LICENSEE EVENT REPORT EVALUATION FORM

EVENT CLASS: MED - MEDICAL EVENT

LICENSEE / REPORTING PARTY INFORMATION:

Licensee/Reporting party name:	Benefis Hospitals		
License number :	25-12710-01		
Docket number :	03002404		
Licensee's City of record :	Great Falls		
Licensees State of record :	MT		
NRC regulated?	yes	If so, what Region?	IV
Working under reciprocity?	N/A		

EVENT INFORMATION:

In what City and State did the event occur?	Great Falls
Event date :	01/05/2012
Discovery date :	01/09/2012
Report date :	01/09/2012
Agreement State reportable?	N/A
NRC reportable?	yes
Reporting regulation :	35.3045(a)(1)(i) and 35.3045(a)(3)
NMED Item Number :	120054

ADDITIONAL PARTIES INVOLVED:

Name :	N/A
License number :	
City :	
State :	

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CONSULTANT INFORMATION (if any):

Consultant name :	Subir Nag, MD
Company :	N/A
Who hired consultant?	NRC

DEVICE INFORMATION:

Manufacturer :	Varian Medical Systems
Model number :	Varisource HDR
Serial number :	NR

RADIATION SOURCE INFORMATION:

Isotope :	Ir-192
Activity :	6.344 Ci
Manufacturer :	Varian Medical Systems
Model number :	VS2000
Serial number :	NR

ADDITIONAL INFORMATION REQUIRED:

Procedure administered?	HDR to Esophagus
Dose intended?	700 cGy
Dose administered?	10 %
Target organ?	Esophagus

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NARRATIVE EVENT DESCRIPTION:

The medical event involved a patient undergoing treatment for esophageal cancer, a modality that was new for the hospital. The patient was treated using a high-dose rate afterloader. To treat the patient, a nasogastric tube was inserted into the patient, and then a catheter was inserted inside the nasogastric tube. The treatment involved a radioactive source traveling out of the shielded position from the high-dose rate afterloader and through the catheter to the catheter's end, which should have been placed at the intended treatment location. However, hospital personnel were not aware that the high-dose rate afterloader's catheter was placed about 29 centimeters from the end of the nasogastric tube. As a result, the licensee did not deliver the treatment to the intended site. An unintended dose of approximately 700 centigray was delivered at 1 centimeter depth to the nasal passages and the nasopharyngeal area, with a maximum dose in excess of 1000 centigray at 1 centimeter depth to a 4 square centimeter area of the nasopharyngeal area.

CORRECTIVE ACTIONS:

Actions included the development and implementation of a policy and program for the addition of new treatment modalities" including the following areas: (1) requires written standard and emergency procedures to be in place prior to implementation of the new modality; (2) requires use of an implementation timeline to ensure safe and accurate implementation of new modalities; (3) allows personnel time to research and review professional standards associated with new modalities; (4) allows for assessment of space, staff and equipment requirements; (5) establishes a clinical conference review process involving all technical and professional staff who have a part to play in new modalities to define roles and responsibilities; and(6) establishes requirements for training and simulation of new modalities so that potential issues can be identified and corrected before the treatment process is implemented.

RECOMMENDED FOLLOWUP:

Was a reactive inspection conducted?	yes	If so, inspection report number :	030-02404/2012-001
Is LER recommended for closure?	yes		
Is this NMED Item Number recommended to reflect "complete"?	yes		

LER Evaluator: Name: Anthony D. Dias Date: 10/24/12	Branch Chief or Designee Review: Name: [signature] Date: 10/25/2012