

February 18, 2009

EA-08-329

Ms. Constance A. Franko  
Vice President, Operations  
St. John Macomb-Oakland Hospital  
Oakland Center  
27351 Dequindre Avenue  
Madison Heights, MI 48071

SUBJECT: NOTICE OF VIOLATION – ST. JOHN MACOMB – OAKLAND HOSPITAL;  
NRC INSPECTION REPORT NO. 030-02101/2008-001(DNMS)

Dear Ms. Franko:

This refers to the inspection conducted on October 22, 2008, with continued in-office review through November 17, 2008, at the St. John Macomb-Oakland Hospital, Madison Heights, Michigan. The purpose of the inspection was to examine activities conducted under your license as they related to safety and compliance with the Commission's rules and regulations and with the conditions in your license. During the inspection, an apparent violation of NRC requirements was identified by the NRC inspector. Details regarding the apparent violation were provided in NRC Inspection Report No. 030-02101/2008-001(DNMS), dated December 11, 2008.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation 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 December 23, 2008, you provided a response to the apparent violation.

Based on the information developed during the inspection and the information that you provided in your December 23, 2008, response to the inspection report, 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 the subject inspection report. The violation is the result of your failure to recognize that the person named in Condition 11.B of your license as the Radiation Safety Officer for the brachytherapy program had not been involved in your program since at least November 2007. As a result, you did not amend your license to name a new individual. The NRC determined that the root cause of the violation was your failure to provide adequate oversight to the radiation safety program involving brachytherapy activities. Instead, you relied on an oncology services consulting group to perform all aspects of the brachytherapy program, including the Radiation Safety Officer's duties. The NRC determined that other factors which also contributed to the failure to recognize the Radiation Safety Officer's departure were: (1) the lack of institutional knowledge due to a recent turnover of management and nuclear medicine senior staff; and (2) a failure of the consulting group to inform you of the departure of the individual contracted to serve as Radiation Safety Officer.

The violation is of concern to the NRC because the Radiation Safety Officer position is vital in ensuring the proper oversight of NRC-licensed activities. In this case, the potential existed for inappropriate use or misuse of byproduct material, although no actual consequences occurred as a result of the Radiation Safety Officer vacancy. Furthermore, we are concerned that hospital management was unaware that this position was unfilled for over a year. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3250 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 in Section VI.C.2 of the Enforcement Policy.

In a letter to the NRC dated December 23, 2008, you described your corrective actions that have been taken and that will be taken. The corrective actions taken included: (1) the assignment of a single Radiation Safety Officer, who is a direct employee of the hospital, to oversee both diagnostic and therapeutic nuclear medicine activities; (2) audits of your Radiation Therapy program, Nuclear Medicine department and Radiology department; and (3) an update to the Radiation Safety Committee Charter to contact Radiation Safety Committee members who have missed two consecutive Radiation Safety Committee meetings without sending representation. The corrective actions that will be taken include a complete review of your Radiation Safety Policy and Procedure Manual, annual audits of the Radiation Therapy department, and additional mini-audits throughout the year.

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 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 to prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the inspection report dated December 11, 2008, and the letter from the St. John Macomb-Oakland Hospital dated December 23, 2008. 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 document 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) 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 Mark A. Satorius Acting for/***

James L. Caldwell  
Regional Administrator

Docket No. 030-02101  
License No. 21-11494-01

Enclosure:  
Notice of Violation

cc w/encls: State of Michigan

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>.

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Notice of Violation

cc w/encls: State of Michigan

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DATE	02/11/09	02/11/09	02/11/09	02/10/09	02/12/09	02/18/09

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1. OE concurrence received via e-mail from K. Day on February 10, 2009.

Letter to Constance A. Franko from James L. Caldwell dated February 18, 2009

SUBJECT: NOTICE OF VIOLATION – ST. JOHN MACOMB – OAKLAND HOSPITAL;  
NRC INSPECTION REPORT NO. 030-02101/2008-001(DNMS)

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## NOTICE OF VIOLATION

St. John Macomb-Oakland Hospital  
Oakland Center  
Madison Heights, Michigan

Docket No. 030-02101  
License No. 21-11494-01  
EA-08-329

During an NRC inspection conducted on October 22, 2008, with continued in-office review through November 17, 2008, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Condition 11.B. of License No. 21-11494-01 authorized a specifically named individual to fulfill the responsibilities of the Radiation Safety Officer (RSO) for the brachytherapy activities.

Contrary to the above, as of November 2007, an individual, specifically authorized by Condition 11.B. of the license to fulfill the Radiation Safety Officer's responsibilities for brachytherapy activities, was no longer employed by the consulting firm retained by the licensee and did not fulfill the Radiation Safety Officer's responsibilities. The licensee failed to name a new individual to perform the duties of the Radiation Safety Officer for brachytherapy activities.

This is a Severity Level III violation. (Supplement VI).

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 to prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report 030-02101/2008-001(DNMS), dated December 11, 2008, and in a letter from St. John Macomb-Oakland Hospital to the NRC, dated December 23, 2008. 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-08-329," 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 document 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.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 18<sup>th</sup> day of February 2009

ENCLOSURE