April 19, 2010

EA-10-025

Mr. Damon R. Harbison, MBA, RT(R)(T)
Executive Director Diagnostic Imaging and
Oncology South Operating Group
SSM St. Clare Health Center
1015 Bowles Ave
Fenton, MO 53026

SUBJECT: NOTICE OF VIOLATION – SSM ST. CLARE HEALTH CENTER
NRC INSPECTION REPORT NO. 03002368/2009-001(DNMS)

Dear Mr. Harbison:

This refers to the inspection conducted on September 23, 2009, and February 4, 2010, at the SSM St. Clare Health Center facility in Fenton, Missouri. The purpose of the inspection was to examine 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. Details regarding the violation were provided in U.S. Nuclear Regulatory Commission (NRC) Inspection Report No. 03002368/2009-001(DNMS), dated March 3, 2010. The circumstances surrounding the violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with you and members of your staff at the inspection exit meeting on February 4, 2010.

In the letter transmitting the inspection report, we provided you 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 March 22, 2010, you provided a response to the apparent violation.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated March 22, 2010, 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 involved your staff's failure to follow written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, your staff failed to perform post-treatment plans for two patients who received prostate implants containing palladium-103 at St. Joseph Hospital in Kirkwood, Missouri. Your staff determined that the root cause of the violation was inattention to detail when the computer software failed to accept the treatment planning information that was entered by the physician authorized user (AU). A contributing factor was the closing of St. Joseph Hospital and relocation of the radiation therapy department to its new location at SSM St. Clare Hospital in Fenton, Missouri.

The violation is of concern to the NRC because the failure to perform post-treatment plans and to verify with certainty that the licensee delivered the prescribed dose to the intended organ would prevent the licensee from identifying a medical event and from identifying if any immediate follow-up or corrective actions are necessary. Furthermore, the licensee's failure to implement the written procedures in the above two cases combined with the failure to follow procedures regarding the post-treatment plans for six other patients before the NRC assumed the authority to regulate the accelerator produced material in the State of Missouri on September 30, 2008, indicated a programmatic weakness. Therefore, the 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 $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 inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process described in Section VI.C.2 of the Enforcement Policy. As a short-term corrective action, you immediately suspended the prostate implant program. Your staff completed the post-treatment plans for the eight individuals based on computed tomography (CT) scans, and the AU reviewed the results. The AU determined that the procedures did not result in any medical events. As long-term corrective action to prevent recurrence, your staff prepared a checklist which covers all steps that must be taken to review a prostate implant procedure. You indicated that all prostate implant procedures will be reviewed, in conjunction with the checklist, during your weekly chart review meetings. In addition, you stated that a copy of the checklist will be included in each patient's electronic medical record to track the process from the initial consultation to the final internal chart audit. Consequently, the NRC concluded that credit was warranted for your corrective actions.

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 have been adequately addressed on the docket in Inspection Report No. 03002368/2009-001(DNMS) and your letter dated March 22, 2010. 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 Title 10 of the Code of Federal Regulations (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. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov/about-nrc/regulatory/enforcement.html.

Sincerely,

/RA by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

Docket No. 030-02368
License No. 24-11858-01

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

Letter to Damon R. Harbison from Mark A. Satorius dated April 19, 2010

SUBJECT: NOTICE OF VIOLATION – SSM ST. CLARE HEALTH CENTER
NRC INSPECTION REPORT NO. 03002368/2009-001(DNMS)

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NOTICE OF VIOLATION

SSM St. Clare Health Center
Fenton, Missouri

Docket No. 030-02368
License No. 24-11858-01
EA-10-025

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on September 23, 2009, and February 4, 2010, 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)(2) states, that for any administration requiring a written directive, licensees are required to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
>
> The licensee's procedure titled, "Protocol for the Permanent Implantation of Radioactive Seeds into the Prostate," which was in effect between September 30, 2008, and September 23, 2009, states, in part, that approximately seven weeks after the implant, the patient should return for a computed tomography (CT) study to show the actual location of the radioactive seeds and that a final computerized treatment plan will be performed based upon this CT study.
>
> Contrary to the above, between November 19, 2008, and September 23, 2009, the licensee did not implement written procedures to provide high confidence that each administration was in accordance with the written directive. Specifically, the licensee failed to prepare final computerized treatment plans for two patients whose prostates had been implanted with radioactive seeds on October 22, 2008, and who had returned for CT studies on November 19, 2008.

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, have been adequately addressed on the docket in Inspection Report No. 03002368/2009-001(DNMS), dated March 3, 2010, and in your letter dated March 22, 2010. 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-10-025," and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, 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, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

ENCLOSURE

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.

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

Dated this 19th day of April 2010

ENCLOSURE

accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov/about-nrc/regulatory/enforcement.html.

Sincerely,

/RA by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

Docket No. 030-02368
License No. 24-11858-01

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

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OFFICE	RIII	RIII	RIII	D:OE	RIII	RIII
NAME	Pelke for Gryglak	Bloomer	Reynolds	Day for Zimmerman[1]	Orth	Pederson for Satorius
DATE	04/16/10	04/16/10	04/16/10	04/14/10	04/19/10	04/19/10

OFFICIAL RECORD COPY

1. OE concurrence received via e-mail from K. Day on April 14, 2010.