



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

June 15, 2016

Dr. Joseph Mirro
West Michigan Cancer Center
200 North Park Street
Kalamazoo, MI 49007

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03036539/2016001(DNMS) AND
NOTICE OF VIOLATION – WEST MICHIGAN CANCER CENTER

Dear Dr. Mirro:

On May 23, 2016, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted an unannounced, routine inspection at your facility in Kalamazoo, Michigan. 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. Mr. Edward Harvey of my staff conducted a final, onsite exit meeting with Dr. Paul Jursinic of your staff on May 23, 2016, 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 a Severity Level IV violation of NRC requirements occurred. The violation was 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>. The violation concerned the licensee's failure to provide annual instruction to all users who operate the high dose-rate remote afterloader (HDR) unit, as required by Title 10 of the *Code of Federal Regulations* (CFR) Section 35.610(d). The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violation in the enclosed Notice because the inspector identified violation.

The inspector determined that the root cause of the violation was lack of management oversight to ensure timely completion of required training. As corrective action to restore compliance, the issue was raised to upper management and the required training was completed by May 31, 2016.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective

Action,” may be useful in preparing your response. 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>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC’s “Rules of Practice,” a copy of this letter, its enclosure, and 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>. 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. Harvey of my staff if you have any questions regarding this inspection. 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. 030-36569
License No. 21-32501-01

Enclosure:
Notice of Violation

cc w/encl: Paul Jursinic, Ph.D., RSO
State of Michigan

J. Mirro

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Aaron T. McCraw, Chief
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Notice of Violation

cc w/encl: Paul Jursinic, Ph.D., RSO
State of Michigan

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NOTICE OF VIOLATION

West Michigan Cancer Center
Kalamazoo, Michigan

License No. 21-32501-01
Docket No. 030-36539

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on May 23, 2016, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (CFR) Section 35.610(d) requires, in part, that a licensee shall provide instruction at least annually to all individuals who operate remote afterloader units, as appropriate to the individual's assigned duties.

Contrary to the above, from January 2009 to May 31, 2016, the licensee failed to provide annual instruction to all individuals who operate the remote afterloader. Specifically, the licensee provided initial instruction to two authorized users who operated the remote afterloader, but the individuals failed to complete subsequent instruction at least annually.

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

Pursuant to the provisions of 10 CFR 2.201, West Michigan Cancer Center is hereby required to submit a written statement or explanation 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). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance was or will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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>. 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.

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 15th day of June, 2016

Enclosure