

May 23, 2007

NMED No. 070235

Ms. Susan Sandberg
Vice President
Woman's and Children's Services/Medical Imaging Services
Community Hospitals of Indiana, Inc.
1500 Ritter Avenue
Indianapolis, IN 46219

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 030-01625/2007-001(DNMS)
AND NOTICE OF VIOLATION - COMMUNITY HOSPITALS OF INDIANA, INC.

Dear Ms. Sandberg:

This refers to the special inspection conducted on April 25, 2007, at Community Hospitals of Indiana, Inc., Indianapolis, Indiana, with continued in-office review through May 1, 2007. The purpose of the inspection was to review the circumstances, root and contributing causes, and proposed corrective actions related to a medical event that occurred on April 18, 2007. The in-office review included a review of your original written event report dated April 18, 2007, and a subsequent revision dated April 30, 2007, as well as patient written directives. The enclosed report presents the results of this inspection.

This inspection consisted of an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, demonstration of related equipment, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at www.nrc.gov. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because it involved the licensee's failure to implement written procedures to provide high confidence that each therapeutic administration was in accordance with the authorized user physician's written directive as required by 10 CFR 35.41, "Procedures for Administrations Requiring a Written Directive."

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed on the docket in Inspection Report No. 030-01625/2007-001(DNMS) and your written reports dated April 18, 2007 and April 30, 2007. Therefore, you are not required to respond to this letter unless the description in our report or your letters does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document 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.

Sincerely,

/RA

Patrick L. Loudon, Chief
Decommissioning Branch

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

Enclosures:

1. Notice of Violation
2. Inspection Report No. 030-01625/2007-001

cc w/encls: Andrea Browne, Ph. D., Radiation Safety Officer, 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 an NRC special inspection conducted on April 25, 2007, with continuing NRC review through May 1, 2007, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 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: (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 written procedure, "Checklist and Data Form for TheraSphere Treatment," developed in January 2007, implements the requirements of 10 CFR 35.41(a). Item 10, of this procedure entitled, "Authorized User Delivers the TheraSpheres," requires, in part, the authorized user to turn the blue stop cock toward the vent vial.

Contrary to the above, on April 18, 2007, the licensee failed to correctly implement written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the authorized user failed to ensure that the blue stop cock was in the correct orientation (towards the vent vial) to allow a proper flow path for the treatment dose to be delivered to the patient in accordance with the written directive.

This is a Severity Level IV violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-01625/2007-001(DNMS) and in the letters dated April 18, 2007 and April 30, 2007. However, you are required to submit a written statement or explanation pursuant to 10 CFR Part 2.201 if the description in the inspection report or your letters does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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

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

Dated this 23rd Day of May 2007

Enclosure 1

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-01625

License No.: 13-06009-01

Report No.: 030-01625/2007-001(DNMS)

Licensee: Community Hospitals of Indiana, Inc.

Location: 1500 N. Ritter Avenue
Indianapolis, IN 46219

Inspection Dates: April 25, 2007, with continuing in-office review through
May 1, 2007

Preliminary Exit Meeting: April 25, 2007

Final Exit Teleconference: May 16, 2007

Inspector: Samuel J. Mulay, Health Physicist

Reviewed By: Patrick L. Loudon, Chief
Decommissioning Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

**Community Hospitals of Indiana, Inc.
Indianapolis, Indiana
NRC Inspection Report No. 030-01625/2007-001(DNMS)**

The inspector conducted a special inspection at Community Hospitals of Indiana, Inc. (licensee) to evaluate the circumstances, root cause, and the proposed corrective actions as a result of a medical event which occurred on April 18, 2007. The event involved the administration of 54.4 Gray (Gy) of Yttrium-90 (Y-90) microspheres (TheraSphere) to the right lobe of the patient's liver for the treatment of metastatic liver carcinoma, rather than a dosage of 120 Gy as prescribed by the authorized user on the written directive. The administration represented an approximate 45 percent underdose. The licensee does not expect the patient to experience any adverse health effects due to the reported medical event and future treatments are planned for this patient.

The root cause of the medical event was determined to be the authorized user's failure to turn the appropriate delivery system stopcock to the correct orientation to facilitate the dose being routed to the patient catheter. As a result, the treatment dose was partially diverted to the delivery system's sterile waste vial and away from the patient catheter as the treatment was initiated. When the incorrect alignment was noticed by the interventional radiologist, the administration was stopped and the stopcock was aligned to the proper configuration and the treatment was subsequently completed. As a result, approximately 65.6 Gy of the Y-90 microsphere solution was diverted to the sterile waste vial and the remaining 54.4 Gy was delivered to the right lobe of the patient's liver.

The inspector identified a violation of 10 CFR 35.41(a) for failure to implement written procedures to provide high confidence that each radiopharmaceutical administration was in accordance with the written directive. Specifically, the authorized user failed to ensure that the blue stopcock was in the correct orientation (towards the vent vial) to allow a proper flow path for the treatment dose to be delivered to the patient in accordance with the written directive. On April 18, 2007, the authorized user visually verified and then verbally acknowledged that the stopcock was in the correct orientation prior to patient treatment, when in fact, the stopcock was turned in the wrong position (towards the patient rather than the vent vial.)

The licensee's proposed corrective actions to prevent recurrence included: (1) the addition of a second, trained individual to provide dual verification of the correct stopcock position prior to patient administration; and (2) documentation of the second verification on a current procedural check list.

Report Details

1 Program Scope and Inspection History

License Number 13-06009-01 authorizes the licensee to use a variety of byproduct materials for medical purposes as permitted in 10 Code of Federal Regulations (CFR) 35.100 through 35.500 and 10 CFR 35.1000, at various authorized locations in the Indianapolis, Indiana area. Since January 2007, the licensee has performed four treatments utilizing yttrium-90 (Y-90) microspheres in an MDS Nordian TheraSphere dose delivery system for the treatment of liver hepatoma and metastatic liver disease.

The last inspection of the licensee was conducted on April 3 through 14, 2006. Two violations of NRC requirements were identified for failure to: (1) develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive; and (2) report a medical event to the NRC by the next calendar day after discovery. The violations pertained to a medical event which occurred on November 8, 2005, involving the licensee's High Dose Rate Afterloader (HDR), but was not identified by the licensee as a medical event at that time (ML0612504831). The licensee's stated corrective actions were reviewed and the violations were closed during the subsequent, follow-up inspection conducted on September 18, 2006.

An inspection conducted on December 2, 2004, did not identify any violations of NRC requirements. An inspection conducted on January 24, 2002, identified one violation, concerning the security of licensed material that was characterized at Severity Level IV.

2 Sequence of Events and Licensee Investigation

2.1 Inspection Scope

The inspection included a review of the sequence of events that led to the medical event on April 18, 2007; the licensee's evaluation of the root cause and any adverse effects to the patient; interviews with cognizant licensee personnel; reviews of selected records; and, observations of equipment associated with the medical event.

2.2 Observations and Findings

The licensee's authorized user completed a written directive, dated April 16, 2007, prescribing a treatment dose to the right lobe of the patient's liver of 120 Gray (Gy) of Y-90 microspheres for the treatment of metastatic liver disease using an MDS Nordian TheraSphere dose delivery system. The system is equipped with two color-coded 3-way stopcocks. The position of the blue stopcock controls fluid direction to the patient catheter and/or to the vent/waste vial. The licensee utilizes a procedural check-list which is completed during initial system set-up and prior to patient administration.

On April 18, 2007, the delivery system was setup without incident. The interventional radiologist (IR) and the authorized user (Radiation Oncologist), connected the dose tubing to the patient catheter. The Radiation Safety Officer (RSO), queried the authorized user if the stopcock was in the correct position. The authorized user visually

observed and verbally acknowledged that the position was correct. The authorized user initiated the treatment by applying light pressure to the system plunger to begin the fluid flow to the patient. The IR noticed fluid in the tubing leading to the vent vial rather than in the tubing toward the patient catheter. The IR told the authorized user to stop the delivery. The authorized user stopped the pressure on the plunger at which time, the blue stopcock was turned to the correct orientation and the treatment completed. As a result of the initial pressure on the plunger, approximately 65.6 Gy of Y-90 microspheres was released to the vent vial. When the stopcock was subsequently turned to the correct position, and the treatment continued, the remaining 54.4 Gy of the original 120 Gy dose was administered. The failure by the authorized user to turn the appropriate stopcock to the correct orientation prior to initiating the treatment dose resulted in the medical event.

Title 10 CFR 35.41(a) states, in part, that for any administration requiring a written directive, the licensee is required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. The licensee's "Check List and Data Form for TheraSphere Treatment," states, in part, in Item 10 ("Authorized User Delivers the TheraSpheres"), that the "authorized user will turn the blue stopcock toward the vent vial." On April 18, 2007, the authorized user failed to turn the blue stopcock toward the vent vial which resulted in 54.4 Gy of the Y-90 microsphere dose to the patient rather than the 120 Gy dose as prescribed on the written directive.

Based on a review of the three previous treatments performed using this modality since January 2007, it was determined that no other or similar medical events occurred. The licensee indicated that additional treatments are being planned for this patient.

The licensee's medical staff evaluated the potential adverse health effects on the patient and concluded that the underdose of yttrium-90 microspheres to the right lobe of the patient's liver would not cause any adverse health effects to the patient. The patient was verbally notified of the event by the interventional radiologist and the referring physician was notified in writing.

2.3 Conclusions

The inspector identified one violation of 10 CFR 35.41(a) involving the licensee's failure to correctly implement written procedures to provide high confidence that each administration is in accordance with the written directive. The licensee's root cause investigation identified that the root cause of the event was the failure of the authorized user to turn the appropriate stopcock to the correct treatment orientation prior to initiating the treatment dose. The error resulted in an approximate 45 percent underdose to the treatment site.

3 Licensee Corrective Actions

3.1 Inspection Scope

The inspector interviewed select licensee personnel and reviewed the licensee's proposed corrective actions to preclude similar events. The review included the licensee's April 18, 2007, written report regarding the medical event and the subsequent report revision dated April 30, 2007.

3.2 Observations and Findings

In response to the medical event, the licensee initiated corrective actions to reduce the likelihood of similar, future events to include: (1) the addition of a second, trained individual to provide dual verification of the correct stopcock position prior to patient administration; and (2) documentation of the second verification on a current procedural check list.

3.3 Conclusions

The inspector determined that the licensee had implemented adequate corrective actions that addressed the root cause of the violation.

4 Notification and Reports

4.1 Inspection Scope

The inspector reviewed the licensee's notification to the NRC Operations Center and associated written reports, dated April 18, 2007, and April 30, 2007, to ensure compliance with NRC reporting requirements.

4.2 Observations and Findings

On April 18, 2007, the licensee determined that a medical event occurred. Within 24 hours, the licensee notified the NRC Operations Center regarding the event. An initial written report was submitted later that day, and a subsequent written report was submitted on April 30, 2007, to clarify and expand on the original report. The licensee also verbally notified the patient and the referring physician, and provided a written notification to the physician. The reports included the information required by 10 CFR 35.3045.

4.3 Conclusions

The inspector determined that the licensee provided the notification and subsequent written reports required by 10 CFR 35.3045 within the specified time periods and included the required information.

5 Exit Meeting

At the completion of the special inspection, the inspector conducted a preliminary exit meeting on April 25, 2007, to discuss the inspection findings, the sequence of events, the root cause of the medical event, and the licensee's proposed corrective action. The licensee did not identify any information reviewed and proposed for inclusion in this report as proprietary in nature. A final exit meeting was conducted on May 16, 2007.

Partial List of Persons Contacted

- +^ Susan Sandberg, Vice President, Woman's and Children's Services/ Medical Imaging Services
- +##^Kathy Steffen, BSRT, Director of Medical Imaging
- *##+^Andrea Browne, Ph.D., Radiation Safety Officer
- * Jianan Graybill, M.D., Authorized User, Radiation Oncologist
- *# Alexandra Thompson, Interventional Radiologic Technologist

+ denotes individuals who participated in the entrance meeting

denotes individuals who participated in the preliminary exit meeting

* denotes individuals contacted during the on-site inspection

^ denotes individuals who participated in the final exit meeting on May 16, 2007