

April 29, 2011

EA-11-094

F. Remington Sprague, M.D.
Vice President and Chief Medical Officer
Mercy Hospital
1500 East Sherman Blvd.
Muskegon, Michigan 49444

SUBJECT: NRC INSPECTION REPORT NO. 030-02016/2011-001(DNMS) –
MERCY HOSPITAL

Dear Dr. Sprague:

This letter refers to the inspection conducted on February 24 and 25, 2011, with continuing NRC review through April 8, 2011, at the Mercy Hospital facilities located at 1500 East Sherman Blvd., Muskegon, Michigan and 1440 East Sherman Blvd., Muskegon, Michigan. The continuing NRC in-office review was to review your written procedures concerning the administration of licensed material to patients, further. The enclosed report documents the results of this inspection.

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

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 involved the licensee's failure to develop written procedures to provide high confidence that each high dose-rate remote (HDR) afterloader 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 you and members of your staff during the February 25, 2011, site exit meeting and during the April 8, 2011, telephonic exit meeting.

Since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff 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 conference. Please contact Tamara E. Bloomer at 630-829-9627 within seven days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to an Apparent Violation in Inspection Report No. 030-02016/2011-001(DNMS); EA-11-094" 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 will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

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

In addition, please be advised that the number and characterization of apparent violations 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 Title 10 of the Code of Federal Regulations (10 CFR) Section 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.

F. Sprague

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If you have any questions concerning this matter, please contact Tamara E. Bloomer of my staff at 630-829-9627.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02016
License No. 21-02187-01

Enclosure:
Inspection Report No. 030-02016/2011-001(DNMS)

cc w/encl: Colleen Flynn, Oncology Services Director
Jennifer Hann Fisher, Radiation Safety Officer

If you have any questions concerning this matter, please contact Tamara E. Bloomer of my staff at 630-829-9627.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02016
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Inspection Report No. 030-02016/2011-001(DNMS)

cc w/encl: Colleen Flynn, Oncology Services Director
Jennifer Hann Fisher, Radiation Safety Officer

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.: 030-02016

License No.: 21-02187-01

Report No.: 030-02016/2011-001(DNMS)

Licensee: Mercy Hospital

Locations: 1500 East Sherman Blvd.
Muskegon, Michigan

1440 East Sherman Blvd.
Muskegon, Michigan

Exit Meeting: April 8, 2011

Inspector: Michael M. LaFranzo, Senior Health Physicist

Reviewed By: Tamara E. Bloomer, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

**Mercy Hospital
Muskegon, Michigan
NRC Inspection Report No. 030-02016/2011-001(DNMS)**

On February 24 and 25, 2011, with continuing U. S. Nuclear Regulatory Commission (NRC) review through April 8, 2011, a routine safety inspection was conducted at Mercy Hospital located at 1500 East Sherman Blvd.; Muskegon, Michigan and 1440 East Sherman Blvd.; Muskegon, Michigan.

The inspector identified one apparent violation involving the licensee's failure to develop written procedures in accordance with Title 10 of the Code of Federal Regulations (CFR) Section 35.41(a) for administrations involving a high dose-rate remote afterloader (HDR) unit.

To reduce the likelihood of similar events, the licensee implemented immediate actions by developing written procedures while the NRC was on site. On April 7, 2011, the licensee submitted its final written procedures. The licensee also informed the NRC that all individuals that would be involved in implementing the written directive had been trained on the new written procedures and that such procedures would be reviewed as part of the licensee's audit program.

Report Details

1 Program Overview

Licensed Activities and Inspection History

License No. 21-02187-01 authorizes Mercy Hospital (licensee) to possess and use a variety of licensed materials for medical purposes including diagnostic and therapeutic nuclear medicine, manual brachytherapy and high dose rate afterloader (HDR) administrations at locations authorized by the license.

NRC conducted a routine inspection on July 31, 2008; no violations of NRC requirements were identified.

NRC conducted a previous routine inspection on September 15, 2005; no violations of NRC requirements were identified.

2. Written Procedures Concerning Medical Administrations

2.1 Inspection Scope

The inspector reviewed and evaluated the licensee program concerning the licensed activities permitted under 10 CFR 35.600.

2.2 Observations and Findings

During a routine inspection on February 24 and 25, 2011, the inspector identified that the licensee had not developed written procedures in accordance with 10 CFR 35.41(a) for administrations involving an HDR unit, which the licensee used to provide therapeutic treatment of cancer using an Ir-192 source. Specifically, the licensee had performed approximately 200 administrations using the HDR unit from June 2008 through February 2011 without written procedures. Written directives, that are dated and signed before any administration, are required by 10 CFR 35.40(a) for any therapeutic dose of radiation from byproduct material. As a written directive was required, the licensee was also required to develop, implement, and maintain written procedures in accordance with 10 CFR 35.41(a). License No. 21-02187-01 permitted the licensee to use the HDR under 10 CFR 35.600.

The inspector interviewed licensee staff that were involved in HDR administrations and determined that the staff relied on verbal procedures and individual technical knowledge. The licensee discussed their verbal procedures with the inspector. The inspector did not identify any specific deficiencies that would negatively impact the licensee's ability to implement a written directive.

The inspector reviewed a representative sample of HDR administrations which included the written directives, documentation associated with the administration, and verification of dose delivered. The inspector determined that no medical events had occurred. The inspector also observed that the licensee's internal audits did not identify any medical

events or significant deviations from the written directive since the program started in June 18, 2008. However, the internal audits did not identify the lack of written procedures.

Title 10 CFR 35.41(a) requires, 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.

Title 10 CFR 35.40(a) requires, in part, that a written directive be dated and signed before the administration of any therapeutic dose of radiation from byproduct material.

Through interviews and review of licensee documentation, the inspector determined that the licensee had not developed written procedures to provide high confidence that each HDR administration was in accordance with the written directive. Furthermore, the licensee's internal audits did not identify the need for written procedures for the HDR as required by regulation. This lack of written procedures is an apparent violation of 10 CFR 35.41(a).

The root cause for the apparent violation can be attributed to a lack of management oversight. The inspector noted, prior to implementation of the new modality the licensee followed the NRC's process to add such modalities, which included submitting an amendment request. Specifically, the licensee's amendment submittal included performing the required shielding calculations, and developing emergency procedures; however, the licensee management failed to recognize that HDR, similar to other modalities for which they are authorized, requires a written directive (NUREG 1556, Volume 9, Section 8.32), and therefore requires written procedures.

The licensee took immediate action by developing written procedures regarding HDR administrations while the NRC was on site. On April 7, 2011, the licensee submitted its final written procedures. The inspector reviewed the final written procedures, and determined that the written procedures appeared adequate. The licensee informed the NRC that they were confident that the written procedures would provide high confidence that each HDR administration would be in accordance with any future written directives. The licensee also informed the NRC that all individuals that would be involved in implementing the written directive had been trained on the new written procedures and that annual reviews will include a review of continued adequacy of all written procedures required by 10 CFR 35.41(a).

2.3 Conclusions

The inspector identified one apparent violation of NRC requirements associated with the licensee's failure to develop written procedures to provide high confidence that each HDR administration was in accordance with the written directive. The licensee implemented corrective actions for the apparent violation.

3. Other Areas of the Radiation Safety Program Inspected

3.1 Inspection Scope

The inspector reviewed and evaluated a representative sample of the remaining licensee's program to determine whether licensed activities were being conducted in accordance with NRC requirements.

3.2 Observations and Findings

The inspector reviewed the licensed activities permitted under 10 CFR 35.100, 35.200, and 35.300. The licensee had two locations where the licensee conducted one or more of these activities under the license. The inspector interviewed selected licensee personnel and determined that each individual had adequate knowledge to ensure the safe use of licensed material. The inspector reviewed a selected and representative sample of records that included dosimetry, radiological surveys, administrations of licensed material, written directives, transportation, and waste disposal. The inspector did not identify any regulatory or safety issues.

The inspector reviewed the licensed activities permitted under 10 CFR 35.400. The licensee was authorized for one location to conduct these permitted activities. The inspector interviewed selected licensee personnel and determined that each individual had adequate knowledge to ensure the safe use of licensed material. The inspector reviewed a selected and representative sample of records that included dosimetry, radiological surveys, administrations of licensed material, written directives, transportation, and waste disposal. The inspector did not identify any regulatory or safety issues.

3.3 Conclusions

The inspector did not identify violations of NRC requirements.

4. Exit Meeting

At the conclusion of the onsite inspection on February 25, 2011, the inspector conducted an exit meeting with licensee management representatives to discuss the inspection activities and the preliminary inspection findings. On April 8, 2011, the inspector had a telephonic exit meeting with the Radiation Safety Officer to discuss the inspection findings. The licensee did not identify any information reviewed during the inspection as proprietary in nature.

Partial List of Persons Contacted

- # F. Remington Sprague, M.D., Vice President and Chief Medical Officer
- *# Colleen Flynn, Oncology Services Director
- *# Brian Dethloff, Imaging Services Director
- *#& Jennifer Hann Fisher, Radiation Safety Officer

- * Individuals present at entrance meeting
- # Individuals present at onsite exit meeting on February 25, 2011
- & Individual present during telephonic exit meeting on April 8, 2011