

# UNITED STATES NUCLEAR REGULATORY COMMISSION

Region III 2443 Warrenville Road, Suite 210 Lisle IL 60532-4352

May 16, 2013

EA-13-049

Mr. Jeff Johnston, Chief Executive Officer Mercy Hospital – St. Louis 615 South New Ballas Road St. Louis, Missouri 63141

SUBJECT: NOTICE OF VIOLATION - MERCY HOSPITAL - ST. LOUIS;

NRC INSPECTION REPORT NO. 03002283/2013001(DNMS)

Dear Mr. Johnston:

This refers to a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on February 25 through March 1, 2013, at several of your Mercy Hospital – St. Louis facilities located in the St. Louis, Missouri area. During the inspection, apparent violations of NRC requirements were identified. The significance of the issues and the need for lasting and effective corrective actions were discussed with Robert Turco of your staff during an exit meeting on March 1, 2013. Details regarding the apparent violations were provided in NRC Inspection Report No. 03002283/2013001(DNMS) dated March 29, 2013.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by providing a written response or requesting a pre-decisional enforcement conference. You provided a written response in a letter dated April 24, 2013.

Based on the information developed during the inspection and the information that you provided in your written response dated April 24, 2013, 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 our inspection report dated March 29, 2013.

Violation A involves your failure to secure licensed material on two occasions contrary to Title 10 of the Code of Federal Regulations (10 CFR) 20.1801. On February 25, 2013, two inspectors entered the New Ballas Road hot lab through an open door where licensed materials were stored. Two nuclear medicine technologists were in the adjoining clean room and were unaware of the presence of the inspectors. The root cause of the violation was that your staff did not recognize that the presence of hospital personnel in the adjoining clean room did not provide adequate control and constant surveillance of licensed materials stored in the hot lab with the door open. The hot lab contained licensed materials in quantities greater than 1000 times the quantities listed in Appendix C, to 10 CFR Part 20. Additionally, during an audit on October 9, 2012, your staff self-identified a similar occurrence at your South Lindbergh Boulevard facility. However, this facility contained licensed materials in quantities less than 1000 times the quantities listed in Appendix C, to 10 CFR Part 20.

Our inspection report also discussed three additional apparent violations of 10 CFR 20.1801 which were self-identified during your audits on April 5, 2011, January 13, 2012, and July 2, 2012. Your letter dated April 24, 2013, indicated that in these three occurrences the auditor gained access to the areas by a key coded entry pad or through a receptionist. We recognize that these controls provided adequate barriers between the licensed material and unauthorized individuals. Therefore, these occurrences were not violations of NRC requirements.

The failure to secure licensed material in quantities greater than 1000 times the quantities listed in Appendix C, to 10 CFR Part 20 is a significant regulatory concern. This resulted in the potential for theft or diversion of licensed material that could have adversely impacted the health and safety of the general public. Additionally, corrective actions taken for the first occurrence did not prevent the second occurrence. Therefore, the two occurrences 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 \$3,500 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 2.3.4 of the Enforcement Policy. The NRC determined that credit was warranted for the corrective actions taken. Your corrective actions taken since February 25, 2013, included locking the door to the New Ballas Road hot lab at all times whether or not an individual is in the main room or in the adjoining clean room; notifying all applicable individuals of this policy change; discussing the policy change at a radiation safety meeting; discussing security of licensed material, the results of the NRC inspection, policy changes, and corrective actions at the radiation safety committee meeting on April 22, 2013; and including the security of licensed material as a topic during annual staff training.

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, to not 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.

Violation B involved your failure to reconcile the inventory of nationally tracked sources of licensed material as required by 10 CFR 20.2207(g). We recognize that you were not provided the reconciliation packet that is routinely sent to licensees who have nationally tracked sources. Notwithstanding, licensees are to meet all of the requirements contained in 10 CFR 20.2207, including the annual reconciliation. After fully considering the circumstances, the violation was evaluated in accordance with the NRC Enforcement Policy and was categorized at Severity Level IV. The NRC is citing the violation in the Notice because it was identified by the inspectors.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations, and the date when full compliance was achieved, was adequately addressed on the docket in NRC Inspection Report No. 03002283/2013001(DNMS) dated March 29, 2013, and in your written response dated April 24, 2013. 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. Therefore, to the extent possible, your response should not include any personal privacy or proprietary 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) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading rm/doc collections/enforcement/actions/.

Sincerely,

/RA by C. Pederson/

Charles A. Casto Regional Administrator

Docket No. 030-02283 License No. 24-00794-03

Enclosure: Notice of Violation

cc w/encl: Robert F. Turco, RSO

State of Missouri

### NOTICE OF VIOLATION

Mercy Hospital – St. Louis St. Louis, Missouri

Docket No. 030-02283 License No. 24-00794-03 EA-13-049

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on February 25 through March 1, 2013, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Title 10 of the Code of Federal Regulations (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 February 25, 2013, the licensee did not secure from unauthorized removal or limit access to licensed material. Specifically, NRC inspectors had unchallenged access to the New Ballas Road hot lab through an open door.

On October 9, 2012, the licensee did not secure from unauthorized removal or limit access to licensed material. Specifically, during an audit, a member of the licensee's radiation safety staff had unchallenged access to the Lindbergh Boulevard hot lab through an open door.

This is a Severity Level III problem (Section 6.7).

B. Title 10 CFR 20.2207(g) requires, in part, that each licensee reconcile the inventory of nationally tracked sources possessed by the licensee against that licensee's data in the National Source Tracking System (NSTS). The reconciliation must be conducted during the month of January each year. The reconciliation process must include resolving any discrepancies between the NSTS and the actual inventory by filing the reports identified by paragraphs (a) through (e) of 10 CFR 20.2207. By January 31 of each year, each licensee must submit to the NSTS confirmation that the data in the NSTS is correct.

Contrary to the above, the licensee failed to reconcile the inventory of its nationally tracked source against the licensee's data in the NSTS during the month of January in 2011, 2012, and 2013.

This is a Severity Level IV violation (Section 6.9).

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 the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03002283/2013001(DNMS) dated March 29, 2013, and in your written response dated April 24, 2013. 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-13-049," 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 <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>. Therefore, to the extent possible, the response should not include any personal privacy or proprietary 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 of Violation within two working days of receipt.

Dated this 16<sup>th</sup> day of May, 2013

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 <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>. Therefore, to the extent possible, your response should not include any personal privacy or proprietary 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) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading.rm/doc.collections/enforcement/actions/.

Sincerely,

/RA by C. Pederson/

Charles A. Casto Regional Administrator

Docket No. 030-02283 License No. 24-00794-03

Enclosure:

Notice of Violation

cc w/encl: Robert F. Turco, RSO

State of Missouri

DISTRIBUTION: See next page

## **SEE PREVIOUS CONCURRENCE**

FILE NAME: G:\ORAII\EICS\ENFORCEMENT\Cases\Enforcement Cases 2013\EA-13-049 Mercy Hospital - St. Louis\EA-13-049 Draft Final Action - Notice of Violation.docx

OFFICE	RIII	RIII	RIII	D:OE	RIII	RIII
NAME	PRPelke	Bloomer	Boland	Zimmerman <sup>1</sup> KDay for		Casto CPederson for
DATE	05/08/13	05/08/13	05/09/13	05/14/13	05/16/13	05/16/13

#### OFFICIAL RECORD COPY

<sup>1</sup> OE concurrence received via email from K. Day on May 14, 2013.

Letter to Jeff Johnston from Charles A. Casto dated May 16, 2013

SUBJECT: NOTICE OF VIOLATION - MERCY HOSPITAL - ST. LOUIS;

NRC INSPECTION REPORT NO. 03002283/2013001(DNMS)

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