

March 3, 2010

EA-10-025

Mr. Damon R. Harbison, MBA, RT(R)(T)
Executive Director Diagnostic Imaging
SSM St. Clare Health Center
1015 Bowles Avenue
Fenton, MO 63026

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

Dear Mr. Harbison:

On September 23, 2009, and February 4, 2010, a U.S. Nuclear Regulatory Commission (NRC) inspector conducted an inspection 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 in your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, one apparent violation 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 website at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). The apparent violation involved the failure to perform post-treatment plans for two patients who received prostate implants at St. Joseph Hospital in Kirkwood, Missouri, in calendar year 2008, as required by your procedure. The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the inspection exit meeting on February 4, 2010. 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.

In addition, since your facility has not been the subject of escalated enforcement actions within the last two inspections, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violation addressed in this 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. The NRC will also issue a press release to

announce the conference. Please contact Tamara Bloomer at 630-829-9627 within seven 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. 03002368/2009-001(DNMS); EA-10-025" 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 NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. You can find the information notice on the NRC website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. 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.

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>. 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.

D. Harbison

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If you have any questions concerning this matter, please contact Tamara Bloomer of my staff at 630-829-9627.

Sincerely,

/RA/Patrick L. Loudon Acting For/

Steven A. Reynolds, Director
Division of Nuclear Materials Safety

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

Enclosure:
Inspection Report No. 03002368/2009-001(DNMS)

cc w/encl: Andre Strzembosz, M.D., RSO
State of Missouri

D. Harbison

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*See previous concurrence

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U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Docket No. 030-02368

License No. 24-11858-01

Report No.: 03002368/2009-001(DNMS)

EA No.: EA-10-025

Licensee: SSM St. Clare Health Center

Location: 1015 Bowles Avenue, Fenton, Missouri

Dates: September 23, 2009 and February 4, 2010

Exit Meeting: February 4, 2010

Inspector: Geoffrey M. Warren, Health Physicist

Approved by: Tamara E. Bloomer, Chief
Materials Inspection Branch

Enclosure

EXECUTIVE SUMMARY

SSM St. Clare Health Center Fenton, Missouri NRC Inspection Report 03002368/2009-001(DNMS)

This was a routine inspection conducted on September 23, 2009, and February 4, 2010, to review the activities conducted under the license as they relate to safety, compliance with the Commission's rules and regulations, and with conditions in the license. No violations were cited as a result of previous inspections of the licensee conducted in August 2005 and July 2007.

The inspector identified an apparent violation of Title 10 Code of Federal Regulations (CFR) Part 35.41(a)(2) associated with the licensee's failure to implement their protocol for permanent implantation of radioactive seeds into the prostate, in that they failed to perform final computerized treatment plans for two patients implanted with seeds containing palladium-103 on October 22, 2008. While both patients had returned for CT studies on November 19, 2008, the licensee did not perform the treatment plans as required by their procedure. The licensee had not performed these treatment plans for the six previous prostate implant patients, but NRC did not assume authority for the palladium-103 seeds used in the implant procedures until September 30, 2008, so no apparent violation is associated with the previous procedures.

The root cause of the apparent violation appeared to be inattention to detail. A contributing factor to the apparent violation was that the computer system used to perform the plans had problems with the planning software. The physician authorized user (AU) stated that he was unable to enter the information because of problems with the computer, which have since been resolved. The physicist and the AU also indicated that they were both distracted by the upcoming move to another hospital. Because of this distraction, neither individual paid appropriate attention to ensure the plans were completed.

As corrective action, licensee personnel performed the final computerized treatment plans for the two individuals, determining that no medical events occurred; this determination was verified by the NRC inspector. In addition, the Executive Director of Diagnostic Imaging stated that the licensee planned to: (1) prepare a checklist for prostate implantation procedures to include all required steps following the procedure, including final treatment plans and appropriate review of these plans; (2) revise their procedure to require review of each implantation procedure in coordination with the checklist at weekly chart review meetings including a physician, physicist, nurse, and therapist; and (3) postpone initiating the performance of prostate implantation procedures at SSM St. Clare Health Center until NRC's enforcement action is complete.

Report Details

1 Program Scope and Inspection History

SSM St. Clare Health Center (St. Clare, licensee) is a 150-bed hospital located in Fenton, Missouri, which served patients from the local and surrounding counties. The licensee is authorized by NRC License No. 24-11858-01 to perform nuclear medicine and radiation oncology activities. As of March 31, 2009, all activities performed under the license had moved to this facility from St. Joseph Hospital (St. Joseph) in Kirkwood, Missouri. St. Joseph had been decommissioned and removed from the license as a location of use prior to this inspection.

The licensee was authorized to perform manual brachytherapy procedures at this facility, but had not yet done so. Although no oncology procedures had taken place (to date) at St. Clare, the licensee had performed prostate implant procedures at its former location at St. Joseph, which involved accelerator produced palladium-103 seeds. The NRC's regulatory authority over those activities became effective on September 30, 2008. At St. Joseph, the licensee had also been authorized to use a High Dose Rate (HDR) remote afterloader device, but this authorization was not transferred to St. Clare.

The licensee operated two nuclear medicine areas at St. Clare; one area served inpatients and one served outpatients. Two full-time technologists performed approximately 220 to 240 diagnostic procedures monthly in both areas combined. These procedures were primarily cardiac, hepatobiliary, and other studies using technetium-99m doses received as unit doses or prepared from bulk technetium received from a licensed radiopharmacy. In addition, licensee technologists performed approximately 10 therapeutic procedures annually using iodine-131 in capsule form.

The licensee was previously inspected in August 2005 and July 2007 while at St. Joseph. No violations were cited as a result of these inspections.

2 Prostate Implant Procedures

2.1 Inspection Scope

The inspector reviewed the licensee's performance of prostate implantation procedures by reviewing selected records, including patient files and related documentation; and by interviewing licensee staff, including authorized users, physicists, and technologists.

2.2 Observations and Findings

The inspector noted that no prostate implant procedures had been performed since the move from St. Joseph. In calendar year 2008 at St. Joseph, the licensee had performed prostate implant procedures for nine patients, from January 9 through December 17. The procedures had been performed using preloaded needles containing palladium-103 seeds. The inspector observed that, while the licensee implanted the radioactive seeds as described in their procedure for prostate implants, the licensee failed to prepare a final computerized treatment plan (post plan) for any of these nine patients.

The licensee did not take a CT scan following the ninth implantation procedure, performed on December 17, 2008, because the patient never returned for the scan, even though the licensee contacted the patient to request that he return. The licensee reviewed the radiograph taken immediately following the implantation procedure to verify that the seeds were correctly placed, but was unable to take any further action.

Palladium-103 is accelerator-produced material; NRC assumed authority for regulating such materials in the State of Missouri on September 30, 2008. Because of this, the two patients whose implants were performed on October 22 were performed under the NRC authority.

Title 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, the licensee 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" states that approximately seven weeks after the implant, the patient should return for a 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. The licensee's failure to implement its written procedure that required a final computerized treatment plan for two patients for whom CT scans had been taken is an apparent violation of 10 CFR 35.41(a)(2).

The inspection reviewed the circumstances surrounding the licensee's failure to perform post treatment plans and concluded that the issue appeared to represent a programmatic weakness in the implementation of written directives or procedures for medical administrations. The licensee's failure to implement the procedure in the above two cases, combined with its additional failures involving the treatment of six patients before the NRC's regulatory authority became effective (January 2008 through September 2008), demonstrated a weakness that was not isolated and that indicated a more systemic problem. In addition, the inspector observed that the licensee's additional programmatic controls were also not effective in preventing or in identifying and correcting the multiple occurrences, in that, the issue was not identified until the NRC conducted an inspection in September 2009. Consequently, the issue is being considered for escalated enforcement in accordance with the NRC's Enforcement Policy.

The root cause of the apparent violation appeared to be inattention to detail. A contributing factor to the apparent violation was that the computer system used to perform the plans was not functioning. The AU stated that he was unable to enter the information because of problems with the computer, which have since been resolved. The physicist and the AU also indicated that they were both distracted by the upcoming move to another hospital. Because of this distraction, neither individual paid appropriate attention to ensure the post plans were completed.

As corrective action, in September and October 2009, the licensee's health physics staff prepared the post plans based on the post-implant CT scans taken of the patients, and the AU reviewed the plans. The AU determined that all procedures had been performed correctly and that no further treatments were necessary. The inspector returned to the licensee's facility on February 4, 2010, to complete the inspection by reviewing the post plans and verifying the AU's conclusions. The inspector observed that no medical events had occurred as a result of the eight prostate implant procedures.

As further corrective action, the Executive Director of Diagnostic Imaging stated that the licensee planned to prepare a checklist for prostate implantation procedures to include all required steps to be taken for each procedure, including post plans and appropriate review of the plans. He further stated that the procedure for prostate implantations would be revised to require that all prostate implant procedures be reviewed in accordance with the checklist during the weekly chart review meeting, which includes a physician, physicist, nurse, and therapist, to ensure that each step is completed for each implantation procedure. The licensee indicated that its use of the checklist would also detect any computer problems preventing preparation of the plans so that any issues could be corrected. In addition, the licensee stated that they would not begin performing prostate implant procedures at SSM St. Clare until the final NRC enforcement action for this apparent violation is issued.

2.3 Conclusions

The inspector identified an apparent violation of 10 CFR 35.41(a)(2) involving the licensee's failure to implement their procedure for prostate implantations. Specifically, licensee personnel failed to perform a final computerized treatment plan for two patients whose prostates had been implanted with seeds containing palladium-103, which the procedure required. The licensee discussed with the inspector its planned corrective actions to prevent a similar violation.

3 **Other Areas Inspected**

3.1 Inspection Scope

The inspector reviewed other areas of the licensee's radiation safety program by reviewing selected licensee records, interviewing nuclear medicine and radiation oncology staff, observing selected activities, and performing independent and confirmatory radiation surveys.

3.2 Observations and Findings

The licensee performed nuclear medicine procedures in accordance with NRC requirements and standard procedures, including dose preparation and administration, dose calibrator and survey meter checks, waste disposal, patient verification, and surveys. Dosimetry records showed no radiation doses of concern for radiation workers. Visitors to nuclear medicine areas were escorted, and staff maintained security of radioactive materials. Records of HDR treatments at St. Joseph showed no issues with the treatments. All hospital personnel received annual radiation safety training, and appropriate audits were performed. Written directives therapeutic procedures in nuclear medicine and radiation oncology contained all required information. Interviews with licensee personnel indicated adequate knowledge of radiation safety procedures and concepts. Surveys indicated radiation levels consistent with licensee records and postings.

3.3 Conclusions

No violations of NRC requirements were identified.

4 **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 February 4, 2010. The inspector discussed the activities reviewed, the inspection findings, and the apparent violation. 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

- David Basler, Therapist, Cancer Care Center
- Michael G. Beat, M.D., Radiation Oncologist, Authorized User
- * Damon R. Harbison, MBA, RT(R)(T), Executive Director Diagnostic Imaging
- * Vincent Joe, MD., Medical Director, Radiation Oncology
- Mark Weismeyer, Ph.D., Authorized Medical Physicist
- Debra Zoeller, Cancer Care Center

- * attended the exit meeting on February 4, 2010