

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 MammoSite therapy instead of the prescribed 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 MammoSite 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 an 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
Responsible 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
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:	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 Activity: 5940 mCi 219780 MBq 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 prescribed 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