UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BLVD
ARLINGTON, TEXAS 76011-4511

October 11, 2012

EA-12-107
NMED No. 120054

Ms. Laura Goldhahn, President
Benefis Hospitals
1101 26th Street South
Great Falls, Montana 59405-5193

SUBJECT: NOTICE OF VIOLATION (REACTIVE NRC INSPECTION REPORT 030-02404/2012-001)

Dear Ms. Goldhahn:

This refers to the reactive inspection conducted January 17-19, 2012, at your hospital in Great Falls, Montana, with continued in-office review through June 26, 2012. The inspection was conducted in response to a medical event that occurred at your facility on January 5, 2012. You documented the medical event in a notification report emailed to the NRC on January 12, 2012, (ML12018A042). You updated the notification in an email dated February 6, 2012 (ML12046A881). The preliminary inspection findings were discussed with you and your staff at the conclusion of the onsite portion of the inspection. Follow-up telephone conversations were conducted and email correspondence was exchanged during our in-office review. A final exit briefing was conducted telephonically with Ms. Kari Cann, Radiation Safety Officer, and members of your Radiation Oncology staff, on June 26, 2012. The inspection results were documented in NRC Inspection Report 030-02404/2012-001, dated July 19, 2012 (ML12201B479).

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.

In the letter transmitting the inspection report, we provided you the opportunity to address the apparent violation identified in the report by either requesting a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated August 6, 2012 (ML12226A594), you provided a written response to the apparent violation.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report, the NRC has determined that a violation of NRC requirements occurred. This violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the inspection report. The violation involves the licensee's failure to develop and implement procedures to provide high confidence that a high-dose rate afterloader brachytherapy treatment was in accordance with the written directive, as required in 10 CFR 35.41(a) and (b). For example, the NRC inspection team noted several deficiencies, including the failure to develop a procedure for the new modality, failure to conduct a pre-job briefing for licensee personnel for the new modality; and failure to conduct a dry run of the procedure.

The NRC has determined that the root cause of the event is the licensee's failure to have procedures for administrations of new modalities that require written directives. Such procedures could have prevented these deficiencies and were important because several key staff were not familiar with this modality. These deficiencies could have resulted in more significant consequences under other circumstances. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3500 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last 2 years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy. The corrective actions implemented by your facility are detailed in your letter dated August 6, 2012. The NRC has determined that *Corrective Action* credit is warranted. Your actions include 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.

Your policy also requires that once the Radiation Oncology Department implements and conducts patient treatment with a new modality, then the department will present procedures, treatment results, and any complications to the facility's Quality Committee and Radiation Safety Committee for review.

Therefore, to encourage prompt identification and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in NRC Reactive Inspection Report 030-02404/2012-001, your e-mails dated January 12 and February 6, 2012, and your letter dated August 6, 2012. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you chose to submit one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response, if you chose to submit one, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its website at (http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/).

Should you have any questions concerning this inspection, please contact Mr. Michael Vasquez, Chief, Nuclear Materials Safety Branch A at (817) 200-1130.

Sincerely,

/RA/

Elmo E. Collins
Regional Administrator

Docket: 030-02404
License: 25-12710-01

Enclosure: Notice of Violation

cc: w/Enclosure:
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Dept. of Public Health & Human Services
Licensure Bureau
P.O. Box 202953
Helena, MT 59620-2953

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ADAMS ☐ No ■ Yes	■SUNSI Review Complete		Reviewer Initials: MCM
■ Publicly Available	☐Non-publicly Available	☐Sensitive	■ Non-sensitive
Category:	**KEYWORD**: NOV EA-12-107 Benefis Hospitals		

ES:ACES	C:NMSBA	RC	ACES
MCMaier	MVasquez	KSFuller	HGepford
/RA/	***/RA/***	***/RA***	***/RA***
9/7/12	9/7/12	09/17/2012	09/18/2012

D:DNMS	DRA	OE	RA
A Vegel	ATHowell	SWoods	EECollins
/RA/ VHC for	***/RA/ TWP for***	***/RA/***	***/RA/***
09/20/2012	09/20/2012	10/11/2012	10/11/2012

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Benefis Hospitals
Great Falls, MT

Docket No. 030-02404
License No. 25-12710-01
EA-12-107

During an NRC reactive inspection conducted January 17-19, 2012, with continued in-office review through June 26, 2012, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.41(a)requires, in part, that for any administration requiring a written directive, licensees shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
>
> Procedures required by 10 CFR 35.41(a) must, at a minimum, address 10 CFR 35.41(b), including the requirement in 35.41(b)(2) to verify that the administration is in accordance with the treatment plan, if applicable, and the written directive.
>
> Contrary to the above, as of January 5, 2012, the licensee failed to develop, implement, and maintain written procedures to provide a high degree of confidence that each administration was in accordance with the written directive. Specifically, the licensee failed to have a written procedure specific for the treatment of esophageal cancer, which resulted in an administration of byproduct material and a dose to a patient that was not in accordance with the written directive.

This is a Severity Level III violation (Section 6.3).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Reactive Inspection Report 030-02404/2012-001 (ML12201B479), the e-mails dated January 12, 2012 (ML12018A042) and February 6, 2012 (ML12046A881), and your letter dated August 6, 2012 (ML12226A594). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-12-107," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region IV, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days of receipt.

Dated this 11th day of October 2012

Enclosure