UNITED STATES
NUCLEAR REGULATORY COMMISSION
Region III
2443 Warrenville Road, Suite 210
Lisle IL 60532-4352

October 16, 2012

EA-12-172

Mr. Terry Hamilton, President
St. John Macomb-Oakland Hospital
11900 E. Twelve Mile Road, Suite 315
Warren, Michigan 48093

SUBJECT: NOTICE OF VIOLATION – ST. JOHN MACOMB OAKLAND HOSPITAL;
NRC REACTIVE INSPECTION REPORT NO. 03002005/2012001(DNMS)

Dear Mr. Hamilton:

This refers to an NRC reactive inspection conducted on July 19 and 20, 2012, with continued in-office review through July 25, 2012. During the inspection, an apparent violation of NRC requirements was identified. The significance of the issue and the need for lasting and effective corrective actions were discussed with you at the final telephonic exit meeting on August 2, 2012. Details regarding the apparent violation were provided in NRC Inspection Report No. 03002005/2012001(DNMS) dated August 29, 2012.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report in one of three ways: (1) by providing a written response; (2) by requesting a pre-decisional enforcement conference, or (3) by verbally responding to the NRC that no additional information would be provided. In a letter dated September 27, 2012, you provided a response to the apparent violation. In that response you referred to your initial report submitted on July 24, 2012. The NRC also considered a letter that you submitted on August 8, 2012.

Based on the information developed during the inspection and the information that you provided in your letters dated July 24, August 8, and September 27, 2012, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in our inspection report dated August 29, 2012. Specifically, the NRC determined that St. John Macomb Oakland's high dose-rate remote afterloader brachytherapy procedures did not provide high confidence that administrations would occur in accordance with the written directives.

The failure to have procedures that provide high confidence that administrations are in accordance with the written directive is of concern to the NRC because of the potential for a patient to have received a dose to an unintended location without anyone being aware of the event, as well as the potential for the intended treatment site not being treated. In this case, had the authorized medical physicist not recognized and reported her error, the event may not have been detectable. While the root cause of the medical event was human error, the underlying cause of the violation was that the procedures did not provide sufficient detail to ensure that there was a way to verify that the correct setup was being applied for the treatment being prescribed. Therefore, this violation has been categorized, in accordance with the NRC Enforcement Policy, at Severity Level III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of $3500 is normally considered for a Severity Level III violation. 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 included, but were not limited to (a) revising your written procedure for all types of high dose-rate remote afterloader treatments to include a requirement for a qualified secondary staff member to perform a "Time Out" procedure to confirm correct high dose-rate remote afterloader connections in conjunction with the physicist and prior to the specific treatment being performed; (b) developing a comprehensive instruction manual, including narrative descriptions and photographs of treatment set-ups of all types of high dose-rate remote afterloader treatments, and making the manual available to all staff members of the Radiation Oncology department; (c) conducting training to all relevant staff, including those qualified to perform the secondary check affected high dose-rate remote afterloader users on the revision; and (d) initiating observation audits on all high dose-rate remote afterloader treatments to verify the occurrence of time out procedures and verification of correct connections.

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 violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation, and the date when full compliance was achieved, was adequately addressed on the docket in NRC Inspection Report No. 03002005/2012001(DNMS) dated August 29, 2012, and in your letters dated July 24, August 8, and September 27, 2012. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective action 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, 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) 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/

Charles A. Casto
Regional Administrator

Docket No. 030-02005
License No. 21-01190-05

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

NOTICE OF VIOLATION

St. John Macomb Oakland Hospital
Warren, MI

Docket No. 030-02005
License No. 21-01190-05
EA-12-172

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on July 19 and 20, 2012, with continuing in-office review through July 25, 2012, 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 (10 CFR) 35.41(a) states that, for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that: (1) the patient's or human research subject's identity is verified before each administration; and (2) each administration is in accordance with the written directive. Procedures must meet the requirements described in 10 CFR 35.41(b).
>
> Contrary to the above, on July 9, 2012, the licensee failed to have written procedures in place that would provide high confidence that each high dose-rate remote afterloader (HDR) brachytherapy administration was in accordance with the written directive. Specifically, the licensee's written procedures failed to ensure that the patient's endobronchial catheters were directly connected to the HDR unit such that the brachytherapy administration would occur in accordance with the written directive.

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

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 the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03002005/2012001(DNMS) dated August 29, 2012, and in your letters dated July 24, August 8, and September 27, 2012. However, you are required to submit a written statement or explanation pursuant to Title 10 CFR Section 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-12-172," 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, 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 16th day of October, 2012

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/

Charles A. Casto
Regional Administrator

Docket No. 030-02005
License No. 21-01190-05

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

DISTRIBUTION:
See next page

SEE PREVIOUS CONCURRENCE

FILE NAME: G:\ORAIII\EICS\ENFORCEMENT\Cases\Enforcement Cases 2012\EA-12-172 St John Macomb Oakland Hospital\EA-12-172 St John Macomb Oakland draft Final Action.docx

OFFICE	RIII	RIII	RIII	D:OE	RIII	RIII
NAME	Lougheed	Bloomer	Boland	Zimmerman[1]	Orth	Casto
DATE	10/04/12	10/04/12	10/11/12	10/15/12	10/15/12	10/16/12

OFFICIAL RECORD COPY

1 OE concurrence received via e-mail from J. Steffes on October 15, 2012.

Letter to Terry Hamilton from Charles A. Casto dated October 16, 2012

SUBJECT: NOTICE OF VIOLATION – ST. JOHN MACOMB OAKLAND HOSPITAL
NRC REACTIVE INSPECTION REPORT NO. 03002005/2012001(DNMS)

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