General Information or Other	Event Number: 42359
Rep Org: NEW YORK STATE DEPT. OF HEALTH Licensee: NOT DISCLOSED BY STATE LAW Region: 1 City: State: NY County: License #: Agreement: Y Docket: NRC Notified By: R. DANSEREAU (via fax) HQ OPS Officer: STEVE SANDIN	Notification Date: 02/22/2006 Notification Time: 15:25 [ET] Event Date: 12/14/2003 Event Time: [EST] Last Update Date: 02/22/2006
Emergency Class: NON EMERGENCY 10 CFR Section: AGREEMENT STATE	Person (Organization): PAMELA HENDERSON (R1) GREG MORELL (NMSS)

Event Text

AGREEMENT STATE REPORT INVOLVING A MEDICAL MISADMINISTRATION

The following information was received via facsimile:

"NY-06-002

"HDR Brachytherapy medical event (NYS DOH Internal Tracking; No. 13)

"New York law prohibits the release of any identities in cases of medical events. Therefore the facility name, etc., is not contained in this report.

"RSO reported a medical misadministration involving a female patient treated on 5/12-14/2003 with SYED(needles)/HDR (Varian unit). Apparently there was an error, with respect to the area treated (incorrect dwell positions), which was not discovered until a final chart review. The treatment plan and double check of the calculations were performed as required. A different physicist than the one who did the treatment plan and double checks discovered the error. The facility submitted a written report. According to the report, since the original catheters had been discarded, reconstructing the scenario to the best of their ability, they concluded that all catheters and connecting tubes had the same lengths as previous similar implants. The measurement of 4 catheters on the first implant day obtained a catheter length of 119.8 cm. It was not repeated for the other 7 catheters and not double-checked by measurement by another physicist. However, the number, 119.8 cm is different from what they usually get for this type of procedure. Therefore, they concluded that the error occurred at this stage of the planning: i.e., (1) the planner did not verify that numbers were similar to what they usually get. (2) physics double check prior to the procedure did not include a second measurement nor did it check if the numbers were reasonable. The measurement was incorrect. Their corrective actions, if followed strictly, should prevent this error from happening again.

"Target (Tumor) Intended 2000 cGy. Delivered 150 cGy.

"Normal Tissue Expected 150 cGy. Delivered 2000 cGy.

"The patient was seen by her gynecological oncologist. This physician and the radiation oncologist determined that the patient should not be adversely affected because the dose was within tolerance of tissue including those of the vagina, rectum and bladder. However they were concerned that the tumor bed did not receive an adequate radiotherapy dose. The patient received additional low dose brachytherapy treatment. The LDR was given on 6/27/03, 1200 cGy to 0.5 cm from the cylinder surface. This treatment was delivered as intended."

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: 150 rad 1.5 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: VAGINA
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 2000 rad 20 Gy

% Dose Exceeds Prescribed: NA
% Dose is Less Than Prescribed: 93
Effect on Patient:

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

Given:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 2000 rad 20 Gy

Intended:
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: NR
Radiopharmaceutical: NA
Radionuclide: NR Activity: NR mCi NR MBq Dose: 150 rad 1.5 Gy

% Dose Exceeds Prescribed: 1233
% 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: VARIAN 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 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:

EN42359	02/27/2006	DCH	EVENT NOTIFICATION REPORTED FROM AN AGREEMENT STATE

Full Report

08/11/2009

Item Number: 060141 **Last Updated:** 02/27/2006

Narrative:

The licensee reported that a female patient prescribed to receive 2,000 cGy (rad) during treatment using a Varian HDR unit and SYED needles only received 150 cGy (rad) to the intended site. Normal tissue that was only to receive a dose of 150 cGy (rad), actually received 2,000 cGy (rad). There was an error with respect to the area treated (incorrect dwell positions), which was not discovered until a final chart review. The treatment plan and double check of the calculations were performed as required. A different physicist than the one that performed the treatment plan and double checks discovered the error. The licensee submitted a written report. According to the report, the original catheters had been discarded and the licensee had to reconstruct the scenario to the best of their ability. They concluded that all catheters and connecting tubes had the same length as previous similar implants. The measurement of four catheters on the first implant day obtained a catheter length of 119.8 cm. It was not repeated for the other seven catheters and not double checked by measurement by another physicist. However, the number of 119.8 cm was different from what they usually got for that type of procedure. Therefore, they concluded that the error occurred at that stage of the planning. The planner had not verified that the numbers were similar to what they usually got. Also, physics' double check prior to the procedure did not include a second measurement nor did it check if the numbers were reasonable. The measurement was incorrect. The State Agency noted that the licensee's corrective actions, if followed strictly, should prevent this type of error from recurring. The patient received additional low dose brachytherapy treatment on 6/27/2003. The State of New York is tracking this incident as NY-06-002 (NYS DOH internal tracking number is 13). The INL has requested additional information for this event.

Event Date: 05/12/2003 **Discovery Date:** 05/14/2003 **Report Date:** 02/22/2006

Licensee/Reporting Party Information:

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

Site of Event:

Site Name: NR
State: NY

Additional Involved Party:

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

Other Information:

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

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	NOT REPORTED

Patient Information: