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

July 19, 2012

EA-12-107
NMED No. 120054

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

SUBJECT: REACTIVE NRC INSPECTION REPORT 030-02404/2012-001

Dear Ms. Goldhahn:

This refers to the reactive inspection conducted on January 17-19, 2012, at your facility 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. The medical event was documented in your notification report which was e-mailed to the NRC on January 12, 2012 (ML12018A042), and updated 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 electronic mail correspondence was exchanged. 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 enclosed report presents the results of this inspection.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation being considered for escalated enforcement involves the licensee's failure to develop and implement procedures to provide high confidence that a high dose-rate remote afterloader brachytherapy treatment was in accordance with the written directive, as required in 10 CFR 35.41(a) and (b). The circumstances surrounding this apparent violation, the significance of the issues, and the need for lasting and effective corrective actions were discussed with Ms. Kari Cann, the RSO during the telephonic meeting on February 2, 2012, and are described in detail in the subject inspection report (Enclosure 1).

In addition, since your facility has not been the subject of escalated enforcement actions within the last 2 years, or last two inspections, and based on our understanding of your corrective actions, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. The final decision will be based on the corrective actions you have taken or will take to prevent recurrence.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either respond in writing to the apparent violation addressed in this inspection report within 30 days of the date of this letter or request a Predecisional Enforcement Conference (PEC). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference. If you decide to participate in a PEC, please contact Mr. Michael Vasquez at 817-200-1130 within 10 days of the date of this letter. A PEC should be held within 30 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a “Response to An Apparent Violation in Inspection Report 030-02404/2012-001; EA-12-107” and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. In particular, your response should provide additional details on actions you plan to take or have taken regarding new or infrequently performed modalities. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

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 choose to provide 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 should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Should you have any questions concerning this inspection, please contact Mr. Anthony Gaines at 817-200-1252 or Mr. Michael Vasquez at 817-200-1130.

Sincerely,

/RA/

Anton Vegel, Director
Division of Nuclear Materials Safety

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

Enclosure:
NRC Inspection Report 030-02404/2012-001
(w/Attachment)

cc w/enclosure:
Montana Radiation Control Program Director

Kari Cann, Radiation Safety Officer
Benefis Hospital (via email)

Vickie Nelson, Radiation Oncology
Department Manager
Benefis Hospital (via email)

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DNMS Secretarial File

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ADAMS ☐ No ☑ Yes	☑SUNSI Review Complete			Reviewer Initials: MCM
☑ Publicly Available	☐Non-publicly Available	☐Sensitive		☑ Non-sensitive
	KEYWORD: Choice Letter, EA-12-107			

NMSBA	NMSBA	DNMS:NMSBA:BC	ACES:ES	RC
MPoston-Brown	ADGaines	GMVasquez	MCMaier	KDFuller
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HJGepford	AVegel			
RKellar for HG	***/RA/***			
07/03/12	07/19/12			

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U.S. Nuclear Regulatory Commission
Region IV

Docket:	030-02404
License:	25-12710-01
Report:	2012-001
EA:	12-107
Licensee:	Benefis Hospitals
Facility:	Field Office
Location:	Sletten Cancer Institute, 1117 29th Street South, Great Falls, Montana
Dates:	January 17 through June 26, 2012
Inspectors:	Anthony D. Gaines, Senior Health Physicist Nuclear Materials Safety Branch A Martha Poston-Brown, Health Physicist Nuclear Materials Safety Branch A
Approved By:	G. Michael Vasquez, Chief Nuclear Materials Safety Branch A
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

Benefis Hospitals, Great Falls, Montana
NRC Inspection Report 030-02404/2012-001

This was a reactive, announced inspection of licensed activities following the licensee's notification to the NRC Headquarters Operations Officer of a medical event that occurred on January 5, 2012. The inspection was limited to a review of the medical event focusing on the direct, contributing, and root cause(s) of the medical event and the licensee's high dose rate (HDR) remote afterloader brachytherapy program.

Summary of Event

The medical event involved the use of a Varian HDR remote afterloader brachytherapy device, loaded with 6.3 curies (Ci) of iridium-192 to deliver a prescribed dose of 700 centigray (cGy) to a patient as part of treatment for esophageal cancer. However, the dose was not delivered to the lower level of the esophagus as planned. Due to human error and lack of planning for this new modality, the dose was delivered to the nasopharyngeal region – approximately 29 cm short of the target area.

Direct Causes

The direct cause of the medical event was attributed to human error. Specifically, the authorized medical physicist (AMP) performing the dose planning failed to recognize that the images on the computed tomography (CT) scans were not consistent with images for a source marker wire used to simulate the source (Section 4.2).

Contributing Causes

Contributing causes include the following: (1) the staff's inexperience with this modality, (2) poor communication between staff members who had experience in this modality and those who did not have experience in this modality, (3) lack of planning for this new modality, and (4) not performing a dry run with a phantom prior to patient treatment to prepare for this new modality (Section 4.2).

Root Causes

The licensee failed to have a procedure specific to the patient treatment modality prior to performing patient treatment and did not have a procedure describing required actions needed prior to performing a new modality. This failure was identified as the root cause of the medical event (Section 4.2).

Notifications and Reports

The licensee fulfilled the regulatory requirements pertaining to patient, referring physician, and NRC notifications (Section 5.2).

Corrective Actions

The licensee instituted corrective actions that appear adequate to prevent similar types of medical events from recurring. Specifically, the licensee developed a treatment procedure

specific to this modality and instituted the collection and uploading of CT images to the planning software along the entire length of the HDR catheter. However, the licensee's corrective action did not address broader lessons learned associated with the introduction of new or infrequently used modalities, such as the need to plan, prepare, practice, discuss, and proceduralize new or infrequently used modalities before patient treatment (Section 6.2).

Regulatory Issues

The inspectors identified one violation of NRC requirements to have in place and implement procedural controls to demonstrate and verify at a high confidence that the administration was in accordance with the written directive as required by 10 CFR 34.51 (Section 8.2).

Report Details

1 Program Overview (87103, 87132)

1.1 Inspection Scope

The inspectors interviewed licensee personnel, reviewed the license application, supporting documentation, high dose rate (HDR) remote afterloader brachytherapy operating procedures, treatment plans, and other records maintained by the licensee.

1.2 Observations and Findings

Benefis Hospitals (Benefis), under NRC License 25-12710-01, Amendment 52, was authorized to use byproduct material in sealed form for use in medical therapeutic treatments as defined in 10 CFR 35.600. The therapeutic treatments performed under the NRC license at Benefis utilized an iridium-192 (Ir-192) sealed source contained in a Varian HDR brachytherapy remote afterloader device. At the time of the event, Benefis used a 6.344 Ci Ir-192 source. The oncology treatment team was comprised of a radiation oncologist authorized user (AU), an authorized medical physicist (AMP), and a registered nurse (RN). All HDR procedures performed at Benefis were under the supervision and direction of the AU. The licensee had performed approximately 3 to 4 HDR treatments a month without incident. The majority of these HDR brachytherapy treatments were gynecological. The licensee's oncology treatment team had not performed an esophageal HDR brachytherapy treatment; however, the AU was experienced with esophageal treatments based on his work at another medical facility.

1.3 Conclusion

The licensee is authorized to perform therapeutic medical HDR brachytherapy procedures utilizing Ir-192 sealed sources as specified in 10 CFR 35.600. Benefis had performed approximately 3 to 4 HDR treatments a month without incident. The licensee's oncology treatment team had not performed an esophageal HDR brachytherapy treatment.

2 Background (87103)

On January 5, 2012, a patient was treated with a Varian HDR remote afterloader brachytherapy device using a 6.344 Ci Ir-192 source. The target was the distal esophagus, approximately 29 cm from the incisors, near where the esophagus was attached to the stomach. The prescription dose was 700 cGy to 1 cm depth. As is standard for esophageal HDR brachytherapy treatment, a nasogastric (NG) tube was inserted into the patient through the nostril. Once the NG tube was in place, the HDR catheter was inserted into the NG tube, followed by a marker wire to simulate the source. CT images were collected from the patient's clavicle to the esophagus/stomach connection and these images were uploaded to the brachytherapy imaging software. Dose planning was done using these images and the patient was treated according to the dose plan developed. At the end of the procedure, the NG tube and HDR catheter were removed as a unit and it was discovered that the HDR catheter was not advanced to the end of the NG tube. Using the planning software, the AMP and AU estimated the HDR catheter did not travel the last 4 cm of the NG tube. The clinical result was that the targeted area was not completely treated and a nontarget portion of the esophagus was treated.

After discussions about whether this was a medical event or not, the licensee contacted the NRC Headquarters Operations Center on January 9, 2012 (EN47579), in accordance with 10 CFR 35.3045(a) about a medical event that involved the treatment of a patient with esophageal cancer. The inspectors were dispatched and arrived onsite on January 17, 2012.

On January 18, 2012, the licensee contacted the NRC Headquarters Operations Center and updated EN 47579 to state that, in its continuing review of the incident, they have determined that the source had been positioned 29 cm back from the intended target area, rather than the 4 cm originally reported. This may have resulted in excessive exposure to portions of the nasal passages and nasopharyngeal region of the patient.

The licensee notified the patient the day of the event. The licensee, based on the dose received, expected that the patient would not incur adverse health effects as a result of the medical event.

3 Event Chronology (87103)

3.1 Inspection scope

The inspectors interviewed licensee personnel, reviewed procedures and corresponding documentation, and inspected equipment associated with the medical event to reconstruct the sequence of events.

3.2 Observations and Findings

The following is a chronological sequence of events that led to the medical event and subsequent licensee identification.

January 3, 2012

The AU contacted the AMP to let him know they were performing an esophageal HDR treatment later in the week. The AMP obtained an NG tube from the RN and the HDR catheter did not fit inside the NG tube. The AMP tested three other NG tubes and determined that an 18 French (6mm diameter) NG tube would accommodate the HDR catheter.

January 5, 2012

The AU performed a consult with the patient and decided to move forward with the HDR treatment. The AU contacted the AMP and let him know they would be treating the patient. The RN prepared the patient by numbing the patient's nose and throat. The AU inserted the NG tube. The AMP held the HDR catheter while the AU inserted it. The AU did not pay attention to the length of the catheter that was inserted before it stopped. The CT manager performed the CT and assisted in identifying slices, so they could check NG tube positioning. The AU approved the positioning. The AMP measured the HDR catheter length by feeding a wire down the catheter until it hit the bottom. He recorded a length of 115 cm. The dosimetrist checked the measurement of the HDR catheter length. He recorded a length of 115 cm.

The AMP inserted the marker wire, and a CT technician took a second set of CT images from the patient's clavicle to the stomach/esophagus connection. The CT technician and the AMP checked the images and the CT technician sent the CT images to the dose planning software (Eclipse). The AMP used the CT images and the software to perform dose planning, which took

about 45 minutes. The AU then reviewed the dose plan. The AMP and the AU both signed and dated the dose plan. The patient was treated according to the plan and, after treatment, the AU removed the NG tube and set it in the sink. The AU helped the patient out of the room. When the AMP looked at the NG tube and noted that the catheter was not at the end of the NG tube, he notified the AU, who verified the catheter was not at the end of the NG tube. They went to look at the Eclipse software and determined based on the CT images that the end of the catheter was positioned 4 cm above the end of the NG tube. They discussed whether a medical event had occurred, and the AU did not think it was a medical event.

January 6, 2012

The AMP and the AU briefed the Radiation Oncology Department manager regarding the situation in the morning between 8 and 8:15 am. At the end of the day, the Radiation Oncology Department manager asked the AMP if the details associated with the event had been entered into the hospital's database and it occurred to the manager that the event might be reportable to the NRC. The manager asked the AMP to call the Radiation Safety Officer (RSO). The AMP contacted the RSO after working hours and briefed the RSO on the situation.

January 9, 2012

The RSO contacted the Radiation Oncology Department manager to gather information associated with the potential event. The Radiation Oncology Department manager and the RSO called the AMP, who had left town to attend an Eclipse software training class, and all three made a determination that the incident was a medical event. The RSO made the notification to the NRC Headquarters Operations Officer (HOO). The RSO began investigating the event for the 15-day report. The AU was informed that the NRC had been notified and indicated that he had contacted the referring physician and the patient.

January 11, 2012

NRC Region IV informed the RSO that inspectors would be coming to the hospital to review the medical event.

January 13, 2012

Via email, the RSO asked the AMP to write a step-by-step procedure for treatment of endo-esophageal cancer.

January 16, 2012

The Radiation Oncology staff met regarding the corrective actions and held a discussion of the rescheduled patient treatment to make sure all issues were identified and addressed. They reviewed and approved a draft procedure which included the corrective action of inserting the catheter into the NG tube prior to insertion of the NG tube into the patient. The AU expressed concern that this might cause the NG tube to be stiffer and therefore harder to insert into the patient. Later that afternoon, phantom runs indicated that the catheter shortfall was much further off then originally estimated using the imaging software in Eclipse. The AMP looked at the NG tube and catheter that was removed from the patient and could see that the catheter was approximately 29 cm from the bottom of the NG tube. This meant that the patient was treated in the head/neck region.

January 17, 2012

Two NRC inspectors arrived at the licensee's facility. The AMP informed the Radiation Oncology Department manager that the distance was much larger than originally estimated, but did not provide the distance. The inspectors performed an entrance meeting at 4 p.m. with the Radiation Oncology Department Manager and the AMP. The distance discrepancy was not mentioned at this meeting.

January 18, 2012

The AMP informed the inspectors, during the onsite interviews, that the distance between the end of the catheter and the end of the NG tube was 29 cm, not the 4 cm originally reported. The inspectors reviewed the CT images uploaded to the dose planning software for the patient treatment on January 5th. The images showed a pearl and string view that was consistent with a marker wire image, but with additional magnification of the images, the pearl and string view was revealed to be a corkscrew configuration, consistent with radio-opaque markers used for catheters. The inspectors also viewed phantom images collected by the AMP during phantom runs conducted on January 17th and 18th. These images clearly showed both the pearl and string image (marker wire) and the corkscrew image (NG tube radio-opaque marker) along the length of the NG tube/HDR catheter pairing.

January 19, 2012

The inspectors completed the interviews and observed the retreatment of the patient. The AU and AMP used the draft procedure created on January 16th, which incorporated their corrective actions for this modality, to ensure that the patient was treated successfully. After the treatment the AU and the AMP confirmed that the HDR catheter was still at the end of the NG tube. With the corrective actions in place for this treatment, the patient was treated successfully and escorted from the room.

4 Causes of the Medical Event (87103)

4.1 Inspection Scope

The inspectors conducted interviews with licensee personnel, evaluated the equipment and CT images used for the HDR administration, and reviewed the procedures and records to determine the direct, contributing, and root causes of the medical event.

4.2 Benefis's Root Cause Analysis

In an email dated January 12, 2012, Benefis determined that the root cause of the medical event was the misidentification of the distal end of the brachytherapy catheter due to radio-opaque markers in the nasogastric catheter and the lack of familiarity with the nasogastric catheter and its radio-opaque marker.

4.3 Direct, Contributing, and Root Causes

4.3.1 Direct Causes

The direct cause of the medical event was attributed to human error. Specifically, the AMP performing the dose planning failed to recognize that the images on the CT scans were not

consistent with images for a source marker wire used to simulate the source. Instead the AMP mistook the radio-opaque markers of the NG tube for the source marker wire.

4.3.2 Contributing Causes

Discussions with the staff indicated that the AU, the RN, and the dosimetrist had limited experience with HDR esophageal cancer treatments. Specifically, the AU had performed five of these procedures in approximately 25 years at another medical facility. The RN and the dosimetrist had performed a case approximately 5 years ago with the AU at another medical facility. None of the other personnel had any experience with the modality used for patient treatment in this medical event. Most of the staff, except the AMP performing the planning, knew that the NG tube was radio-opaque, but this fact was never discussed with the AMP, as there were no pre-planning meetings. The AMP was on vacation prior to the procedure and arrived back to work on January 3, 2012, two days before the procedure was performed. When asked about performing a dry run with a phantom prior to the procedure, the AMP indicated that there had been time to perform a dry run with a phantom. The AMP indicated at the time, he thought that there was only one HDR catheter in stock, so he chose not to perform a phantom run. The AMP acknowledged that a dry run with a phantom would have shown that the NG tube was radio-opaque, and the AMP would have seen the marker in the NG tube and the marker wire.

Contributing causes include the following: 1) the staff's inexperience with this modality, 2) poor communication between staff members who had experience in this modality and those who did not have any experience in this modality, 3) lack of planning for this new modality, and 4) not performing a dry run with a phantom prior to patient treatment to prepare for this new modality.

4.3.3 Root Cause

The licensee had procedures for all of the other HDR treatment modalities that they have performed, but did not have procedures for the HDR treatment of esophageal cancer. The failure to have detailed written procedures for the treatment of new modalities, and in this case esophageal cancer, was identified as the root cause of the medical event.

4.4 Conclusions

The direct cause of the medical event was failure to recognize that the NG tube was radio-opaque, and manipulation of the CT images of the NG tube so that it mimicked images seen for a marker wire. Contributing causes include the following: (1) the staff's inexperience with this modality, (2) poor communication between staff members who had experience in this modality and those who did not have experience in this modality, (3) lack of planning for this new modality, and (4) not performing a dry run with a phantom prior to patient treatment to prepare for this new modality. The failure to have written detailed procedures for the treatment of esophageal cancer was identified as the root cause of this particular medical event.

Furthermore, the licensee does not have in place any program or process for addressing new or infrequently used modalities to ensure that the appropriate level of planning, practice, communication, and documentation is implemented to prevent undesired outcomes.

5 Notifications and Reports (87103)

5.1 Inspection Scope

The inspectors interviewed Benefis personnel and reviewed licensee records and documentation relative to the patient, referring physician, and NRC notification requirements.

5.2 Observations and Findings

The inspectors determined that the event was reported by the AU and AMP to the radiation oncology department manager on January 6, 2012, and reported by the AMP to the RSO after hours on Friday, January 6, 2012. The medical event was reported to NRC by the RSO on Monday, January 9, 2012, after the RSO had a chance to review the facts and determine that it met the criteria of a medical event. The AU contacted the referring physician and the patient on January 9, 2012. On January 12, 2012, NRC Region IV received the written report of the medical event from the licensee by email (ML12018A042) as required by 10 CFR 35.3045, with a subsequent revision of the report received by email on February 6, 2012 (ML12046A881).

5.3 Conclusions

The licensee properly identified and reported the HDR medical event to the patient, referring physician, and NRC.

6 Licensee Corrective Actions (87103)

6.1 Inspection Scope

The inspectors interviewed licensee personnel, reviewed the licensee's proposed corrective actions, and reviewed the licensee's written reports submitted to the NRC in accordance with 10 CFR 35.3045.

6.2 Observations and Findings

As previously discussed during the onsite portion of the inspection on January 17-19, 2012, and as noted in the licensee's written report, dated January 12, 2012, the licensee implemented corrective actions. Specifically, the licensee developed a treatment procedure specific to this modality and instituted the collection and uploading of CT images to the planning software along the entire length of the HDR catheter. The inspectors observed the retreatment of the esophageal cancer patient with these implemented corrective actions and noted that the treatment was performed successfully.

6.3 Conclusions

The licensee has instituted corrective actions that appear adequate to address the causes of this individual medical event. However, the licensee's corrective actions did not address broader lessons learned associated with the introduction of new or infrequently used modalities, such as the need to plan, prepare, practice, discuss, and proceduralize new or infrequently used modalities before patient treatment.

7 Radiation Dose Assessment (87103, 87132)

7.1 The Licensee's Radiation Dose Assessment

The licensee performed a dose assessment for the medical event using phantom modeling based on the source placement 29 cm proximal to the proposed treatment site. The licensee's dose assessment indicated that a dose of 700 cGy at 1 cm was delivered to the majority of the nasal passages and nasopharyngeal area, but did indicate there is an area of approximately 4 cm along those same areas where the dose is estimated to be 1000 cGy. The licensee, based on the dose received, expected that the patient would not incur adverse health effects as a result of the medical event.

7.2 Medical Consultant's Independent Radiation Dose Assessment

The NRC contracted with a medical consultant to review the medical event and the licensee's dose assessment. The medical consultant reviewed the licensee's report and dose assessment and agreed with the dose assessment performed by the licensee as well as the causes and corrective actions. The consultant also agreed with the licensee that the patient would not incur adverse health effects as a result of the medical event.

8 Regulatory Issues (87103)

8.1 Inspection Scope

The inspectors also reviewed the regulatory requirements, the license commitments, and the licensee's HDR written directive procedures and the records and reports related to the medical event.

8.2 Observations and Findings

Although there were several issues identified that contributed to the medical event, the inspectors concluded that the licensee failed to develop, implement, and maintain written procedures as required by 10 CFR 35.41. 10 CFR 35.41(a) states, in part, that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration will be conducted in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b). 10 CFR 35.41(b) requires, in part, that at a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material: (1) verifying the identity of the patient or human research subject; and (2) verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive. The licensee had not developed or implemented written procedures to provide a high confidence that each administration would be in accordance with the written directive. Specifically, the licensee had no written procedures for the HDR treatment of esophageal cancer prior to performing the treatment nor did the licensee have an established program for addressing planning and execution of new treatment modalities. This was identified as an apparent violation of 10 CFR 35.41(a) and (b). As a result of this failure, the licensee failed to administer the treatment in accordance with the written directive and instead administered the dose to the wrong site.

8.3 Conclusions

One violation was identified during the inspection. The inspectors determined that prior to January 5, 2012, the licensee's written procedures for administrations requiring a written directive did not provide high confidence that each administration was in accordance with the written directive. This failure was identified as an apparent violation of 10 CFR 35.41 (a) and (b).

LIST OF PERSONS CONTACTED

Licensee

Vickie Nelson, Radiation Oncology Department Manager@#*
Andrew Andreessen, Medical Physicist@#*
Jeffery Stephenson, MD – Radiation Oncologist and Authorized User@*
Kari Cann, Radiation Safety Officer@*
Crystal Cook, CT Manager
Amber Pinski, Registered Nurse
Matt Widhalm, CT Technician
Jon Schroeder, Dosimetrist
Joe LoDuca, Chief Administrative Officer@*
Laura Goldhahn, President*
Adam Elliott, Medical Physicist@

Present at entrance
* Present at preliminary exit (on-site)
@ Present at final exit (telephonic)

INSPECTION PROCEDURES USED

87103	Inspection of Materials Licensees Involved In An Incident or Bankruptcy Filing
87132	Brachytherapy Programs

ITEMS OPENED, CLOSED AND DISCUSSED

Opened

030-02404/2012-001	APV	Failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive as required by 10 CFR 35.41(a) and (b).

Closed

None

Discussed

None

LIST OF ACRONYMS USED

AMP	Authorized Medical Physicist
APV	apparent violation
AU	authorized user
CFR	Code of Federal Regulations
CT	computed tomography
HDR	high dose rate
NG	nasogastric
NRC	Nuclear Regulatory Commission
RSO	Radiation Safety Officer
RN	Registered Nurse