

September 15, 2009

EA-09-181

Mr. David Keren, Medical Director
Mercy Health Services
Warde Medical Laboratory
300 West Textile Road
Ann Arbor, MI 48108

SUBJECT: NOTICE OF VIOLATION – MERCY HEALTH SERVICES WARDE MEDICAL LABORATORY; NRC INSPECTION REPORT NO. 030-18680/2009-001(DNMS)

Dear Mr. Keren:

This refers to the inspection conducted on June 11, 2009, at your facility located in Ann Arbor, Michigan, with continuing in-office review through July 1, 2009. The purpose of the inspection was to examine 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. During the inspection, two apparent violations of U.S. Nuclear Regulatory Commission (NRC) requirements were identified by the NRC inspector. Details regarding the apparent violations were provided in NRC Inspection Report No. 030-18680/2009-001(DNMS), dated August 6, 2009.

In the letter transmitting the inspection report, we offered you the opportunity to address the apparent violations identified in the report by either attending a Predecisional Enforcement Conference or by providing a written response before we made our final enforcement decision. In a letter dated August 18, 2009, you provided a response to the apparent violations which outlined your corrective actions.

Based on the information developed during the inspection and the information that you provided in your August 18, 2009, response to the inspection report, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved your staff's failure to: (1) make required surveys to assure compliance with sewer disposal concentration limits; and (2) ensure that licensed material discharged to the sewer did not exceed the concentration limits. Specifically, during May 2008, your staff released into the sanitary sewer an amount of iodine-125 that, when divided by the average monthly volume of water also released into the sewer, exceeded the concentration listed in 10 CFR Part 20, Appendix B, Table 3. The NRC determined that the root cause of the violations was your staff's assumption that, given the low microcurie quantities of iodine-125 being used and your previous NRC inspection history, the amount of iodine-125 waste being disposed of in the sanitary sewer system would be well below the applicable sewer disposal limits.

The violations are of concern to the NRC because the failure to survey could have resulted in the regulatory limits being exceeded more frequently than actually occurred. Therefore, the violations have been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3250 is normally considered for a Severity Level III problem. Because your facility has not been the subject of escalated enforcement actions within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process described in Section VI.C.2 of the Enforcement Policy. As an immediate corrective action, at the time of the inspection, you began surveying and temporarily collected the iodine-125 waste to allow for it to decay in storage. As a long term corrective action to prevent recurrence, you revised your radiation safety manual to require that the liquid iodine-125 be collected and stored until at least ten half lives have passed. You now require the containers to be kept in a locked storage room, and you log the containers and the level after ten half lives have passed.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III problem constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and to prevent recurrence, and the date when full compliance was achieved was already adequately addressed on the docket in the inspection report dated August 6, 2009, and in your reply dated August 18, 2009. Therefore, you are not required to respond to this letter unless the description therein 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 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. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b)

D. Keren

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to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at www.nrc.gov/about-nrc/regulatory/enforcement.html.

Sincerely,

/RA by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

Docket No. 030-18680
License No. 21-24614-01

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

D. Keren

-3-

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Regional Administrator

Docket No. 030-18680
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Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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NAME	Lougheed	Bloomer	Reynolds	Day for Carpenter ¹	Orth	Pederson for Satorius
DATE	09/11/09	09/14/09	09/14/09	09/11/09	09/15/09	09/15/09

OFFICIAL RECORD COPY

1. OE concurrence received via e-mail from K. Day on September 11, 2009.

Letter to David F. Keren from Mark A. Satorius dated September 15, 2009

SUBJECT: NOTICE OF VIOLATION – MERCY HEALTH SERVICES WARDE MEDICAL
LABORATORY; NRC INSPECTION REPORT NO. 030-18980/2009-001(DNMS)

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NOTICE OF VIOLATION

Mercy Health Services
Warde Medical Laboratories
Ann Arbor, Michigan

Docket No. 030-18680
License No. 21-24614-01
EA-09-181

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on June 11, 2009, with continuing review through July 1, 2009, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

1. Title 10 of the Code of Federal Regulations (CFR) Section 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Title 10 CFR 20.1003 defines, "survey" as an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Contrary to the above, as of June 11, 2009, the licensee failed to make surveys to assure compliance with 10 CFR 20.2003(a), which limits the disposal of licensed material by release into a sanitary sewerage system. Specifically, on numerous occasions, including May 5, 6, and 7, 2008, the licensee disposed of iodine-125 to the sanitary sewer system without evaluating the radioactivity of iodine-125 waste that was disposed or evaluating the average monthly volume of water released to the sewer to assure compliance with the monthly concentration limit in 10 CFR 20.2003(a).

2. Title 10 CFR 20.2003 states, in part, that licensees may discharge licensed material into sanitary sewerage if the quantity of licensed material that the licensee releases into the sewer in one month divided by the average monthly volume of water released into the sewer by the licensee does not exceed the concentration listed in Table 3 of Appendix B to Part 20. The iodine-125 concentration listed in Table 3 of Appendix B to Part 20 is 2E-5 microcurie per milliliter.

Contrary to the above, in May 2008, the quantity of iodine-125 that the licensee released into the sewer divided by the average monthly volume of water released into the sewer by the licensee exceeded the concentration listed in Table 3 of Appendix B to Part 20. Specifically, the licensee released 2.29E-5 microcurie per milliliter of iodine-125. This exceeded the 2E-5 microcurie per milliliter limit listed in Table 3 of Appendix B to Part 20.

This is a Severity Level III problem (Supplement IV).

ENCLOSURE

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and to prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report 030-18680/2009-001(DNMS), dated August 6, 2009, and in a letter from the licensee dated August 18, 2009. 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 EA-09-181," 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, 2443 Warrenville Road, Suite 210, Lisle IL 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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.

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 Agencywide Documents Access and Management 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 15th day of September 2009