August 6, 2009

EA-09-181

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

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

Dear Mr. Keren:

On June 11, 2009, the Nuclear Regulatory Commission (NRC or Commission), performed a routine inspection at your Ann Arbor, Michigan facility, with continued in-office review through July 1, 2009. The in-office review included receipt and review of radioactive waste disposal information that was unavailable during the onsite inspection. The enclosed report presents 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, two apparent violations were identified and are 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 violations pertain to 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. The preliminary inspection findings were discussed with members of your staff during the onsite inspection exit meeting on June 11, 2009. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff during a telephone exit meeting on July 9, 2009. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

In addition, 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 VI.C.2 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 either: (1) respond to the apparent violations addressed in this inspection report within 30 days of the date of this letter or (2) request a Predecisional Enforcement Conference (PEC). If a PEC is held, it will be open for public observation. The NRC will also issue a press release to announce the conference. Please contact Tamara 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 Apparent Violations in Inspection Report 030-18680/2009-001(DNMS); EA-09-181," and should include for each 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. 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 violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful. Your response may reference or include previous 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 predecisional enforcement conference.

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: 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. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

In addition, please be advised that the number and characterization of the apparent violations described in the enclosed inspection report 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.

The NRC has also determined, based on the inspection, a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. 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 was identified by the inspector.

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 030-18680/2009-001(DNMS). Therefore, you are not required to respond to the Notice unless the description in the inspection report 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 enclosures, 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 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.

We appreciate your cooperation and will gladly discuss any questions you have concerning this inspection.

Sincerely,

***/RA/***

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

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

Enclosures:
1. Notice of Violation
2. Inspection Report 030-18680/2009-001(DNMS)
3. Excerpt from NRC Information Notice 96-28

cc w/encls: Krista Byberg, RSO
State of Michigan

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, 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 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.

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Steven A. Reynolds, Director
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cc w/encls: Krista Byberg, RSO
State of Michigan

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Letter to David Keren from Steven A. Reynolds dated August 6, 2009.

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

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NOTICE OF VIOLATION

Mercy Health Services Warde Medical Laboratory
Ann Arbor, Michigan

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

During an NRC inspection conducted on June 11, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.
>
> Contrary to the above, on June 11, 2009, the licensee did not secure from unauthorized removal or limit access to 237 microcuries of iodine-125 located in a walk-in refrigerator, which was in a controlled area. Specifically, the inspector was able to enter a building and open the door of an unlocked walk-in refrigerator containing the licensed material, resulting in the inspector having unchallenged access to the material for about two minutes.
>
> This is a Severity Level IV violation (Supplement IV).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in Inspection Report 030-18680/2009-001(DNMS). 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," 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 and the Enforcement Officer, 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 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.

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, United States 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.

Dated this day of 6th August 2009

NUCLEAR REGULATORY COMMISSION

REGION III

| | |
|---|---|
| Docket No.: | 030-18680 |
| License No.: | 21-24614-01 |
| Report No.: | 030-18680/2009-001(DNMS) |
| Licensee: | Mercy Health Services Warde Medical Laboratory |
| Location: | 300 West Textile Road, Ann Arbor, Michigan |
| Date of Inspection: | June 11, 2009, with continued in-office review through July 1, 2009 |
| Final Exit Meeting: | July 9, 2009 |
| Inspector: | Robert G. Gattone, Jr., Senior Health Physicist |
| Reviewed By: | Tamara Bloomer, Chief<br>Materials Inspection Branch |

Enclosure 2

## EXECUTIVE SUMMARY

### Mercy Health Services Warde Medical Laboratory
### Ann Arbor, Indiana
### Inspection Report 030-18680/2009-001(DNMS)

During a routine inspection, the inspector identified two apparent violations involving failure to make surveys to assure compliance with sewer disposal concentration limits as required by Title 10 Code of Federal Regulations (CFR) 20.1501, and failure to ensure that licensed material discharged to the sewer did not exceed the concentration limits as required by 10 CFR 20.2003(a). In addition, the inspector identified a violation involving failure to secure from unauthorized removal or access licensed material that was stored in a walk-in refrigerator as required by 10 CFR 20.1801.

The inspector determined that the cause of the apparent violations of 10 CFR 20.1501 and 20.2003(a) was the licensee's presumption that, since low microcurie quantities of iodine-125 were used to conduct radioimmunoassay studies and no violations of NRC regulatory requirements were identified during the previous NRC inspection, the iodine-125 waste that was disposed to the sanitary sewer system would be well below the applicable sewer disposal limits. The inspector determined that the cause of the violation of 10 CFR 20.1801 was a lack of attention to licensee security practices.

The licensee's corrective actions to prevent similar violations included: (1) surveying the radioactive concentration of iodine-125 waste that was being disposed to the sewer to ensure compliance with the limit; (2) holding iodine-125 waste in decay-in-storage for about six half-lives and verifying that, prior to disposing of the material into the sanitary sewerage system, the radioactive concentration is in compliance with the limit; (3) committing to train all staff to require that, if they let an unfamiliar person into the building, they will ask who the person is, why they are there, and who they need to see; (4) requiring that any unfamiliar person be escorted to the individual to be seen and remains escorted at all times; (5) committing to record the training and to conduct annual refresher training; (6) committing to conduct periodic security drills by having unfamiliar persons try to gain unescorted access to the building; and (7) implementing a new policy to require that all visitors sign in and wear a visitor's badge.

## Report Details

### 1 Program Scope and Inspection History

The NRC License Number 21-24614-01 authorized Mercy Health Services Warde Medical Laboratory (licensee) to use iodine-125 and phosphorus-32 pre-packaged kits for in-vitro laboratory studies. The licensee conducted numerous radioimmunoassay studies with iodine-125 pre-packaged kits. Low microcuries of iodine-125 were used per study. Licensed material was used by, or under the supervision of, the authorized user who was also the Radiation Safety Officer (RSO).

No violations of NRC requirements were identified during the two previous NRC inspections conducted on February 24, 2003, and August 13, 1997.

### 2 Disposal Into Sanitary Sewerage

#### 2.1 Inspection Scope

The inspector reviewed the licensee's disposal of licensed material into sanitary sewerage by interviewing the authorized user and RSO. In addition, the inspector reviewed selected records including licensee water utility bills, sewer disposal records, and the licensee's calculations of monthly sewer disposal concentrations.

#### 2.2 Observations and Findings

On numerous occasions as of June 11, 2009, including May 5, 6, and 7, 2008, the licensee disposed of iodine-125 to the sanitary sewer system. A member of the licensee's staff presumed that, since low microcurie quantities of iodine-125 were used to conduct radioimmunoassay studies, the iodine-125 waste that was disposed to the sanitary sewer system would be well below the applicable limits. In addition, a member of the licensee's staff presumed that, since no violations of NRC regulatory requirements were identified during the previous NRC inspection, the licensee was in compliance with the applicable sewer disposal regulatory limits. As a result, the licensee had not evaluated the radioactivity of iodine-125 waste that was disposed to the sanitary sewer system, nor had it evaluated the average monthly volume of water released to the sewer to assure compliance with the limits in Title 10 Code of Federal Regulations (CFR) 20.2003(a) regarding the monthly concentration of licensed material released into a sanitary sewerage system. Rather, the licensee's records of sewer disposal were limited to the volume of iodine-125 waste that was disposed to the sanitary sewer system.

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. Title 10 CFR 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. The licensee's failure to evaluate

the radioactivity of iodine-125 waste that was disposed and evaluate the average monthly volume of water released to the sewer to assure compliance with 10 CFR 20.2003(a), which limits the disposal of licensed material by release into a sanitary sewerage system, is an apparent violation of 10 CFR 20.1501.

The inspector requested the licensee evaluate the radioactivity of iodine-125 waste that was disposed and the average monthly volume of water released to the sewer to assure compliance with 10 CFR 20.2003(a) during the period of May 2008 through April 2009. The licensee completed the evaluation based on information obtained from a licensed material supplier, iodine-125 use and disposal records, water utility bills for the entire period in question, and other sources. The licensee provided the results of its evaluation and supporting information to the inspector in late June 2009.

During review of the licensee's evaluation results, the inspector identified that, in May 2008, the licensee released 96.68 microcuries of iodine-125 into the sewer and the average monthly volume of water released into the sewer by the licensee was 4,219,211 milliliters, resulting in a concentration of 2.29E-5 microcurie per milliliter. The inspector also noted that, during the period in question, the licensee released 2E-5 microcurie per milliliter of iodine-125 into the sewer in June 2008, March 2009, and April 2009. In addition, the inspector noted that the licensee disposed of 907 microcuries of iodine-125 into the sewer during the period of May 2008 through April 2009.

Title 10 CFR 20.2003(a) 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. The licensee's release of 2.29E-5 microcurie per milliliter of iodine-125 to the sewer in May 2008 is an apparent violation of 10 CFR 20.2003(a).

The inspector determined that the cause of the apparent violations was the licensee's presumption that, since low microcurie quantities of iodine-125 were used to conduct radioimmunoassay studies and no violations of NRC regulatory requirements were identified during the previous NRC inspection, the iodine-125 waste that was disposed to the sanitary sewer system would be well below the applicable sewer disposal limits.

### 2.3 Conclusions

The inspector identified two apparent violations of NRC regulatory requirements involving failure to make surveys to assure compliance with sewer disposal concentration limits as required by 10 CFR 20.1501, and failure to ensure that licensed material was not disposed to the sewer if it exceeded the concentration limits as required by 10 CFR 20.2003(a).

## 3 Security

### 3.1 Inspection Scope

The inspector toured selected licensee facilities, interviewed selected licensee staff, and reviewed selected records to review the licensee's security of licensed material.

3.2 Observations and Findings

Upon arrival to the licensee's facility, the inspector pulled on an exterior door and noted that it was locked and equipped with a key card reader. The inspector pulled on another exterior door and noted that it was also locked and equipped with a key card reader; however, an individual inside of the facility let the inspector in. The inspector walked past the individual without being challenged. The inspector walked unchallenged through the facility and opened the door of a walk-in refrigerator that was unoccupied. The walk-in refrigerator contained 237 microcuries of iodine-125 that was in storage. The inspector closed the door and stood near it for two minutes before being challenged by a member of the licensee's staff.

Title 10 CFR 20.1801 requires that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas. The licensee's failure to secure from unauthorized removal or access licensed material that was stored in a walk-in refrigerator is a violation of 10 CFR 20.1801.

The inspector determined that the cause of the violation of 10 CFR 20.1801 was a lack of attention to licensee security practices.

3.3 Conclusions

The inspector identified a violation involving failure to secure from unauthorized removal or access licensed material that was stored in a walk-in refrigerator as required by 10 CFR 20.1801.

## 4 Licensee Corrective Actions

4.1 Inspection Scope

The inspector interviewed the RSO to obtain information about the licensee's proposed corrective actions to prevent similar violations.

4.2 Observations and Findings

The licensee implemented immediate and long-term corrective actions to achieve compliance with 10 CFR 20.1501 and 20.2003(a). As an immediate corrective action, the RSO began surveying the radioactive concentration of iodine-125 waste that was being disposed to the sewer to ensure compliance with 10 CFR 20.2003(a). To prevent recurrence of similar violations, the licensee implemented revised procedures to hold iodine-125 waste in decay-in-storage for about six half-lives and verify that, prior to disposing of the material into the sanitary sewerage system, the radioactive concentration is in compliance with the limit.

The licensee implemented immediate and long-term corrective actions to achieve compliance with 10 CFR 20.1801. The licensee committed to train all staff to require that, if they let an unfamiliar person into the building, they will ask who the person is, why they are there, and who they need to see. In addition, the training will require that the unfamiliar person is escorted to the individual to be seen and remains escorted at all times. The licensee committed to record the training and to conduct annual refresher

training. In addition, the licensee committed to conduct periodic security drills by having unfamiliar persons try to gain unescorted access to the building. The licensee also implemented a new policy to require that all visitors sign in and wear a visitor's badge.

4.3 Conclusions

The inspector determined that the licensee developed corrective actions to prevent violations of 10 CFR 20.1501, 20.2003(a), and 20.1801.

## 5 Other Areas Inspected

5.1 Inspection Scope

The inspector reviewed other areas of the licensee's radiation protection program by interviewing selected staff, observing licensed activities, observing demonstrations of how licensed activities had been or would be conducted based on scenarios posed by the inspector, and reviewing selected records. Areas reviewed included personnel dosimetry, radiation surveys, safe use practices, radioactive spill response, package receipt, contamination control, and decay-in-storage disposal.

5.2 Observations and Findings

Licensee staff wore whole body dosimeter badges when conducting licensed activities. Based on the dosimetry badge records, licensee staff received radiation doses well below ten percent of the regulatory limit between 2003 and 2008. The RSO knew the dosimetry badge ALARA limit and what to do if it was exceeded.

Licensee staff conducted appropriate operability checks on survey instruments prior to conducting ambient exposure rate surveys. The staff used calibrated instruments to conduct the surveys. The licensee analyzed removable contamination survey samples on a well counter. Selected staff knew the survey trigger levels and what to do if the trigger levels were exceeded.

Licensee staff wore gloves and lab coats when conducting licensed activities to protect against radioactive contamination. In addition, time, distance and shielding were used to reduce radiation exposure.

The RSO demonstrated proper techniques in response to a radioactive spill scenario posed by the inspector. The RSO demonstrated actions to properly contain the spill, decontaminate the affected area, identify personnel contamination, and dispose of radioactive waste generated by the decontamination.

When packages of licensed material were received, licensee staff conducted the required package receipt surveys and entered the new material into an inventory control log. Receiving dock staff knew how to recognize and respond to packages containing licensed material.

The inspector conducted independent count rate surveys at selected areas of the licensee's facility using a calibrated NRC survey instrument affixed to a pancake probe. The inspector noted that the handle of a walk-in refrigerator containing licensed material,

selected walk-in refrigerator door surfaces, and selected floor areas near the walk-in refrigerator measured less than 50 counts per minute (background). In addition, the inspector measured background count rates in selected areas within a walk-in refrigerator containing licensed material and at selected surfaces in a radioimmunoassay lab. The inspector also measured a maximum of 150 counts per minute (three times background) at selected surfaces of decay-in-storage waste bags that were stored in a secured area. The measured count rates were within the expected range.

Solid radioactive waste disposed by decay-in-storage was contained in sealed plastic bags to prevent leakage. The waste was held for ten half lives and surveyed to ensure that the exposure rate was indistinguishable from background in a low background area prior to disposal as non-radioactive waste.

5.3 Conclusions

The licensee effectively implemented other areas of its radiation safety program.

## 6 Exit Meeting

At the completion of the onsite inspection, the inspector discussed the preliminary inspection findings in this report with licensee management during an exit meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. A final telephone exit meeting was conducted on July 9, 2009.

### Partial List of Persons Contacted

*# Richard Bak, Ph.D., Technical Director
*# Krista Byberg, RSO
Belinda Dinius, Medical Technologist
Shirley Law, Customer Service Manager

* Attended the onsite exit meeting
# Participated in the telephone exit meeting on July 9, 2009