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

June 13, 2012

EA-12-090
NMED: 120067

Judy Blauwett
Senior Vice President of Operations
Avera McKennan Hospital
1325 South Cliff Avenue
Sioux Falls, South Dakota 57117-5045

SUBJECT: NRC INSPECTION REPORT 030-11252/2012-001

Dear Ms. Blauwett:

This refers to the special inspection conducted from January 30 through February 2, 2012, at your facility in Sioux Falls, South Dakota, with continued in-office review through June 13, 2012. The inspection was conducted in response to a reportable medical event that was initially reported as an underexposure to a patient undergoing a cancer treatment. The inspection was an examination of activities conducted under your license as they relate to radiation safety and compliance with the Commission's rules and regulations, as well as the conditions in your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records relevant to the medical event, observations of activities, and interviews with personnel. Preliminary inspection findings were discussed with you and members of your staff at the conclusion of the onsite portion of the inspection on February 2, 2012. A final exit briefing was conducted telephonically with members of your staff on June 13, 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 of 10 CFR 35.41(a) and (b) involved the failure by Avera McKennan Hospital to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with members of your staff at the exit briefing on June 13, 2012. As a result, it may not be necessary to conduct a predecisional enforcement conference (PEC) in order to enable the NRC to make an enforcement decision.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond in writing to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a 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. Please contact Mr. Michael Vasquez at 817-200-1130 within 10 days of the date of this letter to inform him of your decision to respond in writing or to request a PEC. 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 NRC Inspection Report 030-11252/2012-001; EA-12-090” and should include for the 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 was, or will be, achieved. In addition, you should describe any clinical effects to the patient as a result of the event. 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, information related to any corrective actions taken or planned to be taken, and a discussion of the clinical effects to the patient as a result of the event. 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. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful."

In addition, please be advised that the number and characterization of the apparent violation 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. James Thompson at 817-200-1538 or Mr. Michael Vasquez at 817-200-1130.

Sincerely,

/RA/

Anton Vegel, Director
Division of Nuclear Materials Safety

Docket: 030-11252
License: 40-16571-01

Enclosures:
(1) NRC Inspection Report 030-11252/12-001 (w/Attachment)
(2) NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action"

cc: w/Enclosure 1:
South Dakota Radiation Control Program Director

OEMailResource;
Elmo.Collins@nrc.gov; Heather.Gepford@nrc.gov; Tyson.Campbell@nrc.gov;
Art.Howell@nrc.gov; Ray.Kellar@nrc.gov; Nick.Hilton@nrc.gov;
Anton.Vegel@nrc.gov ; Christi.Maier@nrc.gov; John.Wray@nrc.gov;
Vivian.Campbell@nrc.gov Karla.Fuller@nrc.gov; S.Woods@nrc.gov;
Bill.Maier@nrc.gov; Marisa.Herrera@nrc.gov; Leelavathi.Sreenivas@nrc.gov;
Jack.Whitten@nrc.gov; Kerstun.Day@nrc.gov; Lauren.Casey@nrc.gov;
Blair.Spitzberg@nrc.gov; Victor.Dricks@nrc.gov; Carolyn.Faria-Ocasio@nrc.gov;
Michael.Vasquez@nrc.gov; Lara.Uselding@nrc.gov; Michele.Burgess@nrc.gov;
Randy.Erickson@nrc.gov; Denise.Freeman@nrc.gov; Duane.White@nrc.gov;
Rachel.Browder@nrc.gov; Sue.Trifiletti@nrc.gov; Christian.Einberg@nrc.gov;
James.Thompson@nrc.gov; Robertoj.Torres@nrc.gov; Jason.Razo@nrc.gov;
Michael.Clark@nrc.gov

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■ Publicly Available		☐Non-publicly Available	☐Sensitive	■ Non-sensitive

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JMRazo	RJTorres	JLThompson	GMVasquez	HJGepford
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U.S. NUCLEAR REGULATORY COMMISSION

Region IV

Docket:	030-11252
License:	40-16571-01
Report:	2012-001
EA:	EA-12-090
Licensee:	Avera McKennan Hospital
Facilities:	Avera Cancer Institute, Prairie Center
Location:	1000 East 23rd Street Sioux Falls, South Dakota
Date:	January 30 through June 13, 2012
Inspectors:	James L. Thompson, Senior Health Physicist (Team Leader) Nuclear Materials Safety Branch A
	Roberto J. Torres, Senior Health Physicist Nuclear Materials Safety Branch B
	Jason M. Razo, 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

Avera McKennan Hospital
NRC Inspection Report 030-11252/2012-001

This was an announced, special inspection in response to a medical event at Avera McKennan Hospital's Cancer Institute (Avera) located in Sioux Falls, South Dakota, that was reported to the NRC on January 17, 2012. The medical event was related to the treatment of a patient using a high dose-rate remote afterloader (HDR) device to deliver 10 fractionated treatments. Two of the fractions were delivered incorrectly and resulted in an underexposure to the treatment site and an excessive and unnecessary exposure to the patient's skin (an unintended treatment site). The NRC has since determined that each of the incorrectly delivered treatments constituted a medical event; therefore, two medical events occurred. This report describes the findings of the special inspection.

Radiation Dose Assessment

Avera initially reported that the patient received an unintended radiation dose between 680 and 2,720 rads (6.8 and 27.2 Gray (Gy)) to the skin. The NRC's independent medical consultant determined that the highest (unintended) dose the patient received was 2720 rads (27.2 Gy) to the skin; Avera agreed with the medical consultant's assessment (Section 4).

Direct, Contributing, and Root Causes

The direct cause of the medical event resulting from the first incorrect fraction was a failure by the authorized medical physicist (AMP) to read the correct catheter length measurement values during patient pre-treatment preparation. The direct cause of the medical event resulting from the second incorrect fraction was a failure by the AMP to select the correct treatment plan from the HDR treatment console (Section 5.3.1).

Several factors contributed to the medical events, including the failure to verify that the catheter length measurements were within the manufacturer's recommended ranges, the failure to limit the number of treatment plans for the same patient at the HDR treatment console, and the failure to have independent verification of correct catheter lengths during the pre-treatment planning process (Section 5.3.2).

The NRC determined that the root cause of the medical events was the hospital's failure to implement effective procedures to ensure that the HDR treatment was in accordance with the written directive (Section 5.3.3).

Inspection Findings

The NRC identified an apparent violation of 10 CFR 35.41(a) and (b) involving the failure by Avera to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive and, at a minimum, address verifying that the administration is in accordance with the treatment plan, checking both manual and computer generated dose calculations and verifying that any computer generated dose calculations are correctly transferred into the consoles of therapeutic medical units (Section 6).

Corrective Actions

Avera instituted immediate and long-term corrective actions to prevent recurrence of this type of event. These corrective actions included, but were not limited to, a revision of the standard operating procedures for use of the HDR device, the hiring of additional medical physics staff, and contracting an external consultant to assist in the development of a safety culture initiative at Avera (Section 7).

Report Details

1 Program Overview (87132)

1.1 Inspection Scope

The inspectors reviewed the NRC license and Avera's documentation related to the medical event, interviewed licensee staff, and observed Avera's re-enactment of the events that led to the medical event. Collectively, these documents described Avera's radiation safety program.

1.2 Observations and Findings

Avera is authorized under NRC License 40-16571-01, Amendment 48, to use byproduct material to perform both diagnostic and therapeutic medical administrations, including the use of iridium-192 in a Nucletron microSelectron V2 HDR afterloader device.

Avera is a large hospital complex with eight storage and use locations in Sioux Falls, Mitchell, and Parkston, South Dakota. The HDR was located in the Prairie Center and was used approximately 10 times per month to treat various forms of cancer. Two AMPs operated the HDR; however, Avera was in the process of hiring a third AMP to assist with the workload. Avera has an active radiation safety committee that meets quarterly.

2 Background (87132, 87103)

The patient arrived at Avera on Friday, January 13, 2012, to have a computerized tomography (CT) simulation for treatment planning purposes, following placement of a SenoRx Contura multicatheter applicator into the patient's right breast. This patient had been diagnosed with breast cancer and was returning for a post-lumpectomy treatment. The written directive and plan specified ten fractions of 340 rads (3.40 Gy) each, for a total of 3400 rads (34.0 Gy) to the treatment site. The AMP, with assistance from a brachytherapy therapist, recorded each of the five catheter lengths on the "Breast HDR Data Sheet," which were 1156, 1156, 1156, 1157, and 1157 mm. However, at the time, the AMP did not recognize that he failed to measure the catheter lengths correctly. The AMP then entered these erroneous values into the treatment planning software. This treatment plan with the erroneous values was then loaded into the treatment console of the HDR unit before the first and third fractions, resulting in two occurrences of the underexposure to the intended treatment volume and an unnecessary exposure to the patient's skin.

3 Event Chronology (87103)

3.1 Inspection Scope

The NRC inspectors conducted interviews with licensee personnel, reviewed procedures and treatment plans, and inspected medical devices associated with the HDR unit. These inspection activities were conducted in an effort to reconstruct the events surrounding the two medical events that occurred on January 16 and 17, 2012.

3.2 Observations and Findings

The following is a sequence of events that preceded the medical event referenced in this section:

January 13, 2012 (Friday):

- Mid-day: The patient arrived at Avera's facility to have a CT simulation for treatment planning purposes. The AMP noted the applicator position, size, and shape and recorded lengths for each of the five catheters using a source position simulator. The catheter length measurements reported by the AMP were 1156, 1156, 1156, 1157, and 1157 mm.

- Mid-day: The catheter length measurements were entered into the treatment planning computer.

- 5:00 pm: The AMP completed the treatment plan and exported it to the treatment console.

January 16, 2012 (Monday):

- Morning: The patient was administered the first of ten fractional treatments using the (incorrect) catheter length measurements of 1156, 1156, 1156, 1157, and 1157 mm. [This was the first medical event.]

- 3:30 pm: Before the second fractional treatment, a second AMP performed an unplanned, independent review of the treatment plan and noted that the catheter length measurements were not consistent with the manufacturer's expected lengths. The catheter lengths were checked again and it was discovered that the correct catheter lengths were 1256, 1256, 1256, 1257, and 1257 mm; therefore, Avera discovered that the first fractional treatment had been delivered 100 mm away from the intended treatment site in the breast.

- 4:00 pm: The catheter length measurements were corrected in the treatment planning system and then re-exported to the treatment console; however, the old incorrect treatment plan was not deleted from the system. The patient was administered the second fractional treatment using the correct catheter length measurements of 1256, 1256, 1256, 1257, and 1257 mm from the corrected treatment plan.

- 4:30 pm: The authorized user (AU) physician notified the patient of the under dosage that occurred during the first fractional treatment and informed the patient that an additional fractional treatment needed to be added to complete the full treatment.

- 5:00 pm: Avera held an occurrence and root cause analysis meeting to analyze the incorrectly administered fraction. The group agreed that Avera's radiation safety officer (RSO) needed to be notified of the medical event. The group discussed corrective actions to prevent recurrence of catheter measurement errors.

- 5:30 pm: Avera's RSO was notified of the medical event. The RSO requested that the skin dose to the unintended site be calculated or simulated to determine if the dose to the skin met the reporting requirements of 10 CFR 35.3045(a)(3).

January 17, 2012 (Tuesday):

- 8:00 am: The patient was administered the third fractionated treatment. Immediately following this third fractionated treatment, one of the brachytherapy therapists noticed that the treatment plan recorded in the chart for the third fraction looked similar to the incorrect first fractionated treatment. The AMP was notified, and the AMP discovered that the old treatment plan with the incorrect catheter length measurements of 1156, 1156, 1156, 1157, and 1157 mm was again used for the third fractional treatment. Avera's RSO was immediately notified. [This was the second medical event.]

- 1:00 pm: After requesting additional information for the second medical event, Avera's RSO provided verbal notification to the NRC Headquarters Operations Center of the two incorrectly delivered fractionated treatments.

4 Radiation Dose Assessment (87103, 87132)

4.1 Avera's Radiation Dose Assessment

In the 15-day written report dated January 24, 2012 (ML12121A689), Avera stated that, after the two erroneous fractionated treatments, the group convened to discuss potential adverse effects to the patient. The group discussed the use of computer simulations to recreate the radiation dose to unintended areas of the patient's body. During this recreation, the group reported that the catheter sat approximately one centimeter from the skin caudal to the right breast. They determined that unintended radiation doses were given to the right breast and to the skin and tissue caudal to the breast near where the applicator exited the breast.

Where the applicator exited the breast, the skin was estimated to have received 952 rads (9.52 Gy), based on the computer simulation using the HDR treatment planning computer. The dose immediately perpendicular to the catheter was estimated to be 2720 rads (27.2 Gy). The skin of the abdomen six centimeters from the exit of the applicator was estimated to have received 680 rads (6.8 Gy).

Avera concluded, based on preliminary estimates, that the highest dose to the patient's skin was approximately 2720 rads (27.2 Gy). Based on this preliminary conclusion, Avera determined that there was a potential for skin erythema (skin reddening) at this location.

4.2 Medical Consultant's Independent Radiation Dose Assessment

The NRC contracted with an independent medical consultant to evaluate the extent of radiation exposure to the patient, as well as to ascertain the potential for any adverse reactions to the patient from this medical event.

On April 5, 2012, the medical consultant completed the independent review of this medical event. The consultant calculated the highest dose to the patient's skin to be 2720 rads (27.2 Gy), which agreed with Avera's preliminary estimates. The consultant

stated that the treatment was displaced by 100 mm for fractions 1 and 3, which resulted in 3x2 cm of the skin surface adjacent to the applicator exit site at the chest wall receiving this unintended dose of 2720 rads (27.2 Gy). The consultant further stated that, clinically, there was a 4x3 cm area of erythema after one week, which had gradually resolved with a residual area of excessive skin pigmentation, as expected from this dose. The patient treatment was not compromised, since two fractions of the HDR treatment had been added to make up for the two erroneous fractionated doses.

In a letter dated April 12, 2012 (ML12104A107), Avera acknowledged the consultant's findings and agreed with the conclusions.

5 Causal Analysis (87103)

5.1 Inspection Scope

The inspectors performed a root cause analysis, using the Management Oversight and Risk Tree (MORT) analysis method, to review human factors, policies and procedures, management oversight, and operational characteristics of the HDR brachytherapy preparation, planning, and treatment system program.

5.2 Avera's Root Cause Analysis

In its letter dated January 24, 2012, Avera determined that the root cause of the medical event was the incorrect measurements taken during the treatment planning simulation. In addition, Avera determined that the root cause of the second incorrect fraction was the AMP choosing the wrong treatment plan at the treatment control station from the two plans available. However, the inspectors found Avera's cause evaluations inadequate to address the true root cause of the medical events; as a result, the inspectors performed an independent evaluation of the causes of these medical events.

5.3 Direct, Contributing, and Root Causes

The NRC determined that there were multiple causes for this medical event. The causes included, but were not limited to, human error, a lack of or inadequate procedures, unfamiliarity with the HDR treatment planning system, and ineffective training.

5.3.1 Direct Cause

The direct cause of the first medical event (first fraction) was determined to be a failure by the AMP to read the correct catheter measurement values on the source position simulator during patient pre-treatment testing. While not explicitly stated in a licensee policy or procedure to be performed prior to each HDR case, both Avera AMP's stated that they performed this catheter measurement before each HDR case. The AMP would take a reading of each of the five catheter lengths and, after each measurement, he or she would dictate the values to a brachytherapy therapist to record on the "Breast HDR Data Sheet." The brachytherapy therapist would repeat the values to the AMP to verify that the correct catheter measurements were recorded.

For this patient, since the AMP did not recognize that the catheter measurements were inaccurate, the AMP entered these incorrect measurements into the Oncentra treatment planning system from the "Breast HDR Data Sheet." The AMP then created a treatment

plan using the wrong catheter lengths and loaded the plan into the HDR treatment console. On the morning of the first fraction, the AMP selected the patient's plan (based on the wrong catheter lengths) and treated the patient from the HDR treatment console.

The direct cause of the second medical event (the second incorrect fraction) was a failure by the AMP to select the correct treatment plan from the HDR treatment control station. Two treatment plans for the patient were available at the treatment control station, and the AMP failed to select the plan with the updated, correct catheter lengths.

5.3.2 Contributing Causes

One contributing cause of the medical event was the failure of the AMP to follow the manufacturer's instructions, which suggested verification that the observed catheter length measurement within the source position simulator was within the manufacturer's recommended range. A manufacturer's representative for the SenoRx specialty applicator (the applicator used during this event) provided training to Avera's AMPs in March 2011. As a part of this training, specific slides referenced expected treatment lengths for the catheters while using standard Nucletron microSelectron V2 HDR transfer tubes. The manufacturer's instructions stated that the length should be 1257 mm (±2 mm). In addition, the instructions included a recommendation to "*have a 'reference treatment length' handy for sanity check,*" which was a reference to the expected 1257 mm length. Had the AMP followed the manufacturer's instructions provided during this training, which suggested having the reference treatment lengths readily available for comparison to the actual observed catheter measurements, the AMP may have noticed that the observed measurement of 1157 mm was 100 mm less than the manufacturer's expected length.

The ability to load multiple plans for the same patient into the treatment console was also a contributing cause to the medical event. There was no policy or procedure in place to ensure that multiple plans for the same patient could not be loaded into the HDR treatment control station. Since multiple plans were available, the second incorrect treatment plan with the erroneous catheter lengths was selected inadvertently.

The failure to have independent verification of catheter lengths during measurement or throughout the treatment planning process also contributed to the medical event. The event consequences were mitigated because a second AMP fortuitously noticed the catheter length error on the first fraction post-treatment record. Avera had no formal procedure in place requiring an independent review of the treatment plan before, during, or after any fractions.

Additionally, the consequences of the medical event were exacerbated because the catheter length measurements by the AMP were 100 mm shorter than stated by the manufacturer's literature. Had the incorrect measurement been 100 mm longer than the manufacturer's expected length, then the treatment would have automatically aborted, because the treatment wire with the attached source would have impacted the end of the applicator, automatically retracting the source, which is a safety feature of this HDR unit.

5.3.3 Root Cause

The root cause of the medical event was determined to be Avera's failure to develop and implement effective procedures to ensure that the HDR treatment was in accordance with the written directive and treatment plan. Prior to the patient treatment, the AMP

developed a treatment plan in conjunction with the AU based on the AU's written directive; however, the written procedures for brachytherapy implants in place at Avera at the time of the medical events failed to ensure that the treatment was performed in accordance with this written directive and this treatment plan. For example, if the brachytherapy procedures had required that a reference treatment length be readily available for comparison to the actual observed catheter measurements, then the HDR treatment would likely have been performed in accordance with written directive. Further, if these written procedures had required that only one treatment plan be present simultaneously in the HDR treatment console for each patient, then the HDR treatment would likely have been performed in accordance with the written directive. Finally, if the written procedures would have required independent verification of catheter length measurements by another AMP prior to the HDR administration, then the medical events may not have occurred, because the patient treatment would have been performed in accordance with the written directive and treatment plan.

5.4 NRC Conclusions

The NRC concluded that the direct and contributing causes of the medical event included human factors, policies and procedures, and operational characteristics of the HDR brachytherapy preparation, planning, and treatment system.

The NRC determined that the root cause of the medical event was the failure of Avera to implement effective procedures to ensure that the patient treatment was in accordance with the written directive and treatment plan.

The NRC determined that, according to the MORT analysis method, the incorrect measurements and incorrect patient treatment plan were direct causes of the two wrong fractions, but not root causes of the medical event.

6 Inspection Findings Associated With the Medical Event (87132)

6.1 Inspection Scope

The inspectors reviewed Avera's NRC license and documentation related to the medical event to include the patient's treatment chart and a representative sample of other patient's treatment charts using the same protocol of treatment. The inspectors also reviewed Avera's standard operating procedures for the use of the HDR unit, as well as Avera's emergency procedures.

Additionally, the inspectors interviewed licensee staff, including the AMPs, the RSO, and the AU assigned to treat the patient involved in this event, as well as several ancillary staff in the Avera Radiation Oncology department. Further, the inspectors observed Avera's re-enactment of the events that preceded the medical event. During this re-enactment, the AMP demonstrated how the measurements were performed and documented, and subsequently transferred from the treatment planning computer to the treatment planning console of the HDR unit.

6.2 Observations and Findings

10 CFR 35.41(a) and (b)(2) requires, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written

directive and, at a minimum, the procedures must address verifying that the administration is in accordance with the treatment plan, checking both manual and computer generated dose calculations and verifying that any computer generated dose calculations are correctly transferred into the consoles of therapeutic medical units.

At the time that the medical event occurred, Avera had in place a document entitled, "Avera Radiation Oncology Nucletron microSelectron HDR Procedures," dated November 24, 2010. In this document, Section 7.D stated that, during full calibration measurements, the source transfer tube length is to be checked. It stated to measure the length of the transfer tube with a tape measure and then compare this measurement to the manufacturer's specifications for that transfer tube's length. It further stated that, if the length measured differs from the manufacturer's specifications by more than one millimeter, the transfer tube should be taken out of service.

Although this procedure (to verify that the length of the measured catheter is within one millimeter of the manufacturer's specifications) was required for the full calibration of the HDR unit, it was not required for routine use of the HDR unit. If this procedure would have required the AU and AMP to cross-check the physical catheter measurement entered into the treatment planning system with the manufacturer's specifications for each patient treated with the HDR (as previously discussed in Section 5 above), then it is possible that the administration during this patient's treatment would have been in accordance with the written directive and treatment plan. Other examples of procedural deficiencies were discussed in Section 5.3.2, "Contributing Causes."

The failure to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive and treatment plan was identified as an apparent violation of 10 CFR 35.41(a) and (b). (030-11252/12001-01)

6.3 Conclusions

The NRC identified an apparent violation of 10 CFR 35.41(a) and (b)(2), involving the failure to develop, implement, and maintain written procedures to provide high confidence that each administration was in accordance with the written directive and, at a minimum, the procedures must address verifying that the administration is in accordance with the treatment plan, checking both manual and computer generated dose calculations and verifying that any computer generated dose calculations are correctly transferred into the consoles of therapeutic medical units.

7 Corrective Actions (87132)

7.1 Inspection Scope

Avera took immediate and long-term corrective actions associated with, and resulting from, the medical event that began on January 16, 2012. Corrective action focus areas included procedures, training, staffing, safety culture, internal evaluations, and independent program assessments.

7.2 Observations and Findings

The inspectors reviewed and evaluated the immediate and selected long-term corrective actions initiated by Avera. The inspectors reviewed records and interviewed staff in

order to evaluate the effectiveness of the corrective actions. The inspectors reviewed the letters and attachments Avera submitted on February 8, 2012 (ML12046A882), and on March 22, 2012 (ML12104A081).

7.2.1 Immediate

- Avera developed and implemented, or revised, standard operating procedures including, but not limited to: (1) HDR treatment plan review by a second qualified individual, (2) transfer of treatment plans from the Oncentra treatment planning system to the HDR treatment control system, and (3) a Time-Out policy.

- Avera implemented an HDR variance log to track "near misses" associated with HDR treatment planning and delivery, for lessons-learned purposes.

7.2.2 Long-Term

- On February 1, 2012, the RSO completed a 100 percent audit of HDR treatments since the NRC added the device to the license. The RSO did not identify any other medical events associated with the audited HDR treatments.

- On February 7, 2012, the medical physics staff provided training to the AUs and AMPs on HDR Catheter Measurement and Hook-Up, HDR Treatment Plan Review, and the Time-Out Policy.

- On February 8, 2012, the medical physics staff provided training to the dosimetry staff on new HDR policies.

- On February 15, 2012, the Assistant Vice President of Cancer Clinics presented training on safety culture to the Avera Radiation Oncology staff. Topics included the preliminary findings of the NRC special inspection, the roles and responsibilities of the RSO, and the implementation of the Action Plan Letter dated February 8, 2012.

- As of April 2, 2012, Avera hired two additional AMP's, one full-time and one temporary, to assist with Avera Radiation Oncology activities.

- On February 15, 2012, the Avera Assistant Vice President of Outpatient Cancer Clinics gave a presentation to the staff on effective communication and safety culture.

- From March 21-23, 2012, Mr. Matt Pacella, an independent consultant from Global Physics Solutions, was on site at Avera to perform a structure and function review of the Avera Radiation Oncology group.

- By June 2012, Avera planned to have an independent contractor assess the safety culture of the Avera radiation safety program.

7.3 Conclusions

Avera implemented immediate and long-term corrective actions that should provide reasonable assurance that similar medical events will not occur in the future and that patient treatments are in accordance with the written directive and treatment plan.

8 Exit Meeting Summary

A preliminary exit briefing was conducted at the conclusion of the on-site inspection on February 2, 2012, to review the inspection findings as presented in this report. A final telephonic exit was performed on June 13, 2012, with Kris Gaster, Assistant Vice President of Cancer Clinics, and other members of Avera's staff. Licensee representatives acknowledged the special inspection team's findings. No proprietary information was identified.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

David Kapaska, DO, Avera Regional President
Kathleen Schneekloth, MD, Radiation Oncologist
Richard Massoth, PhD, Radiation Safety Officer
Judy Blauwett, Senior Vice President of Operations
Kris Gaster, Assistant Vice President of Cancer Clinics
Jeffrey Masten, MS, Authorized Medical Physicist
Jamie Harris, MS, Authorized Medical Physicist
Traci Hollingshead, Physics Associate
Lisa Rockafellow, Brachytherapy Therapist

INSPECTION PROCEDURES USED

87132	Brachytherapy Programs
87103	Inspection of Material Licensees Involved in an Incident

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-11252/12001-01	APV	Apparent violation involving the failure to maintain procedures to provide high confidence that the administration was in accordance with the written directive and treatment plan

Closed

None

Discussed

None

LIST OF ACRONYMS USED

AMP	authorized medical physicist
APV	apparent violation
AU	authorized user
CFR	*Code of Federal Regulations*
CT	computerized tomography
EA	Enforcement Action
Gy	Gray
HDR	high dose rate remote afterloader
NRC	Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	radiation safety officer