT STATE LETTER

Item Number: 050326

Last Updated: 05/30/2007

Narrative:

The licensee reported that the I-131 doses for two patients were inadvertently switched. Patient #1 was administered 0.55 GBq (14.8 mCi) instead of the prescribed 0.44 GBq (12 mCi), 23% more than prescribed and a reportable medical event. Patient #2 was administered 0.44 GBq (12 mCi) instead of the prescr bed 0.52 GBq (14 mCi), 14% less than prescribed and not a reportable medical event. This event was caused by the technician's failure to assay the doses and ensure that the administered doses matched the written directives. Patent #1 and the referring physician were notified. No effects to the patients are expected because the administered doses are within the typical prescribed dose range. Corrective actions included personnel retraining.

Event Date: 05/11/2005 **Discovery Date:** 05/11/2005 **Report Date:** 05/12/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	29-11642-01	Name:	SHORE MEMORIAL HOSPITAL
NRC Docket Number:	03002535	City:	SOMERS POINT
NRC Program Code:	02120	State: NJ	Zip Code: 08244
Respons ble NRC Region:	1		

Site of Event:

Site Name: SOMERS POINT
State: NJ

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED
Old Cause: PROCEDURE NOT FOLLOWED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed:

Given:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 12 mCi 444 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 23
% 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):	I-131		
Manufacturer:	NR	Activity:	0.0148 Ci	0.5476	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:
EN41693	05/16/2005		DCH	EVENT NOTIFICATION
LTR050819	08/24/2005		DCH	NRC LETTER
LTR050825	08/29/2005		DCH	NRC LETTER
ML051950441	09/23/2005		RLS	INSPECTION REPORT
ML051950441	09/23/2005		RLS	LICENSEE REPORT
ML051950441	09/23/2005		RLS	REGION REPORT
ML051670316	05/30/2007		RLS	NOTICE OF VIOLATION
ML051670316	05/30/2007		RLS	NRC LETTER

Item Number: 050301

Last Updated: 10/30/2006

Narrative:

The licensee reported that a patient received 27% less dose than prescribed during a 29 hour 22 minute gynecological brachytherapy procedure. The patient received 1,825 cGy (rad) instead of the intended 2,500 cGy (rad). The dose was administered using a 2.5 cm solid vaginal cylinder with two Cs-137 sources, each with an activity of 19.56 Radium-milligram equivalent, or 1.81 GBq (48.9 mCi). The planned procedure specified that a 1.93 cm vaginal cylinder be used. This event was discovered on 5/4/2005 during a summary review. The patient was contacted and the licensee planned to administer the remaining dose on 5/5/2005. To prevent recurrence, the licensee will provide additional training to staff.

Event Date: 05/02/2005 **Discovery Date:** 05/04/2005 **Report Date:** 05/05/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-16457-01	Name:	UNION HOSPITAL
NRC Docket Number:	03011072	City:	TERRE HAUTE
NRC Program Code:	02120	State: IN	Zip Code: 47804
Respons ble NRC Region:	3		

Site of Event:

Site Name: TERRE HAUTE
State: IN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: ERROR IN EQUIPMENT SELECTION

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed:

Given:

Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 1825 rad 18.25 Gy

Intended:

Therapeutic Procedure: BRACHY, MANUAL AFTERLOADER
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 97.8 mCi 3618.6 MBq Dose: 2500 rad 25 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 27
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:	0.0489 Ci	1.8093	GBq
Model Number:	NR				
Serial Number:	NR				

Source Number: 2

Source/Radioactive Material:	SEALED SOURCE BRACHYTHERAPY	Radionuclide or Voltage (kVp/MeV):	CS-137		
Manufacturer:	NR	Activity:	0.0489 Ci	1.8093	GBq
Model Number:	NR				
Serial Number:	NR				

Device/Associated Equipment:

MD2

Device Number: 1

Device Name:	APPLICATOR	Model Number:	NR
Manufacturer:	NR	Serial Number:	NR

Reporting Requirements:

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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN41666	05/06/2005		RLS	EVENT NOTIFICATION
LTR050608	06/13/2005		DCH	NRC LETTER
LTR061011	10/11/2006		DCH	NRC LETTER
ML062900530	10/30/2006		RLS	INSPECTION REPORT

Item Number: 050237

Last Updated: 08/23/2005

Narrative:

The licensee reported that a patient being treated for spinal cord compression using a teletherapy device received a dose that was less than prescribed. The teletherapy device [redacted] serial #21) was manufactured by [redacted] and contained a Co-60 source [redacted] serial #S-5336) with an activity of 292.3 TBq (7,900 Ci). The patient was treated on 4/9 and 4/10/2005. The written directive prescribed a dose of 500 cGy (rad) in two equal daily fractions for a total dose of 1,000 cGy (rad). The treatment time for the fractions on 4/9 and 4/10/2005 was miscalculated and doses of 330 cGy (rad) were administered for a total dose of 660 cGy (rad). An additional fraction of 200 cGy (rad) will be administered to the patient. Corrective actions taken by the licensee included staff retraining, development of new forms, and designation of after hours on-call physics/dosimetry staff support.

Event Date: 04/09/2005 **Discovery Date:** 04/12/2005 **Report Date:** 04/12/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: DALLAS
State: TX

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: INCORRECT DATA USED IN THERAPY DOSE PLANNING

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Therapeutic Procedure: TELETHERAPY
Organ: SPINE
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: 660 rad 6.6 Gy

Intended:
Therapeutic Procedure: TELETHERAPY
Organ: SPINE
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: 7900 mCi 292300 MBq Dose: 1000 rad 10 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 34
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE TELETHERAPY Radionuclide or Voltage (kVp/MeV): CO-60
Manufacturer: [redacted] Activity: 7900 Ci 292300 GBq
Model Number: [redacted]
Serial Number: S-5336

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: TELETHERAPY UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 21

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN41592	04/13/2005		DCH	EVENT NOTIFICATION
LTR050628	06/28/2005		DCH	NRC LETTER
LTR050819	08/23/2005		DCH	NRC LETTER

Item Number: 050236

Last Updated: 05/17/2006

Narrative:

The licensee reported a medical event involving a breast cancer patient treated with a [redacted] remote high dose rate afterloading unit [redacted] and Ir-192 source with an activity of 277.5 GBq (7.5 Ci). Ten fractional treatments were administered from 1/24 to 1/28/2005. The prescr bed dose was 350 cGy/fraction (rad/fraction) at 1 cm from the surface of the balloon, with two fractions per day, for a total of 3500 cGy. The patient returned on 3/18/2005 complaining of pain in her breast. A moist desquamation was noted at the breast surface where the catheter had entered the breast. Re-evaluation of the treatment plan revealed that the wrong catheter length parameter (source travel distance) was used during the treatment. The Ir-192 source was implanted 8 cm short of its planned location, near the catheter breast entry point. Dosimetry reconstruction indicated that the maximum dose delivered to tissue (area of 2.5 by 2.1 by 0.5 cm) at the entrance point was 7,000 cGy (rad). Corrective actions taken by the licensee included instituting a QA checklist requiring two persons to verify treatment parameter determinations and correct treatment computer inputs (and to document their verifications), to include the catheter length parameter. Additionally, normal catheter length parameters for standard treatments will be documented and checked before treatments. Staff will be trained in these new procedures before using the HDR unit.

Event Date: 01/24/2005 **Discovery Date:** 03/18/2005 **Report Date:** 04/08/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	CA-2652-30	Name:	SADDLEBACK MEMORIAL HOSPITAL
NRC Docket Number:	NA	City:	LAGUNA HILLS
NRC Program Code:	NA	State: CA	Zip Code: 92653
Respons ble NRC Region:	4		

Site of Event:

Site Name: LAGUNA HILLS
State: CA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: ERROR IN EQUIPMENT SELECTION

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: SKIN
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: 7000 rad 70 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 700
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Radiopharmaceutical: NA
Radionuclide: IR-192 Activity: NR mCi NR MBq Dose: 3500 rad 35 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 70
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): IR-192
Manufacturer: [redacted] Activity: 7.5 Ci 277.5 GBq
Model Number: [redacted]
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: NR
Manufacturer: [redacted] Serial Number: NR

Device Number: 2
Device Name: CATHETER Model Number: NA
Manufacturer: NR Serial Number: NA

Reporting Requirements:

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 prescr bed 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:
CA-XCA716	04/13/2005		DCH	AGREEMENT STATE EVENT REPORT
EN41580	04/13/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR050414	04/19/2005		DCH	AGREEMENT STATE LETTER
LTR050720	07/21/2005		DCH	AGREEMENT STATE LETTER
AS 05-03	05/17/2006		RLS	ABNORMAL OCCURRENCE NUMBER
ML061170171	05/17/2006		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 050235

Last Updated: 05/17/2006

Narrative:

The licensee reported that a patient was administered a 1.78 GBq (48 mCi) dose of Y-90 Zevalin; based upon patient weight and platelet count, the intended dose should have been 1.04 GBq (28 mCi). The Zevalin product insert indicates that as a result of the 1.78 GBq (48 mCi) dosage, the patient received an exposure of 107 to 320 cGy (rad) to the red marrow, with a median exposure of 231 cGy (rad). The dose was dispensed as a unit dose by a nuclear pharmacy and administered as received. A written directive, required by Wisconsin regulations, was not prepared for the therapy. The error was not discovered until 4/7/2005 during a licensee review of records. The State of Wisconsin initiated a special inspection at the licensee's facility on 4/11/2005. The licensee suspended use of Y-90 Zevalin and conducted a root cause investigation of the event. A medical consultant was contracted by the State of Wisconsin to provide the State with a medical analysis of the consequences of the event. The patient and referring physician were notified of the event. It was determined that the licensee failed to prepare a written directive prior to administering the Y-90, failed to prevent usage of a dose that differed from the intended dosage by more than 20%, failed to establish appropriate administrative procedures, failed to ensure that radiation safety activities were performed, and failed to instruct individuals working under the supervision of an authorized user of the licensee's written directive procedures. Corrective actions taken by the licensee included writing new policies and procedures, implementing new training programs, and hiring new personnel.

Event Date: 04/05/2005 **Discovery Date:** 04/07/2005 **Report Date:** 04/07/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-025-1323-01	Name:	UNIVERSITY OF WISCONSIN
NRC Docket Number:	NA	City:	MADISON
NRC Program Code:	NA	State: WI	Zip Code: 53715
Respons ble NRC Region:	3		

Site of Event:

Site Name: MADISON
State: WI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: MANAGEMENT DEFICIENCY
Old Cause: QUALITY MANAGEMENT INADEQUATE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW PROCEDURE WRITTEN
2	PERSONNEL RECEIVE NEW TRAINING
3	NEW PERSONNEL HIRED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 04/07/2005

Given:

Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE MARROW
Radiopharmaceutical: IBRITUMOMAB TIUXETAN
Radionuclide: Y-90 Dose: 231 rad 2.31 Gy

Intended:

Therapeutic Procedure: RADIOPHARMACEUTICAL - T
Organ: BONE MARROW
Radiopharmaceutical: IBRITUMOMAB TIUXETAN
Radionuclide: Y-90 Activity: 28 mCi 1036 MBq Dose: 135 rad 1.35 Gy

% Dose Exceeds Prescribed: 71
% 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: BIOGEN IDEC Activity: 0.048 Ci 1.776 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:
EN41576	04/13/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
ML051040561	04/19/2005		DCH	PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
PN305008	04/19/2005		DCH	PRELIMINARY NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI050006	06/21/2005		DCH	AGREEMENT STATE EVENT REPORT
WI050006A	09/08/2005		DCH	AGREEMENT STATE EVENT REPORT
WI050006B	01/03/2006		DCH	AGREEMENT STATE EVENT REPORT
AS 05-04	05/17/2006		RLS	ABNORMAL OCCURRENCE NUMBER
ML061170171	05/17/2006		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 050174

Last Updated: 05/25/2005

Narrative:

The licensee reported that during a quarterly review of written directives, it was noted that a patient was administered a dosage of 462.9 MBq (12.51 mCi) of I-131 for hyperthyroidism instead of the prescribed dosage of 777 MBq (21 mCi). Radiopharmaceutical unit dose dispensing records as well as internal scheduling paperwork confirm that a 444 MBq (12 mCi) dose was in fact ordered and subsequently administered to the correct patient. The licensee determined that the root cause of the event was a lack of strict attention to detail. The licensee has evaluated their policy and procedures to prevent recurrence. The attending physician reviewed the patient's records and felt that there would be no adverse affect. He will notify the patient of the event.

Event Date: 03/21/2005 **Discovery Date:** 03/21/2005 **Report Date:** 03/22/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	21-04127-02	Name:	HARPER UNIVERSITY HOSPITAL
NRC Docket Number:	03002045	City:	DETROIT
NRC Program Code:	02120	State: MI	Zip Code: 48201
Respons ble NRC Region:	3		

Site of Event:

Site Name: DETROIT
State: MI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: INATTENTION TO DETAIL
Old Cause: INATTENTION TO DETAIL

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1

Patient Informed: N Date Informed:

Given:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Dose: NR rad NR Gy

Intended:

Therapeutic Procedure: SODIUM IODIDE - T
Organ: THYROID
Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 21 mCi 777 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 40.4
Effect on Patient:

Source of Radiation:

MD2

Source Number: 1

Source/Radioactive Material:	UNSEALED SOURCE RADIOPHARM	Radionuclide or Voltage (kVp/MeV):	I-131		
Manufacturer:	NR	Activity:	0.01251 Ci	0.46287	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:
EN41515	03/23/2005		DCH	EVENT NOTIFICATION
LTR050425	04/26/2005		RLS	NRC LETTER
LTR050523	05/25/2005		DCH	NRC LETTER

Item Number: 050172

Last Updated: 03/23/2005

Narrative:

The licensee reported that a patient received approximately 146.2 MBq (3.95 mCi) of I-131 instead of the prescribed 185 MBq (5 mCi). The event was caused by a clogged filter in the IV tubing used to administer the radionuclide. The manufacturer's protocol states that if the filter clogs, the remainder of the radionuclide is to be administered without the presence of the filter. When the filter clogged, the nuclear medicine technologist first attempted to flush the clog with saline and then bypassed the filter to complete the administration. After the administration, it was determined by dose cal brator that 43.7 MBq (1.18 mCi) of I-131 was trapped in the tubing behind the filter. As a corrective action, the RSO has recommended immediately bypassing the filter during administration instead of attempting to unclog it. The RSO plans to contact the vendor to get a protocol clarification.

Event Date: 03/17/2005 **Discovery Date:** 03/17/2005 **Report Date:** 03/17/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WA-WN-M008-1	Name:	SWEDISH MEDICAL CENTER
NRC Docket Number:	NA	City:	SEATTLE
NRC Program Code:	NA	State: WA	Zip Code: NR
Respons ble NRC Region:	4		

Site of Event:

Site Name: SEATTLE
State: WA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: DEFECTIVE OR INADEQUATE PROCEDURE
Old Cause: INADEQUATE PROCEDURE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: U Date Informed:

Given:
Diagnostic Study: WHOLE BODY I-131/THYROID

Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131

Intended:
Diagnostic Study: WHOLE BODY I-131/THYROID

Radiopharmaceutical: SODIUM IODIDE
Radionuclide: I-131 Activity: 5 mCi 185 MBq

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 21
Effect on Patient:

Source of Radiation:
MD2

Source Number: 1
Source/Radioactive Material: UNSEALED SOURCE RADIOPHARM Radionuclide or Voltage (kVp/MeV): I-131
Manufacturer: NR Activity: 0.00395 Ci 0.14615 GBq
Model Number: NA
Serial Number: NA

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: FILTER, OTHER Model Number: NA
Manufacturer: NR 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:
EN41501	03/23/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WA-05-010	03/23/2005		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 050143

Last Updated: 05/16/2006

Narrative:

The licensee reported that a 5-month-old infant was administered 414.4 MBq (11.2 mCi) of Tc-99m tetrofosmin (Myoview), instead of the prescribed dosage of 18.5 MBq (0.5 mCi) of Tc-99m sulfur colloid for a gastric emptying study. The Myoview dose had been prepared for an adult patient scheduled for a cardiac myocardial perfusion examination. Although the licensee's policy is that four standard items of identification be reviewed prior to the administration of radiopharmaceuticals, the technologist failed to verify the patient's identity. The whole body dose to the infant was calculated to be between 5.2 to 10 cSv (5.2 to 10 rem), instead of the expected dose of 0.009 cSv (rem). The physician informed the infant's parents. Corrective actions included counseling the technologist, revising procedures, and retraining staff. The NRC's medical consultant determined that there were no acute or subacute effects noted in the patient, but recommended that a pediatric gastroenterologist monitor the patient for cancer for an extended period of time.

Event Date: 03/09/2005 **Discovery Date:** 03/09/2005 **Report Date:** 03/11/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	24-00794-03	Name:	SAINT JOHNS MERCY MEDICAL CENTER
NRC Docket Number:	03002283	City:	SAINT LOUIS
NRC Program Code:	02120	State: MO	Zip Code: 63141
Respons ble NRC Region:	3		

Site of Event:

Site Name: SAINT LOUIS
State: MO

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: FAILURE TO FOLLOW PROCEDURE OR WRONG PROCEDURE USED
Old Cause: WRONG PATIENT SELECTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Diagnostic Study: CARDIAC SCAN

Radiopharmaceutical: MYOVIEW
Radionuclide: TC-99M

Intended:
Diagnostic Study: GASTRIC EMPTYING

Radiopharmaceutical: SULFUR COLLOID
Radionuclide: TC-99M Activity: 0.5 mCi 18.5 MBq

% Dose Exceeds Prescribed: NA
% 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): TC-99M
Manufacturer: NR Activity: 0.0112 Ci 0.4144 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:
EN41483	03/14/2005		DCH	EVENT NOTIFICATION
LTR050504	05/09/2005		DCH	NRC LETTER
LTR050523	05/25/2005		DCH	NRC LETTER
ML051450214	06/09/2005		RLS	INSPECTION REPORT
ML051450214	06/09/2005		RLS	NRC LETTER
LTR050608	06/13/2005		DCH	NRC LETTER
ML051730732	08/11/2005		RLS	LICENSEE REPORT
ML052380298	09/13/2005		RLS	NOTICE OF VIOLATION
ML052380298	09/13/2005		RLS	NRC LETTER
05-02	05/16/2006		RLS	ABNORMAL OCCURRENCE NUMBER
ML061170171	05/16/2006		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 050124

Last Updated: 05/17/2006

Narrative:

The licensee reported that a patient scheduled to receive 0.63 MBq (17 uCi) of I-131 for a thyroid uptake study received 133.2 MBq (3.6 mCi) of I-131 for a total body scan. A nuclear medicine technologist received the appointment roster form, posted it on the exam scheduling bulletin board, and incorrectly placed the order for a total body scan without looking at the diagnosis. The total body scan ordered on the roster was reviewed by a nuclear medicine physician and checked off for that day's activity. On the day of the exam, a second nuclear medicine technologist retrieved the paper work and administered 133.2 MBq (3.6 mCi) of I-131 for a total body scan. The patient was sent home and came back two days later for a thyroid scan. A third nuclear medicine technologist noted that the thyroid scan did not look as expected, reviewed all of the paperwork, and discovered that the wrong procedure had been administered. The patient was notified of the event. The administration resulted in a thyroid dose of 13,111 cGy (rad) and a TEDE of 2.6 cGy (rad). Corrective actions taken by the licensee included modifying procedures to include removing Central Booking from radionuclide ordering (referring physician will fax order directly to Nuclear Medicine), switching from I-131 to I-123 for thyroid uptake studies, revising the nuclear medicine request form for thyroid procedures, and other procedure changes.

Event Date: 01/07/2005 **Discovery Date:** 01/09/2005 **Report Date:** 02/24/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	MA-60-0095	Name:	BAYSTATE HEALTH SYSTEMS
NRC Docket Number:	NA	City:	SPRINGFIELD
NRC Program Code:	NA	State: MA	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: SPRINGFIELD
State: MA

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: INATTENTION TO DETAIL
Old Cause: WRONG DIAGNOSTIC STUDY OR THERAPY REQUESTED

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1

Patient Informed: Y Date Informed: 01/07/2005

Given:

Diagnostic Study: WHOLE BODY I-131/THYROID

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131

Intended:

Diagnostic Study: THYROID UPTAKE MEASUREMENT

Radiopharmaceutical: SODIUM IODIDE

Radionuclide: I-131 Activity: 0.017 mCi 0.629 MBq

% Dose Exceeds Prescribed: NA

% 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): I-131

Manufacturer: NR Activity: 0.0036 Ci 0.1332 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:
EN41438	03/01/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR050520	05/25/2005		DCH	AGREEMENT STATE LETTER
LTR050728	07/29/2005		DCH	AGREEMENT STATE LETTER
AS 05-02	05/17/2006		RLS	ABNORMAL OCCURRENCE NUMBER
ML061170171	05/17/2006		RLS	ABNORMAL OCCURRENCE NUMBER

Item Number: 050121

Last Updated: 05/23/2005

Narrative:

The licensee reported that a patient received a permanent brachytherapy seed implant procedure to the prostate, but a number of seeds were mistakenly placed in fatty tissue outside the intended area of treatment. The procedure involved 84 I-125 seeds that contained an activity of 14.8 MBq (0.4 mCi) each. The patient's prostate received less than 80% of the prescribed dose and the unintended site received more than 50 cGy (rad) and greater than 50% of the prescribed dose. The authorized user notified the patient and will notify the referring physician. The cause of the event was determined to be misidentification of the base of the prostate due to the patient's size and weight. Corrective actions taken by the licensee included modifying procedures used to locate the prostate to incorporate fluoroscopy, in addition to ultrasonic imaging.

Event Date: 02/24/2005 **Discovery Date:** 02/25/2005 **Report Date:** 02/25/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	03-23853-01VA	Name:	DEPARTMENT OF VETERANS AFFAIRS
NRC Docket Number:	03034325	City:	NORTH LITTLE ROCK
NRC Program Code:	03613	State: AR	Zip Code: 72114
Respons ble NRC Region:	3		

Site of Event:

Site Name: DURHAM
State: NC

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: FAILURE TO VERIFY TREATMENT SITE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 02/25/2005

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 33.6 mCi 1243.2 MBq Dose: NR rad NR Gy

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

Patient Number: 1A
Patient Informed: Y Date Informed: 02/25/2005

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PERI-PROSTATIC TISSUE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: NR rad NR 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): I-125
Manufacturer: NR Activity: 0.0336 Ci 1.2432 GBq
Model Number: NR
Serial Number: AGGREGATE

Reporting Requirements:
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 prescr bed 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:
EN41443	02/28/2005		DCH	EVENT NOTIFICATION
LTR050413	04/14/2005		DCH	NRC LETTER
LTR050523	05/23/2005		DCH	NRC LETTER

Item Number: 050104

Last Updated: 04/14/2005

Narrative:

The licensee reported that a patient received a radiation dose that was greater than 50% of the expected dose to a site outside of the intended treatment volume during a gamma knife treatment. [redacted] manufactured the gamma knife unit [redacted] serial #4149), which contained 119.6 TBq (3231.5 Ci) of Co-60. The patient was prescribed to receive 1,800 cGy (rad) to the intended treatment volume. During the process of manually programming the positioning system, the Y and Z coordinates were transposed. The error was not noticed during the double check of the treatment coordinates. As a result, the unintended site received an estimated dose of 506 cGy (rad) instead of the intended 40 cGy (rad). The volume of the unintended treatment site was 0.7 cm3 and the treatment duration was 2.42 minutes. The prescribed dose of 1,800 cGy (rad) was delivered and the patient's treatment was completed. The referring physician was notified of the event. State of Wisconsin Radiation Protection Section personnel were dispatched on 2/18/2005 to investigate the event. The cause of the event was determined to be the licensee's failure to conduct an adequate verification of the patient positioning parameters prior to administration. Contributing factors included; the individual who placed the Y/Z trunnion bar onto the head frame reversed their usual sequence of setting the Y and Z settings; and the independent coordinate verification by multiple individuals failed to detect the incorrect coordinates. The licensee has implemented additional procedural steps requiring more attention to detail and confirmation of patient positioning parameters on the frame.

Event Date: 02/16/2005 **Discovery Date:** 02/16/2005 **Report Date:** 02/17/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	WI-141-1162-01	Name:	MARSHFIELD CLINIC
NRC Docket Number:	NA	City:	MARSHFIELD
NRC Program Code:	NA	State: WI	Zip Code: 54449
Respons ble NRC Region:	3		

Site of Event:

Site Name: MARSHFIELD
State: WI

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: INATTENTION TO DETAIL
Old Cause: FAILURE TO VERIFY TREATMENT SITE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Dose: 506 rad 5.06 Gy

Intended:
Therapeutic Procedure: GAMMA KNIFE
Organ: BRAIN
Radiopharmaceutical: NA
Radionuclide: CO-60 Activity: NR mCi NR MBq Dose: 40 rad 0.4 Gy

% Dose Exceeds Prescribed: 1165
% Dose is Less Than Prescribed: NA
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: [redacted] Activity: 3231.5 Ci 119565.5 GBq
Model Number: [redacted]
Serial Number: AGGREGATE

Device/Associated Equipment:
MD2
Device Number: 1
Device Name: GAMMA KNIFE UNIT Model Number: [redacted]
Manufacturer: [redacted] Serial Number: 4149

Reporting Requirements:
MD2
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:
EN41420	02/23/2005		DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
WI050003	04/14/2005		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 050098

Last Updated: 05/10/2005

Narrative:

The licensee reported that a patient was implanted with 63 I-125 seeds that contained an activity of 13.69 MBq/seed (0.37 mCi/seed) instead of the prescribed 9.99 MBq/seed (0.27 mCi/seed). The licensee ordered I-125 seeds with activities of 9.99 MBq/seed (0.27 mCi/seed) from Anazaohealth Corporation (dba Custom Care Pharmacy), but received seeds with activities of 13.69 MBq/seed (0.37 mCi/seed). The order had been placed and confirmed with Anazaohealth, but the incorrect seeds were sent for the first of three implants for the patient. The documentation supplied with the order correctly identified that the seeds contained 13.69 MBq/seed (0.37 mCi/seed). As a result of the difference in activity, the patient's dose was approximately 37% more than intended during the first implant procedure. Both the patient and the referring physician were notified of the error. The licensee has implemented actions that would prevent loading seeds of an activity different than prescr bed without notification to the manufacturer and licensed medical institution.

Event Date: 02/16/2005 **Discovery Date:** 02/17/2005 **Report Date:** 02/17/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	13-17073-01	Name:	PORTER VALPARAISO HOSPITAL CAMPUS
NRC Docket Number:	03012150	City:	VALPARAISO
NRC Program Code:	02120	State: IN	Zip Code: 46383
Respons ble NRC Region:	3		

Site of Event:

Site Name: VALPARAISO
State: IN

Additional Involved Party:

License Number:	FL-2975-1	Name:	ANAZAOHEALTH CORP.
NRC Docket Number:	NA	City:	TAMPA
NRC Program Code:	NA	State: FL	Zip Code: 33634
Respons ble NRC Region:	1		

Other Information:

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: INATTENTION TO DETAIL
Old Cause: SOURCES SELECTED WITH INCORRECT ACTIVITY

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed: 02/17/2005

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Dose: NR rad NR Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: PROSTATE
Radiopharmaceutical: NA
Radionuclide: I-125 Activity: 17.01 mCi 629.37 MBq Dose: NR rad NR Gy

% Dose Exceeds Prescribed: 37
% 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): I-125
Manufacturer: NR Activity: 0.02331 Ci 0.86247 GBq
Model Number: NR
Serial Number: AGGREGATE

Reporting Requirements:
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 prescr bed 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.

References:

Reference Number:	Entry Date:	Retraction Date:	Coder Initials:	Reference Type:
EN41416	02/21/2005		DCH	EVENT NOTIFICATION
LTR050404	04/07/2005		DCH	NRC LETTER
FL05-034	05/10/2005		DCH	AGREEMENT STATE EVENT REPORT

Item Number: 050090

Last Updated: 04/14/2008

Narrative:

The licensee (dba Brown Cancer Center) reported that a patient received the wrong dose to the intended treatment site during an HDR procedure using a 3.0 cm vaginal cylinder. The patient was prescribed to receive 750 cGy (rad) to the site of interest. The catheter was placed in position under the supervision of the attending physician. When the setup was complete, and upon leaving the room, the resident physician noticed that the catheter was draped around the patient's foot as it ran from the cylinder to the HDR machine. The resident physician undraped the catheter and then left the room. The treatment ran for the scheduled 5.5 minutes. After the treatment was complete, the medical physicist removed the catheter. He noticed that the catheter was not fully inserted into the cylinder as required and estimated that it had been withdrawn from the desired location by approximately 15 cm. The treatment was the second of three prescribed treatments. The event occurred due to the lack of a positive mechanical lock of the HDR catheter to metal guide insert tube. The system uses a movable nylon collar surrounding the catheter, which is slid into position once the catheter is placed into the metal guide insert tube. A nut is then screwed over the nylon collar forming a compression fitting. The event may have occurred when the resident physician undraped the catheter from around the patient's foot. The manufacture also offers a different type of collar/nut compression fitting that uses a stainless steel collar that is glued onto the catheter at the appropriate distance. The licensee will use the alternate compression fitting system henceforth. Additionally, the catheter is now length/position marked and is checked by both the physician and the physicist prior to treatment and upon completion of treatment. The patient and referring physician were informed of the event. The patient was also informed that the second treatment would not be repeated. With the source offset by 15 cm, the delivered dose would have been 4 cGy (rad) to the intended site. Assuming that the source was approximately 2 cm exterior to the vagina, the dose to the labia would have been 100 cGy (rad). The INL has requested additional information for this event.

Event Date: 01/18/2005 **Discovery Date:** 01/18/2005 **Report Date:** 02/03/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	YS	Reciprocity:	NONE
License Number:	KY-202-029-22	Name:	UNIVERSITY OF LOUISVILLE
NRC Docket Number:	NA	City:	LOUISVILLE
NRC Program Code:	NA	State: KY	Zip Code: NR
Respons ble NRC Region:	1		

Site of Event:

Site Name: LOUISVILLE
State: KY

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: INATTENTION TO DETAIL
Old Cause: FAILURE TO VERIFY TREATMENT SITE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	NEW EQUIPMENT OBTAINED
2	PROCEDURE MODIFIED

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: NR Dose: 4 rad 0.04 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 750 rad 7.5 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 99.5
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: LABIA
Radiopharmaceutical: NA
Radionuclide: NR Dose: 100 rad 1 Gy

Intended:
A therapeutic procedure/diagnostic study was not intended.

% Dose Exceeds Prescribed: 100
% 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): NR
Manufacturer: NR Activity: NR Ci NR GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: REMOTE AFTERLOADER HDR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
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 prescr bed 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:

EN41399	02/15/2005	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE
LTR080409	04/14/2008	DCH	AGREEMENT STATE LETTER

Item Number: 050065

Last Updated: 05/16/2006

Narrative:

The licensee reported that a patient being treated for cervical cancer received an incorrect dose distribution. One area of the cervix received 821 cGy (rad) instead of the intended 1,643 cGy (rad), while another area of the cervix received received 372 cGy (rad) instead of the intended 465 cGy (rad). Other locations also received higher than intended doses. The intended doses to the bladder and the rectum were 1,147 cGy (rad) each, but they received 1,448 cGy (rad) and 2,012 cGy (rad), respectively. The 31-hour treatment was delivered using a low dose rate brachytherapy device with a tandem-ovoid applicator. The tandem portion of the applicator required an insert to properly position three sources within the tandem. The licensee cut the insert 6 cm too short, such that when the tandem was positioned in the patient, the three Cs-137 tandem sources (one with an activity of 1,295 MBq [35 mCi], and two with activities of 906.5 MBq [24.5 mC]) were not extended the proper distance. The ovoid sources were positioned properly. The referring physician and patient were informed of this event. The licensee does not believe that this event will have any adverse effect on the patient. The patient subsequently received a follow-up treatment to deliver the full intended dose to the treatment sites. Corrective actions taken by the licensee included stopping all LDR treatments until all individuals are trained and modifying procedures to incorporate a dual verification system.

Event Date: 01/24/2005 **Discovery Date:** 01/27/2005 **Report Date:** 01/27/2005

Licensee/Reporting Party Information:

Agreement State Regulated:	NO	Reciprocity:	NONE
License Number:	22-00187-46	Name:	UNIVERSITY OF MINNESOTA
NRC Docket Number:	03000842	City:	MINNEAPOLIS
NRC Program Code:	02110	State: MN	Zip Code: 55455
Respons ble NRC Region:	3		

Site of Event:

Site Name: MINNEAPOLIS
State: MN

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

Event Type:

MD2 - MEDICAL EVENT

Event Cause:

MD2

Cause: HUMAN ERROR
Old Cause: FAILURE TO VERIFY TREATMENT SITE

Corrective Actions Information:

Action Number:	Corrective Action:
MD2	
1	PROCEDURE MODIFIED
2	PERSONNEL RECEIVED ADDITIONAL TRAINING

Patient Information:

Patient Number: 1
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 821 rad 8.21 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 84 mCi 3108 MBq Dose: 1643 rad 16.43 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 50
Effect on Patient:

Patient Number: 1A
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 372 rad 3.72 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: CERVIX
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 84 mCi 3108 MBq Dose: 465 rad 4.65 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 20
Effect on Patient:

Patient Number: 1B
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: BLADDER
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 1448 rad 14.48 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: BLADDER
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 84 mCi 3108 MBq Dose: 1147 rad 11.47 Gy

% Dose Exceeds Prescribed: 26
% Dose is Less Than Prescribed: NA
Effect on Patient:

Patient Number: 1C
Patient Informed: Y Date Informed:

Given:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: CS-137 Dose: 2012 rad 20.12 Gy

Intended:
Therapeutic Procedure: BRACHY, MANUAL IMPLANT
Organ: RECTUM
Radiopharmaceutical: NA
Radionuclide: CS-137 Activity: 84 mCi 3108 MBq Dose: 1147 rad 11.47 Gy

% Dose Exceeds Prescribed: 75
% 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: 0.035 Ci 1.295 GBq
Model Number: NR
Serial Number: NR

Source Number: 2
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: NR Activity: 0.0245 Ci 0.9065 GBq
Model Number: NR
Serial Number: NR

Source Number: 3
Source/Radioactive Material: SEALED SOURCE BRACHYTHERAPY Radionuclide or Voltage (kVp/MeV): CS-137
Manufacturer: NR Activity: 0.0245 Ci 0.9065 GBq
Model Number: NR
Serial Number: NR

Device/Associated Equipment:
MD2

Device Number: 1
Device Name: APPLICATOR Model Number: NR
Manufacturer: NR Serial Number: NR

Reporting Requirements:
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 prescr bed 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:
EN41361	01/28/2005		RLS	EVENT NOTIFICATION
ML050280423	01/31/2005		RLS	PRELIMINARY NOTIFICATION
PN305002	01/31/2005		RLS	PRELIMINARY NOTIFICATION
LTR050404	04/07/2005		DCH	NRC LETTER
LTR050422	04/22/2005		DCH	NRC LETTER
05-01	05/16/2006		RLS	ABNORMAL OCCURRENCE NUMBER
ML061170171	05/16/2006		RLS	ABNORMAL OCCURRENCE NUMBER