

Hospital	Event Number: 43685
Rep Org: CARILION CLINIC Licensee: CARILION CLINIC Region: 1 City: ROANOKE State: VA County: License #: 45-25395-01 Agreement: N Docket: NRC Notified By: JOE SURACE HQ OPS Officer: STEVE SANDIN	Notification Date: 10/03/2007 Notification Time: 14:21 [ET] Event Date: 08/31/2006 Event Time: [EDT] Last Update Date: 10/03/2007
Emergency Class: NON EMERGENCY 10 CFR Section: 35.3045(a)(3) - DOSE TO OTHER SITE > SPECIFIED LIMITS	Person (Organization): RAY POWELL (R1) MICHELE BURGESS (FSME)

### Event Text

#### MEDICAL EVENT INVOLVING HIGHER THAN PRESCRIBED DOSE

On August 31, 2006 a female patient received mammosite treatment for a breast lesion using a HDR with an Ir-192 source. The treatment consisted of placing a catheter into the treatment site, inflating a balloon with between 35-75 ml saline and positioning the Ir-192 source inside the catheter into the center volume of the saline balloon. This allows for a homogenous dose to the treatment site. While in the OR (Operating Room), the catheter was inserted and saline introduced through one of the two catheter connections to inflate the balloon. The patient was taken to the HDR location where the technologist inadvertently connected the HDR to the saline vice the HDR connector. This resulted in draining the saline balloon into the HDR unit. The technologist recognized that the HDR was improperly connected, broke the connection and reconnected to the proper port. When the prescribed 416 second treatment was commenced, the HDR automatically shutdown after 223 seconds retracting the Ir-192 source to the safe position. An evaluation by the licensee concluded that the incident was not reportable since it did not meet the criteria for an underdose.

During an inspection conducted 7/26/07 (Inspection Report No. 2007-001), the NRC Inspector noted that since the saline balloon had been inadvertently drained tissue in a .5 cubic centimeter volume adjacent to the source received a significantly higher dose (approximately 20 Gray) than prescribed. In a followup call from NRC Region I on 10/03/07, the licensee was requested to notify the NRC Operations Center of this finding.

The licensee informed the prescribing physician and the patient was also notified. No adverse effects to the patient have been noted.

A "Medical Event" may indicate potential problems in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient.