

March 1, 2011

EA-11-016
NMED No. 100506 (Closed)

Mr. Joseph C. Heckman
Vice President
Cancer Care Services
Community Health Network
1500 N. Ritter Avenue
Indianapolis, Indiana 46219

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001625/2010003(DNMS) AND
NOTICE OF VIOLATION – COMMUNITY HOSPITALS OF INDIANA, INC.

Dear Mr. Heckman:

On October 18-20, 2010, with continued U.S. Nuclear Regulatory Commission (NRC) in-office review through January 18, 2011, two NRC inspectors conducted a reactive inspection at Community Hospital East in Indianapolis, Indiana. The in-office review included, among other things, receipt and review of the NRC medical consultant's report. The purpose of this inspection was to review the circumstances, root and contributing causes, and proposed corrective actions for a potential medical event that your staff reported to the NRC on October 8, 2010. The findings of the inspection were discussed with you and selected members of your staff at a preliminary exit meeting on October 20, 2010, and at a final, telephonic exit meeting with Dr. Andrea Browne, Radiation Safety Officer (RSO), on February 3, 2011. 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 NRC Enforcement Policy is included on the NRC's website 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 fully implement its procedures to provide high confidence that a high dose-rate remote afterloader brachytherapy treatment was in accordance with the written directive, as required by Title 10 of the Code of Federal Regulations (CFR), 35.41(a). The circumstances surrounding this apparent violation, the significance of the issues, and the need for lasting and effective corrective actions were discussed with the RSO during the telephonic exit meeting on February 3, 2011, and are described in detail in the subject inspection report (Enclosure 2). As a result, it may not be necessary to conduct a pre-decisional enforcement conference in order to enable the NRC to make an enforcement decision.

In addition, because you identified the violation, 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 NRC Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the inspectors have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter, or (2) request a pre-decisional enforcement conference (PEC). If a PEC is held, it will be open for public observation and the NRC will issue a press release to announce the time and date of the 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 an apparent violation occurred, information to determine the significance of the violation, information related to the identification of the violation, information related to any corrective actions taken or planned to be taken, and the licensee's position on the need to evaluate all of its written directive procedures to identify potential improvements to reduce the potential for future medical events. 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.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in Inspection Report No. 03001625/2010003(DNMS); EA-11-016" and should include: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation; (2) the corrective actions that have been taken and the results achieved, thus far; (3) the corrective actions that will be taken to avoid further violations; (4) the date when full compliance was or will be achieved; and (5) the licensee's position on the need to evaluate all of its written directive procedures to identify potential improvements to reduce the potential for future medical events, given the licensee's compliance history regarding the adequacy and implementation of written directive procedures. 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 NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the Information Notice on the NRC website at <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>.

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 the NRC has not granted an extension of time, the NRC will proceed with its enforcement decision or schedule a PEC. Please notify Tamara E. Bloomer at 630-829-9627 of your intentions within seven days of the date of this letter.

Please be advised that the number and characterization of any 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.

The NRC has also determined that, based on the results of this inspection, a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The violation involves the licensee's failure to notify the NRC Operations Center by telephone, the next calendar day after discovery of a medical event. The violation is cited in the enclosed Notice of Violation (Enclosure 1). The violation is being cited

because the inspectors identified it during the October 18-20, 2010, inspection. The inspection report (Enclosure 2) describes the circumstances surrounding the violation in detail.

The NRC has concluded that information regarding the reason for the Security Level IV violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date that full compliance was or will be achieved is already adequately addressed on the docket in Inspection Report 03001625/2010003(DNMS). Therefore, you are not required to respond to the Notice of Violation unless the description in the enclosed inspection report 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 enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website 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 publicly available without redaction.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-01625
License No. 13-06009-01

Enclosures:

1. Notice of Violation
2. Inspection Report No. 03001625/2010003(DNMS)

cc w/encls: Andrea Browne, Ph.D., Radiation Safety Officer
State of Indiana
Sarah Longmire-Cook, M.D.
Douglas B. Einstein, M.D

J. Heckman

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Douglas B. Einstein, M.D.

*See previous concurrence

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Letter to Joseph C. Heckman from Anne T. Boland, dated March 1, 2011.

SUBJECT: NRC REACTIVE INSPECTION REPORT NO. 03001625/2010003(DNMS) AND
NOTICE OF VIOLATION – COMMUNITY HOSPITALS OF INDIANA, INC.

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NOTICE OF VIOLATION

Community Hospitals of Indiana, Inc.
Indianapolis, Indiana

Docket No. 030-01625
License No. 13-06009-01

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on October 18-20, 2010, with continued U.S. Nuclear Regulatory Commission (NRC) in-office review through January 18, 2011, the NRC inspectors identified one violation of NRC requirements. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (CFR) 35.3045(c) requires the licensee to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event.

Contrary to the above, on October 6, 2010, the licensee's authorized medical physicist and authorized user had sufficient patient treatment data to determine that a medical event occurred and did not notify the NRC until October 8, 2010, which was later than the next calendar day. Specifically, on October 6, 2010, the administration of radiation from byproduct material for a high dose-rate remote afterloader brachytherapy treatment resulted in doses to the patient that met the definition of a "Medical Event" in 10 CFR 35.2, and at that time the licensee's authorized medical physicist and authorized user had sufficient patient treatment data to determine that a medical event occurred.

This is a Severity Level IV violation (Section 6.9).

The NRC has concluded that information regarding the reason for the violation, the corrective action taken and planned to correct the violation and prevent recurrence, and the date when full compliance was or will be achieved is already adequately addressed on the docket in Inspection Report 03001625/2010003(DNMS); 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 all of 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-11-016" 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 III, within 30 days of the date of the letter transmitting this Notice of Violation."

If you choose to respond, your response will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website 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 publicly available without redaction.

Notice of Violation

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If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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

Dated this 1st day of March 2011.

NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-01625

License No.: 13-06009-01

EA No.: EA-11-016

Report No.: 03001625/2010003(DNMS)

Licensee: Community Hospitals of Indiana, Inc.

Location: Community Hospital East
1500 N. Ritter Avenue
Indianapolis, Indiana 46219

Dates of Inspection: October 18 through 20, 2010, with continued
in-office review through January 18, 2011

Exit Meeting: February 3, 2011

Inspectors: Robert G. Gattone, Jr., Senior Health Physicist
Aaron T. McCraw, Senior Health Physicist

Reviewed By: Tamara E. Bloomer, Chief
Materials Inspection Branch

EXECUTIVE SUMMARY

Community Hospitals of Indiana, Inc. Indianapolis, Indiana Inspection Report 03001625/2010003(DNMS)

The U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection on October 18 through 20, 2010, to review the events and circumstances associated with a potential medical event that the licensee reported to the NRC on October 8, 2010. The inspectors determined that a medical event occurred as a result of a high dose-rate remote afterloader brachytherapy (HDR) breast treatment planning error. The medical event involved the mispositioning of the iridium-192 HDR source in the patient's body resulting in doses that differed from the prescribed doses by more than 50 rem to an organ or tissue; and: (1) the total dose delivered differed from the prescribed dose by 20 percent or more; and (2) the fractionated dose delivered differed from the prescribed dose, for a single fraction, by more than 50 percent. The mispositioning of the HDR source also resulted in doses to tissues other than the treatment site (skin and muscle) that exceeded 50 rem and 50 percent of the doses expected from the administration defined in the written directive. The licensee did not anticipate any long-term medical effects on the patient as a result of the medical event; however, the licensee did indicate that there could be erythema (reddening of the skin) near the entry point of the applicator into the breast about one month after the treatment. As of December 7, 2010, the patient reported no complaints, health problems, or breast problems. The NRC's medical consultant determined that the medical impact of this event on the patient is likely small.

The root cause of the medical event was human error in that the licensee did not accurately reconstruct the applicator in the treatment planning computer. Contributing factors to the medical event included: (1) the licensee's practice of starting applicator reconstruction during treatment planning at the connector end for all HDR treatments except breast treatments combined with the need to change the treatment planning computer default from, "start at connector end" to "start at tip end" for all HDR breast treatments; and (2) difficulty with identifying if the "start at" selection was correct for applicator reconstruction during use of the treatment planning system.

The inspectors identified an apparent violation involving the licensee's failure to fully implement its procedures to provide high confidence that a HDR brachytherapy treatment was in accordance with the written directive, as required by Title 10 of the Code of Federal Regulations (CFR), "Energy," Part 35.41(a). The inspectors also identified a violation of 10 CFR 35.3045(c), regarding the licensee's failure to notify the NRC Operations Center, by telephone, about a medical event in a timely manner.

The licensee implemented corrective actions to prevent a similar event and similar violations that included adding a step to its procedure for multi-catheter HDR breast treatments to verify that the applicator is properly oriented in the three-dimensional image; revising its written directive form to add a checkbox indicating "tip end selected" as a means of reminding staff to change the default from "start at connector end" to "start at tip end" during applicator reconstruction; training its staff about the revised written directive form; committing to train applicable staff on the requirements in 10 CFR 35.3045; committing to develop and implement a procedure for medical event notification by November 26, 2010; and committing to train applicable staff on the new procedure by November 26, 2010.

Report Details

1 Program Scope and Inspection History

The NRC License, Number 13-06009-01, authorizes Community Hospitals of Indiana, Inc. (licensee) to use, in part, byproduct material for in-vitro clinical testing, diagnostic and therapeutic nuclear medicine, manual brachytherapy, and HDR at several locations in Indiana. As of October 18, 2010, the licensee performed 40 partial breast irradiations with an authorized HDR unit since January 1, 2010. Four of the HDR breast treatments conducted in 2010 involved the use of a Strut Adjusted Volume Implant (SAVI®) applicator, and the other 36 HDR breast treatments conducted in 2010 involved the use of a MammoSite® applicator.

No violations of NRC requirements were identified during the NRC's last radiation safety inspection conducted on May 11 through 13, 2010, and the previous radiation safety inspection conducted on May 14, 2008.

As a result of an NRC special inspection that was conducted on April 25, 2007, to review a medical event involving yttrium-90 labeled TheraSpheres®; the NRC cited the licensee for a Severity Level IV violation of 10 CFR 35.41(a), concerning the licensee's failure to correctly implement written procedures to provide high confidence that each administration is in accordance with the written directive.

During a routine NRC inspection conducted on April 3 and 4, 2006, the NRC identified two violations of NRC requirements. One of the violations involved the licensee's failure to develop and implement written procedures to provide high confidence that each administration requiring a written directive was in accordance with the written directive, as required by 10 CFR 35.41. Specifically, the licensee's written procedure for HDR did not describe that the HDR metal interface connector was to be attached during treatment simulation to determine appropriate location of the sources within the patient. The other violation involved the licensee's failure to notify the NRC Operations Center of an HDR medical event, as required by 10 CFR 35.3045(c). The NRC categorized the violations as Severity Level III violations, violations that resulted in or could have resulted in moderate safety or security consequences. On September 18, 2006, the NRC conducted a followup inspection to verify the licensee's implementation of corrective actions. The inspectors verified that the licensee implemented corrective actions. The NRC closed the violations based on the results of the followup inspection.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspectors interviewed the authorized user (AU), an authorized medical physicist (AMP), the Radiation Safety Officer (RSO), and other licensee personnel to determine the sequence of events that resulted in the medical event. In addition, the inspectors reviewed selected licensee records, licensee procedures, and the licensee's compliance with regulatory requirements for HDR treatments.

2.2 Observations and Findings

The licensee was treating the post-surgical cavity in the left breast of a female patient following excision of a cancerous tumor. The licensee used an authorized HDR unit and a SAVI® applicator for the treatment. The "Written Directive" section of the "SAVI® Accelerated Partial Breast Irradiation/HDR Brachytherapy Prescription" form (written directive) for the treatment prescribed a total dose of 3,400 centigray (cGy) to breast tissue at 1 centimeter (cm) from the cavity to be delivered over 10 fractions, with each fraction delivering 340 cGy. The AU signed and dated the written directive on September 30, 2010, and the treatment began that day.

Following the eighth fraction on October 6, 2010, the licensee discovered that it had made an error in the treatment plan. While reviewing and revising the licensee's procedure titled, "Accelerated Partial Breast Irradiation (APBI) Multiple Lumen HDR Procedure," (APBI Procedure), an AMP remembered that he did not implement a step in the licensee's procedure when reconstructing the applicator in the treatment planning computer system. Specifically, the AMP did not switch the "start at" position, which tells the computer where to start the applicator reconstruction and tells the HDR device where to start source placement, to "tip end" from the program default of "connector end." The failure to correctly set the "start at" position caused the source placement to be flipped 180 degrees along the applicator's long axis (i.e., mirror image); therefore, a portion of the treatment site at the tip end of the applicator did not receive the prescribed dose, and a portion of the treatment site at the connector end of the applicator received a higher-than-prescribed dose.

Title 10 CFR 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b). The licensee's APBI Procedure was used to provide high confidence that multiple lumen HDR breast administration was in accordance with the written directive. Item 5 of the "Treatment Planning" section of the APBI Procedure states, "When reconstructing catheters, choose 'tip end' and start the reconstruction 4 millimeters from the tip end of each catheter." The licensee failed to fully implement its APBI Procedure to provide high confidence that each administration was in accordance with the written directive when it did not choose the tip end when reconstructing the catheter during treatment planning. The licensee's failure to fully implement its procedure to provide high confidence that each administration was in accordance with the written directive is an apparent violation of 10 CFR 35.41(a).

After detecting the error, the AMP informed the AU and the RSO. The AMP developed a mock treatment plan to determine the doses that the patient actually received during the first eight fractions. Using this information, the AU revised the written directive on October 6, 2010, prior to the next scheduled fraction.

In accordance with the AU's revised written directive, the AMP and the AU modified the patient's treatment plan for the ninth fraction to make up for the underdosed area of the treatment site near the tip of the applicator. The ninth fraction was delivered on October 6, 2010. In addition, the AU modified the written directive on October 7, 2010,

to add two additional fractions beyond the 10 prescribed fractions (i.e., fractions 11 and 12) to provide additional dose to the underdosed area of the treatment site near the applicator's tip. The tenth fraction was delivered on October 7, 2010, and it was administered in accordance with the original treatment plan with the "start at" position corrected to "tip end." The eleventh and twelfth fractions were delivered on October 7 and October 8, 2010, respectively. Fractions 9 through 12 were administered in accordance with the written directive and treatment plans.

To evaluate this incident, the inspectors, with the assistance of the AMP, reviewed doses received at various prescription locations 1 cm from the cavity and at areas of interest adjacent to the treatment site.

The following table presents the doses received by the patient during the first eight fractions based on treatment planning computer system data that was available to the licensee on October 6, 2010:

Organ or Tissue	CT Slice #	Dose (cGy)	Dose Delivered (cGy)	Percent Difference
Treatment Site – High-Dose Location	40	4,624 (Prescribed)	26,600	+475%
Skin – High-Dose Location	20	2,880 (Expected)	10,488	+265%
Muscle – High-Dose Location	19	3,024 (Expected)	100,160	+3,212%

Note: The doses per fraction can be calculated by dividing the prescribed or expected doses and the administered doses by eight.

Based on the information in the above table, the administration of the first eight fractions resulted in a medical event as defined in 10 CFR 35.2. The first eight fractions resulted in doses that differed from the prescribed doses by more than 50 rem (1 rem equals 1 cGy) to an organ or tissue; and: (1) the total dose delivered to the high-dose location of the treatment site differed from the prescribed dose by 20 percent or more; and (2) each of the first eight fractionated doses delivered to the high-dose location of the treatment site differed from the prescribed dose by more than 50 percent. In addition, the administration of the first eight fractions resulted in doses to: (1) the skin that exceeded 50 rem and 50 percent of the dose expected from the administration defined in the written directive; and (2) tissue other than the treatment site (muscle) that exceeded 50 rem and 50 percent of the dose expected from the administration defined in the written directive.

The licensee did not anticipate any long-term radiological consequences as a result of the higher-than-expected dose to the area near the connector end of the applicator, which was toward the skin of the breast. The AU indicated that there could be erythema (reddening of the skin) near the entry point of the applicator into the breast. The AU expected effects, including erythema, to appear approximately 1 month after treatment. As of December 7, 2010, the patient reported no complaints, health problems, or breast problems.

The licensee determined that the root cause of the medical event was that the licensee did not accurately reconstruct the applicator in the treatment planning computer because the licensee inadvertently left the “start at” position as the program default “connector end” instead of switching the position to “tip end” as required by the APBI Procedure. The inspectors verified that the root cause was human error.

The inspectors identified several contributing factors for the medical event. The licensee routinely started reconstruction of applicators during treatment planning at the connector end for all HDR treatments except breast treatments. The treatment planning software default for applicator reconstruction was “start at connector end” and the default could not be changed by the licensee; therefore, for each HDR breast implant, the licensee had to change the default from “start at connector end” to “start at tip end.” The licensee’s practice of starting applicator reconstruction during treatment planning at the connector end for all HDR treatments except breast treatments combined with the need to change the default from “start at connector end” to “start at tip end” for all HDR breast treatments was a contributing factor for the event.

The treatment planning software did not allow the user to easily identify if the “start at” selection was correct for applicator reconstruction. For example, printouts from the treatment planning software did not clearly indicate the “start at” position; therefore, the user could not easily detect a potential error in the “start at” position if not correctly switched to “tip end” for breast treatments by means of the printed treatment plan. In order to identify if the “start at” selection was incorrect for multiple catheter HDR treatments, the licensee had to view the three-dimensional (3D) image of the reconstructed applicator and use visual indicators to determine if the applicator was in the proper orientation. The visual indicators for SAVI® applicators were: (1) pink coloration and flattened catheter ends showing the connector end of the applicator; (2) rounded catheter ends showing the tip end of the applicator; and (3) whether or not the numbers of each catheter increased in the counterclockwise direction while viewing the tip end of the applicator. The visual indicator for MammoSite® applicators with three or more catheters was whether or not the numbers of each catheter increased in the counterclockwise direction while viewing the tip end of the applicator. Viewing the 3D image of the reconstructed applicator for MammoSite® applicators with less than three catheters did not allow the user to identify if the “start at” selection was incorrect. Instead, the user had to check multiple computerized tomography (CT) images and compare patient anatomy with the catheter orientation to identify if the “start at” selection was incorrect.

In addition, when displaying the dose distribution image (dose cloud) superimposed upon the applicator image, the treatment planning software did not clearly indicate an incorrect dose distribution if the “start at” selection was incorrect. Specifically, the dose cloud appears correct, or as expected, upon a quick glance at the image. In order to properly verify if the dose distribution was incorrect due to an incorrect “start at” selection, the user had to ignore the displayed image and focus on the visual indicators discussed in the previous paragraph. In other words, if an incorrect “start at” selection occurred, the applicator image would show pink coloration and flattened catheter ends indicating the connector end at what appeared to be the tip end of the applicator when viewed with the eyes, and it would show rounded catheter ends indicating the tip end at what appeared to be the connector end of the applicator when viewed with the eyes.

The difficulties of identifying, and thereby correcting, a mistake in the “start at” position during use of the treatment planning system and prior to treatment were contributing factors of this medical event.

2.3 Conclusions

The inspectors identified an apparent violation of 10 CFR 35.41(a), concerning the licensee’s failure to fully implement its procedures to provide high confidence that an HDR treatment was administered in accordance with the written directive.

3 Notifications and Reports

3.1 Inspection Scope

The inspectors reviewed selected records and interviewed selected staff to understand the licensee’s response to its discovery of the treatment planning error, as it pertained to determining if the error resulted in a medical event as defined in 10 CFR 35.2. The inspectors also reviewed the licensee’s notification of a potential medical event to the NRC Operations Center dated October 8, 2010, and its updated notification confirming the medical event to the NRC Operations Center on October 26, 2010. In addition, the inspectors reviewed the licensee’s associated written report of the medical event dated October 8, 2010, to assess compliance with reporting requirements.

3.2 Observations and Findings

On October 7, 2010, the AU notified the patient about the treatment error. In addition, the AU dictated a notification to the referring physician that day about the treatment error; however, the referring physician stated that she was unaware of the treatment error until the inspectors informed her of the error on October 19, 2010.

The RSO was notified of the treatment error on October 8, 2010. The RSO relied on the AMPs to determine if an HDR medical event occurred because she was more involved with nuclear medicine technology. The RSO was unsure if the treatment error resulted in a medical event as defined in 10 CFR 35.2; therefore, on October 8, 2010, the RSO conservatively reported it as a potential medical event to the NRC Operations Center by telephone. In addition, on October 8, 2010, the RSO sent the written report of the event to the NRC in accordance with 10 CFR 35.3045(d), and it included all of the required information. The licensee ceased reviewing the incident as a medical event when the NRC informed the licensee of its plan to conduct this reactive inspection.

As discussed in Section 2.2, one of the licensee’s AMPs and an AU had pertinent data to determine if a medical event occurred on October 6, 2010. Title 10 CFR 35.3045(c) requires the licensee to notify the NRC Operations Center, by telephone, no later than the next calendar day after discovery of the medical event. The licensee’s failure to notify the NRC Operations Center, by telephone, no later than October 7, 2010, the next calendar day after the licensee should have discovered the medical event, is a violation of 10 CFR 35.3045(c).

The violation occurred because licensee staff did not fully understand the definition of “medical event” in 10 CFR 35.2. For example, the AMP and the AU initially concluded that the error did not result in a medical event, based on volumetric dose data obtained from the mock treatment plan. The licensee noted that the “Treatment Criteria and Planning Information” section of the “SAVI® Accelerated Partial Breast Irradiation/HDR Brachytherapy Prescription” form indicated that no more than 50 cubic centimeters (cc) of the planning target volume (PTV) would receive 150 percent of the prescribed dose, and no more than 20 cc of the PTV would receive 200 percent of the prescribed dose. The AMP and the AU determined that, because 35 cc of the PTV received 150 percent of the prescribed dose and 16 cc of the PTV received 200 percent of the prescribed dose, no medical event occurred. However, the written directive prescribed dose to breast tissue at 1 cm from the cavity rather than to a treatment volume.

In the licensee’s volumetric analysis, the licensee did not evaluate if the first eight fractions resulted in an overdose to a part of the treatment site near the connector end of the applicator that was at least 20 percent more than the prescribed total dose for that area had the treatment gone according to plan for the prescribed 10 fractions. An overdose of 20 percent or more of the total prescribed dose at that part of the treatment site constitutes a medical event per 10 CFR 35.3045(a)(1)(i) even though the full treatment had not concluded. Conversely, the licensee did evaluate the underdosed area of the treatment site and made a medical decision to revise the written directive to deliver additional dose to the underdosed area via the two remaining and two additional fractions. An underdosing of 20 percent or more of the prescribed dose after eight fractions would not necessarily constitute a medical event, per 35.3045(a)(1)(i), as long as the licensee recognizes the underdosing and takes corrective action (i.e., revising the written directive and altering the treatment plan). The licensee’s volumetric analysis also failed to identify a volume of tissue other than the treatment site that received an unintended dose of greater than 50 rem and 50 percent or more of the dose expected from the administration as defined in the written directive as a result of the treatment planning error. This constitutes a medical event per 10 CFR 35.3045(a)(3).

On October 26, 2010, the RSO notified the NRC Operations Center by telephone to confirm that the treatment error, previously reported as a potential medical event, met the criteria for a medical event, as defined in 10 CFR 35.2.

3.3 Conclusions

The inspectors identified a violation of 10 CFR 35.3045(c), regarding the licensee’s failure to notify the NRC Operations Center, by telephone, about a medical event in a timely manner.

4 **Licensee Corrective Actions**

4.1 Inspection Scope

The inspectors reviewed the licensee's proposed corrective actions to prevent similar events and similar violations by interviewing selected staff and reviewing the licensee’s revised APBI procedure.

4.2 Observations and Findings

To prevent recurrence of a similar violation of 10 CFR 35.41(a) and a similar medical event, the licensee added a step to its procedure for multi-catheter HDR breast treatments to verify that the applicator is properly oriented in the 3D image. On October 22, 2010, the licensee also revised its written directive form to add a checkbox indicating "tip end selected" as a means of reminding staff to change the default from "start at connector end" to "start at tip end" during applicator reconstruction. The licensee also trained its staff on the revised written directive form. In addition, prior to the NRC inspection, the licensee reviewed the other three SAVI® treatments that it completed in 2010 to verify that the treatments were in accordance with the written directives and the treatment plans. The inspectors also observed the licensee evaluate all of the other HDR breast treatments that were conducted in 2010 to verify that the applicators were accurately reconstructed in the treatment planning computer.

As corrective action to prevent similar violations of 10 CFR 35.3045(c), the licensee committed to train applicable staff on the requirements in 10 CFR 35.3045, develop and implement a procedure for medical event notification by November 26, 2010, and train applicable staff on the new procedure by November 26, 2010.

4.3 Conclusions

The inspectors determined that the licensee planned and implemented corrective actions to prevent similar violations and medical events.

5 **Independent Patient Dose Assessment**

5.1 Inspection Scope

NRC contracted a medical expert consultant to assess probable deterministic effects of the radiation exposure to the patient as a result of the medical event. The inspectors reviewed the medical expert consultant's report.

5.2 Observations and Findings

The medical expert consultant determined that the overall impact of the medical event on the patient is likely small; however, about 2 cc of breast tissue, chest wall, and skin received an unexpected dose of more than 200 percent of the prescribed dose. The medical expert consultant determined that this could result in increased fat necrosis that can mimic tumor recurrence on followup mammograms, late skin breakdown, and potential for compromised visual appeal. In addition, the medical expert consultant noted that about 6 cc of breast tissue, representing 7 percent of the lumpectomy cavity, was underdosed. The medical expert consultant determined that this could result in decreased tumor control in that location; however, since the area is small and the patient is receiving chemotherapy, the medical expert consultant determined that the risk of decreased tumor control in that location is likely small.

5.3 Conclusions

The medical expert consultant determined that the overall impact of the medical event on the patient is likely small.

6 **Exit Meeting**

At the completion of the on-site inspection, the inspectors discussed the preliminary inspection findings in this report with licensee management during an exit meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. A final telephonic exit meeting was conducted on February 3, 2011.

Partial List of Persons Contacted

- ^ Andrea Browne, Ph.D., Radiation Safety Officer
 - Janan Graybill, M.D., Authorized User
 - + Robert Gregory, M.S., Authorized Medical Physicist
 - + Joe Heckman, Vice President of Cancer Care Services
 - Shawn Hollars, M.A., Authorized Medical Physicist
 - + William Howard, M.S., Authorized Medical Physicist
 - Sarah Longmire-Cook, M.D., Referring Physician
 - + Jennifer Stigler, Radiation Oncology Manager
 - + Shih Jack Wei, M.D., Authorized User
- + Attended the on-site exit meeting October 20, 2010
- ^ Participated in the telephone exit meeting on February 3, 2011