



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

July 7, 2015

Mr. Ralph Lieto, MSE
St. Joseph Mercy Health System
5301 E. Huron River Drive
Ann Arbor, MI 48106

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001997/2015001(DNMS) AND
NOTICE OF VIOLATION – ST. JOSEPH MERCY HEALTH SYSTEM

Dear Mr. Lieto:

On May 19 and 20, 2015, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your facilities in Ann Arbor and Howell, Michigan, with continued in-office review through June 15, 2015. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included further evaluation of security-related items. Mr. Ryan Craffey of my staff conducted a final exit meeting by telephone with you on June 17, 2015, to discuss the inspection findings.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that two violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. One violation concerned the failure to assure the proper operation of timer accuracy in the periodic spot-checks of your remote afterloader unit, as required by Title 10 of the *Code of Federal Regulations* (CFR) Part 35.643(d)(6). The second violation was of a security-related nature, and is discussed further in the enclosed, non-public Security Addendum (Enclosure 3). The violations are cited in the enclosed Notices of Violation (Notices) (Enclosures 1 & 2). The NRC is citing the violations in these Notices because they were identified by the inspectors.

The inspectors determined that the root cause of the violation of 10 CFR 35.643(d)(6) was a misunderstanding of regulatory requirements. As corrective action, your staff revised the

Enclosures 2 and 3 contain Sensitive
Unclassified Non-Safeguards Information.
When separated from the Enclosures, this
transmittal letter is decontrolled.

R. Lieto

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remote afterloader daily Quality Control worksheet to include instructions for a check of timer accuracy, and discussed the requirement and worksheet revision with other individuals who regularly perform the spot checks.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and to address the potential for recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter and in the enclosed Security Addendum. Therefore, you are not required to respond to this letter unless the description herein 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 and Enclosure 1 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's website at <http://www.nrc.gov/reading-rm/adams.html>. Enclosures 2 and 3 will not be made publicly available, as they include security-related information. If you choose respond to this letter, your response will be made publicly available, unless it also includes security-related information, in which case you should mark the top of each page "Security-Related Information – Withhold Under 10 CFR 2.390." 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.

Please feel free to contact Mr. Craffey or Mr. Ed Harvey of my staff if you have any questions regarding this inspection. Mr. Craffey can be reached at 630-829-9655, and Mr. Harvey can be reached at 630-829-9819.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-01997
License No. 21-00943-03

Enclosures:

1. Notice of Violation (publicly available)
2. Notice of Violation (non-public)
3. Security Addendum (non-public)

cc w/o encl 2&3: State of Michigan

R. Lieto

-2-

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cc w/o encl 2&3: State of Michigan

Distribution w/encl:

See next page

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Letter to Ralph Lieto from Aaron T. McCraw dated July 7, 2015

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03001997/2015001(DNMS) AND
NOTICE OF VIOLATION – ST. JOSEPH MERCY HEALTH SYSTEM

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NOTICE OF VIOLATION

St. Joseph Mercy Health System
Ann Arbor, Michigan

License No. 21-00943-03
Docket No. 030-01997

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on May 19 and 20, 2015, with continued in-office review through June 15, 2015, one violation of NRC safety requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (CFR) Part 35.643(a)(1) states that a licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit before the first use of a high dose-rate remote afterloader unit on a given day.

Title 10 CFR Part 35.643(d)(6) states that, to satisfy the requirements of paragraph (a) of this section, spot-checks, must assure proper operation of timer accuracy.

Contrary to the above, on multiple occasions, including May 11, 14 and 15, 2015, the licensee did not assure the proper operation of timer accuracy before first use of its remote afterloader unit on a given day.

This is a Severity Level IV violation (Section 6.3).

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 this letter. 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 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, IR 03001997/2015001(DNMS)" 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 (Notice).

If you choose to respond to this Notice, 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's website 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 publicly available without redaction.

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 within two working days of receipt.

Dated this 7th day of July 2015.

Enclosure 1