

December 11, 2008

EA-08-329

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

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

Dear Ms. Franko:

This refers to the inspection conducted on October 22, 2008, at the St. John Macomb-Oakland Hospital, Madison Heights, Michigan. Additional information provided by you via facsimile on October 30, 2008, and a letter dated November 19, 2008, was also reviewed as part of this inspection. The inspection findings were also discussed with you on November 17, 2008, and with your new radiation safety officer, Ms. Laura T. Smith, M.S., on November 18, 2008. The enclosed report presents the results of this inspection.

This inspection consisted of an examination of 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. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation of License Condition 11.B was identified and is 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 violation involved the failure to appoint a new radiation safety officer named in License Condition 11.B to oversee your brachytherapy activities. Specifically, the individual named as radiation safety officer had not served in this position since approximately November 2007.

The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective action were discussed with your staff during the exit meeting on October 22, 2008 and by phone with you on November 17, 2008. 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.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violation addressed in the inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference. If a conference is held, it will be open for public observation. Please contact John R. Madera at (630) 829-9721 within 7 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 an Apparent Violation in Inspection Report No. 030-02101/2008-001; EA-08-329" and should include for the 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 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. Your response may reference or include previously 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.

In addition, please be advised that the number and characterization of 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.

Based on the results of this inspection, the NRC determined that one Severity Level IV violation of NRC requirements also occurred. The violation involves the failure to perform a complete review of the radiation protection program as required by 10 CFR 20.1101. Specifically, reviews of your radiation protection program were incomplete in that the reviews did not include your brachytherapy activities.

The Severity Level IV violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it is described in detail in the subject inspection report. The violation is being cited in the Notice because it was identified by NRC staff.

The NRC has concluded that information regarding the reason for the Severity Level IV violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved, is already adequately addressed on the docket in the enclosed inspection report. Therefore, you are not required to respond to the violation unless the description in our report does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, you should follow the instructions in the enclosed Notice.

C. Franko

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This letter, its enclosures, and your response, should you provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), and will be made publicly available 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/adamas.html>.

Sincerely,

***/RA by J. Andersen Acting for/***

Steven A. Reynolds, Director  
Division of Nuclear Materials Safety

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

Enclosures:

1. Notice of Violation
2. Inspection Report No. 030-02101/2008-001(DNMS)
3. Excerpt from NRC Information Notice 96-28

cc w/encls: State of Michigan

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See next page

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Letter to Constance A. Franko from Steven A. Reynolds dated December 11, 2008

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

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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 on October 22, 2008, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.1101(c) requires, in part that a licensee periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, since at least 2003, the licensee did not adequately review the radiation protection program content and implementation. Specifically, reviews of the radiation protection program were inadequate in that they did not include a review of the brachytherapy program.

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 correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in NRC Inspection Report 030-02101/2008-001. 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 with a copy to the Regional Administrator, Region III, 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 placed in the NRC Public Document Room (PDR); therefore, to the extent possible, it should not include any personal, privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

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

Dated this 11<sup>th</sup> day of December 2008



U.S. NUCLEAR REGULATORY COMMISSION  
REGION III

Docket No. 030-02101

License No. 21-11494-01

Report: 030-02101/2008-001(DNMS)

Licensee: St. John Macomb-Oakland Hospital  
Oakland Center

Locations Inspected: St. John Macomb-Oakland Hospital  
Oakland Center  
27351 Dequindre Avenue  
Madison Heights, Michigan

21<sup>st</sup> Century Oncology/ Michigan Institute of  
Radiation Oncology (MIRO) (consultant for  
brachytherapy activities)  
30365 Dequindre Avenue  
Madison Heights, Michigan

Date: October 22, 2008, with continued in-office  
through November 17, 2008

Exit Meeting: November 17, 2008

Inspector: Deborah A. Piskura, Health Physicist

Approved by: John R. Madera, Chief  
Materials Inspection Branch

## **EXECUTIVE SUMMARY**

### **St. John Macomb-Oakland Hospital Madison Heights, Michigan NRC Inspection Report 030-02101/2008-001 (DNMS)**

This was a routine inspection conducted on October 22, 2008, with continued in-office review through November 17, 2008, at the St. John Macomb-Oakland Hospital. The inspection included a review of the licensee's diagnostic and therapeutic nuclear medicine activities and the brachytherapy program. The licensee relied on a contract authorized user and a contract medical physicist to ensure that the brachytherapy activities were performed in accordance with NRC requirements.

The inspector identified that the licensee had provided inadequate management oversight of its brachytherapy program which resulted in one apparent violation and one additional violation of NRC requirements. The apparent violation includes the failure to appoint a new radiation safety officer (RSO) for the brachytherapy activities, as named in License Condition 11.B. An additional violation involves the failure to perform a complete review of the radiation protection program to include the brachytherapy activities as required by 10 CFR 20.1101.

The inspector determined that the root cause of the apparent violation and the additional violation was attributed to the licensee's failure to provide adequate oversight to the radiation safety program involving brachytherapy activities. The licensee relied on an oncology services consulting group (a medical physicist and an authorized physician user) to perform all aspects of the brachytherapy program. Licensee staff and the nuclear medicine RSO were aware that neither the brachytherapy RSO nor any other representative from the oncology consulting group attended the radiation safety committee (RSC) meetings but did not raise the issue during the RSC meetings or to hospital management. Contributing factors which also attributed to the failure to recognize the RSO's departure was: (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 the licensee of the departure of the individual contracted to serve as RSO.

The licensee implemented prompt corrective actions regarding the apparent violation concerning the brachytherapy RSO, including: (1) conducting a radiation safety committee meeting on October 30, 2008, to discuss restructuring the duties and responsibilities of the RSO and to appoint one individual (a consultant and half-time employee of the hospital) to serve as RSO for the entire radiation safety program; (2) termination of the contract with the oncology service firm; (3) utilizing the physics staff at the sister hospital (employees of the hospital system) for future brachytherapy implants; and (4) submitting an amendment request to the NRC (received on November 4, 2008) to name a new RSO. For the violation concerning the failure to review the radiation protection program, the licensee's newly appointed RSO performed a review of the brachytherapy activities in November 2008. The new RSO identified no violations of NRC requirements. The licensee revised its policies and procedures to require the RSO to present at the RSC an annual audit summary of the radiation safety program. In addition, the licensee revised its RSC charter to require monitoring attendance of members at the meetings with possible disciplinary action for unexcused absences.

The inspection included a review of other radiation safety program areas including survey instrument calibration, radiation surveys, personnel monitoring, procedures for written directives, and sealed source leak tests and inventory. No apparent violations of NRC regulatory requirements were identified for these program areas.

## Report Details

### 1 Program Scope and Inspection History

St. John Macomb-Oakland Hospital (licensee) operates a diagnostic and therapeutic nuclear medicine program as well as a radiation therapy program. The licensee is authorized by NRC License No. 21-11494-01 to possess and use byproduct material for medical use permitted by Title 10 Code of Federal Regulations (CFR) 35.100, 35.200, 35.300 and 35.400, including permanent iodine-125 prostate seed implants. Prostate implants are performed on a contractual basis by an authorized physician user and a medical physicist at the surgery center within the hospital. All aspects of the implant procedures including preparation of the written directive, treatment planning, and post-treatment planning were performed by the oncology contractor. Until November 2008, all implant patient records were maintained at the contractor's out-patient clinic. During the year-to-date 2008 period, the licensee administered approximately 26 iodine-125 prostate implants. In 2007, the licensee administered approximately 60 prostate implants.

No violations of NRC requirements were identified during the previous routine inspections on March 15, 2006, and February 25, 2003.

### 2 Management Oversight of the Radiation Protection Program

#### 2.1 Inspection Scope

The inspector reviewed the minutes of Radiation Safety Committee (RSC) meetings held since the last routine inspection as well as selected minutes between 2003 and 2006. The inspector also reviewed periodic audit reports performed by the nuclear medicine consultant. The inspector interviewed selected licensee and contractor personnel to discuss business described in the RSC minutes.

#### 2.2 Observations and Findings

St. John Macomb-Oakland Hospital has two radiation safety officers (RSO) named on the license. License Condition 11.A named one individual as the RSO for the diagnostic and therapeutic nuclear medicine activities. License Condition 11.B named another individual as the RSO for the brachytherapy activities. Both individuals were consultants retained by the hospital to serve as the RSO for their respective areas.

The RSO for the brachytherapy activities was not serving as RSO and had not been involved in the licensee's program since at least November 2007. The former RSO for brachytherapy activities was the co-owner of MIRO, an oncology out-patient clinic contracted to perform all aspects of prostate implants for the licensee. In 2007, MIRO was acquired by 21<sup>st</sup> Century Oncology and the former RSO/consultant sold her interest in the company. Discussions with hospital senior management revealed that the hospital received monthly invoices from 21<sup>st</sup> Century Oncology for "RSO services." The licensee paid these invoices for RSO services, unaware that the individual contracted to serve as RSO was no longer associated with 21<sup>st</sup> Century Oncology/MIRO.

License Condition 11.B specifically names an individual as RSO for the brachytherapy activities. The licensee's failure to appoint a new RSO for the brachytherapy activities is an apparent violation of License Condition 11.B.

The licensee held RSC meetings every calendar quarter. RSC membership included representatives of senior management, the radiation safety officers, and authorized users from nuclear medicine and radiation oncology areas. During the RSC meetings, the nuclear medicine RSO presented his quarterly radiation safety audit findings which were specific to the nuclear medicine program. The representatives from MIRO did not report any brachytherapy audit findings to the licensee since at least 2003. In addition, the licensee did not perform any independent reviews of the brachytherapy activities.

Title 10 Code of Federal Regulations (CFR) Part 20.1101(c) requires that the licensee periodically (at least annually) review the radiation protection program content and implementation. The licensee failure to review the radiation protection program specified to the brachytherapy activities on an annual basis is a violation of 10 CFR 20.1101(c).

According to the RSC minutes for 2007 and year-to-date 2008, a radiation oncology member was not routinely present at the meetings. The RSC meeting minutes did not indicate any discussion on the brachytherapy activities even though implant cases were performed. Interviews with licensee staff, the oncology staff at 21<sup>st</sup> Century Oncology/MIRO (the consulting firm providing the brachytherapy services), and the consulting RSO for the nuclear medicine activities, revealed that no individuals from 21<sup>st</sup> Century Oncology consistently attended the radiation safety committee meetings since at least 2007. The nuclear medicine RSO stated that he noticed no one from the oncology firm attended the RSC meetings since at least 2007 and that he would contact the contract medical physicist and inquire if they had anything to report to the RSC. According to the nuclear medicine RSO, the medical physicist never had anything to report to the committee.

In letter dated November 19, 2008, the licensee stated that according to staff recollection, the contract medical physicist attended an RSC meeting on March 24, 2008. The licensee noted that his attendance was not documented in the minutes because he arrived to the meeting late and left the meeting prior to adjournment.

The inspector determined that the root cause of the apparent violation and the additional violation was attributed to the licensee's failure to provide adequate oversight to the radiation safety program involving brachytherapy activities. The licensee relied on an oncology services consultant group (a medical physicist and an authorized physician user) to perform all aspects of the brachytherapy program. Licensee staff and the nuclear medicine RSO were aware that neither the brachytherapy RSO nor any other representative from the oncology consulting group routinely attended the RSC meetings but did not raise the issue during the RSC meetings or to hospital management. Contributing factors which also attributed to the failure to recognize the brachytherapy RSO's departure was: (1) the lack of institutional knowledge due to a recent turnover of management and nuclear medicine senior staff; and (2) the oncology consulting group failed to inform the licensee of the departure of the individual contracted to serve as the brachytherapy RSO.

### 2.3 Conclusions

The inspector identified an apparent violation of License Condition 11.B involving the licensee's failure to have an RSO for the brachytherapy activities. In addition, the inspector identified a violation of 10 CFR 20.1101(c) involving the licensee's failure to annually review the radiation protection program specific to the brachytherapy activities. The licensee implemented corrective actions in response to the apparent violation and the additional violation.

## **3 Licensee Corrective Actions**

### 3.1 Inspection Scope

The inspector reviewed the licensee's proposed corrective actions to preclude similar violations. The inspector also interviewed selected licensee personnel and the contract RSO for the nuclear medicine activities as well as the new RSO.

### 3.2 Observations and Findings

The licensee implemented prompt corrective actions regarding the apparent violation concerning the brachytherapy RSO, including: (1) conducting a radiation safety committee meeting on October 30, 2008, to discuss restructuring the duties and responsibilities of the RSO and to appoint one individual (a consultant and half-time employee of the hospital) to serve as RSO for the entire radiation safety program; (2) termination of the contract with the oncology service firm; and (3) utilizing the physics staff at the sister hospital (employees of the hospital system) for future brachytherapy implants; and (4) submitting an amendment request to the NRC (received on November 4, 2008) to name a new RSO. For the violation concerning the failure to review the radiation protection program, the licensee's newly appointed RSO performed a review of the brachytherapy activities in November 2008. The new RSO identified no violations of NRC requirements. The licensee revised its policies and procedures to require the RSO to present at the RSC an annual audit summary of the radiation safety program. In addition, the licensee revised its RSC charter to require monitoring attendance of members at the meetings with possible disciplinary action for unexcused absences.

### 3.3 Conclusions

The inspector concluded that the licensee developed and implemented corrective actions to address the root causes of the apparent violation and the additional violation.

## **4 Other Areas Inspected**

### 4.1 Inspection Scope

The inspector reviewed other areas of the licensee's radiation protection program by interviewing selected staff, observing licensed activities in progress, observing demonstrations of how staff had performed certain activities, and reviewing selected records. Areas reviewed included equipment and instrumentation, daily operational checks, leak tests, personnel dosimetry, emergency procedures, area surveys, and procedures requiring written directives.

## 4.2 Observations and Findings

Licensee staff used proper, calibrated instrumentation to perform required radiation surveys. The staff demonstrated their knowledge of the survey trigger levels and action to take when trigger levels were exceeded. The staff performed daily operational checks on radiation survey instruments prior to use. The staff also demonstrated recognition of abnormal operational check results, and appropriate response.

The licensee ensured that sealed sources were leak tested at 6-month intervals as required by 10 CFR 35.67. Leak test results were less than 0.005 microcuries. In addition, sealed sources were inventoried at the required 6-month frequency.

Licensee staff wore personnel whole body and extremity dosimetry badges and exchanged these badges on a monthly basis. The maximum whole body and extremity doses received by monitored staff year-to-date were 210 millirems and 3800 millirems, respectively. Licensee staff promptly reviewed dosimetry results to identify trends.

The staff demonstrated their knowledge regarding response to emergencies. Proper emergency response equipment was available, and the staff understood how to use it. Nuclear medicine staff used time, distance, and shielding to reduce radiation exposure. Physician authorized users prescribed iodine-131 dosages and iodine-125 permanent prostate implants using written directives.

The licensee and oncology contract staff demonstrated its processes to provide high confidence that administered dosages and implants were in accordance with the written directives. The inspector reviewed several patient charts and treatment plans for prostate implants administered at the hospital by the consulting oncology services firm and did not identify any medical events. Further discussions with the oncology services firm determined that the corporate physics staff also reviewed patient charts and checked treatment plans to ensure the prostate implants were performed in accordance with the physician's written directives. The corporate reviews did not identify any medical events or violations of NRC requirements. However, the results of these reviews were not communicated to the licensee.

## 4.3 Conclusions

The licensee implemented the areas of its radiation safety program described in this section in accordance with NRC requirements and its license commitments. No violations of NRC requirements were identified.

## **5 Exit Meeting Summary**

The inspector discussed the preliminary conclusions, as described in this report, with licensee management during the exit meeting conducted at the licensee's facility on October 22, 2008, and during a telephone exit conference on November 17, 2008. The inspector discussed the activities reviewed, the inspection findings, and the apparent violations. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in the inspection report as proprietary in nature.

### **List of Personnel Contacted**

- \*Constance A. Franko, Vice President, Operations
- Michael L. Bearss, RT(R)(N), CNMT, Lead Technologist
- DeWayne Bridge, CNMT
- +Ray Carlson, M.S., Consultant, RSO for nuclear medicine activities
- +Laura Smith, M.S., Consultant, new RSO
  
- +Linda Flipczak, Administrative Director, 21<sup>st</sup> Century Oncology/MIRO
- \*Mike Klein, M.S. Medical Physicist, 21<sup>st</sup> Century Oncology/MIRO
- +Eric Lee, Ph.D., Assistant Director of Physics, 21<sup>st</sup> Century Oncology
  
- \*Individuals present during exit meeting
- +Individuals contacted by telephone