

Full Report

10/28/2010

Item Number: OH2007-11

Last Updated: 10/17/2007

Event Type: MD2 - MISADMINISTRATION

Total Persons Affected:

Event Cause: HUMAN ERROR

Event Date: 09/27/2006

Report Date: 02/27/2007

Licensee/Reporting Party Information:

Name: AKRON GENERAL MEDICAL CENTER
City: AKRON

License Number: 02120-78-0000
State: OH **Zip Code:** 44307

Other Information:

Reportable Event:	Y	Reciprocity:	
Atomic Energy Act Material:	Y	Abnormal Occurrence:	N
Investigation:	Y	Send this Report to NRC:	Y
Consultant Hired:	N	Event Closed by State:	Y

Narrative:

On September 28, 2006. The licensee notified the ODH Bureau of Radiation protection that they had an event which did not meet the reporting requirement of a medical event but they were revising their HDR program to prevent a reoccurrence. The Bureau requested a report that was received on February 26, 2006. The patient was to receive a total dose of 3400 rad total dose through 10 fractions of 340 rad each. The patient received 5 fractions of 680 rad for a total dose of 3400 rad. Upon review of the report it was determined by consultation with NRC Region 3 that a medical event did occur because "Prescribed Dose" for remote afterloaders includes Total Dose and Fractionated dose. The reason for the event was the Physicist entered the wrong planning film magnification into the treatment system. The patient has experienced some tissue necrosis at the treatment site, although some necrosis is expected with this therapy (MammoSite). The necrosis may have been exacerbated by the dosage scheme. The patient is being followed by her attending physician. The patient and attending physician were notified on 09/27/2006. The Bureau conducted an inspection on November 2, 2006 and identified problems with the licensee's HDR program. An additional inspection will be conducted during the week of March 5, 2007 to ascertain licensee's corrective actions and the status of the patient.

Corrective Actions:

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

Patient Information:

Patient Number: 1
Patient Informed: Y
Date Informed: 09/27/2006
Therapeutic Procedure: BRACHY, REMOTE AFTERLOADER, HDR
Organ: BREAST
Dose: 3400 rad 34 Gy
% Dose Exceeds Prescribed: 0
% Dose is Less Than Prescribed: 0
Effect on Patient: UNKNOWN
Administered By: PHYSICIAN

Dose to Family: 0 rem 0 Sv
Dose to Newborn: 0 rem 0 Sv
Dose to Fetus: 0 rem 0 Sv

Source of Radiation:

Source Number: 1
Form of Radioactive Material: SEALED SOURCE
Source Use: BRACHYTHERAPY
Manufacturer: 
Model Number: 
Serial Number: D36A-9791
Radionuclide or Voltage (kVp/MeV): IR-192
Activity: 5.9414 Ci 219.8318 GBq

Device/Associated Equipment:

Device Number: 1

Device Name: REMOTE AFTERLOADER HDR

Model Number: [REDACTED]

Manufacturer: [REDACTED]

Serial Number:

31472

Reporting Requirements:

Reporting Requirement: OH3701:1-58-101 - Medical Event "Prescribed dose" includes Total Dose and fractionated dose for remote afterloaders.

Mode Reported:

References:

Reference Number:	Entry Date:	Coder Initials:	Type of Report:
OH2007-11	02/28/2007	MHL	