October 28, 2012

EA-12-202

Mr. David E. Sieffert
Radiation Safety Officer
Lakeland Medical Center, Saint Joseph
1234 Napier Boulevard
Saint Joseph, Michigan 49085

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002049/2012001(DNMS) – LAKELAND MEDICAL CENTER, SAINT JOSEPH

Dear Mr. Sieffert:

On September 13, 2012, with continued in-office review through October 15, 2012, a U. S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at the Lakeland Medical Center facilities in Saint Joseph, Michigan, and Niles Michigan. The purpose of the inspection was to determine whether activities authorized under your license were conducted safely and in accordance with NRC requirements. The in-office review was to review corrective actions. The enclosed report presents the results of this inspection.

During this inspection, the NRC staff examined activities conducted under your license as they relate to public health and safety, compliance with the Commission's rules and regulations, and compliance 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, an apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current NRC Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violation involves the licensee's failure to have an authorized user sign and date three written directives. Specifically, an individual not authorized on your NRC license for the medical use prescribed by the written directives signed three written directives that were dated February 28, 2012; February 29, 2012; and March 20, 2012. The licensee has not provided the NRC with information on the individual's training and experiences that could demonstrate whether the individual was qualified as an authorized user for medical uses under Title 10 of the Code of Federal Regulations (CFR) 35.300, therefore, the apparent violation is being considered for escalated enforcement.

The NRC has not made a final determination on this matter; therefore, a Notice of Violation is not being issued for this inspection finding at this time. The circumstances surrounding this apparent violation, the significance of the issues, and the need for lasting and effective corrective actions were discussed with select representatives of Lakeland Medical Center during a final exit meeting on October 17, 2012, and are described in detail in the subject inspection report.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (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 (PEC). If a PEC is held, it will be open for public observation, and the NRC will issue a press release to announce the time and date of the conference. Please contact Tamara Bloomer, Chief of the Materials Inspection Branch, at (630) 829-9627 within 10 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 "Response to the Apparent Violation in Inspection Report No. 03002049/2012001 (DNMS); EA-12-202," 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 was or will be achieved. Your response may reference or include previously docketed correspondence, including the enclosed inspection report, if the correspondence adequately addresses the requested response. If a 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.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken.

As your facility has not been the subject of escalated enforcement actions within the last two inspections, a civil penalty may not be warranted in accordance with Section 2.3.4 of the Enforcement Policy. In addition, based upon NRC's understanding of the facts and your corrective actions, it may not be necessary to conduct a PEC in order to enable the NRC to make a final enforcement decision. Our 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.

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. In addition, please be advised that the number and characterization of apparent violations described 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 Section 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's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website 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 publicly available without redaction.

Please feel free to contact Mr. Aaron McCraw of my staff if you have any questions concerning this inspection. Mr. McCraw can be reached at 630-829-9650.

Sincerely,

/RA/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-02049
License No. 21-04177-01

Enclosure:
Inspection Report No. 03002049/2012001(DNMS)

cc w/encl: State of Michigan

Please feel free to contact Mr. Aaron McCraw of my staff if you have any questions concerning this inspection. Mr. McCraw can be reached at 630-829-9650.

Sincerely,

/RA/

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cc w/encl: State of Michigan

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NUCLEAR REGULATORY COMMISSION

REGION III

Docket No.:	030-02049
License No.:	21-04177-01
Report No.:	03002049/2012001(DNMS)
EA No.:	12-202
Licensee:	Lakeland Medical Center, Saint Joseph
Locations:	1234 Napier Boulevard Saint Joseph, Michigan 31 North Saint Joseph Avenue Niles, Michigan
Dates of Inspection:	September 13, 2012, through October 15, 2012
Exit Meeting:	October 17, 2012
Inspector:	Aaron T. McCraw, Senior Health Physicist
Reviewed By:	Tamara E. Bloomer, Chief Materials Inspection Branch Division of Nuclear Materials Safety

Enclosure

EXECUTIVE SUMMARY

Lakeland Medical Center, Saint Joseph
Saint Joseph, Michigan, and Niles, Michigan
Inspection Report 03002049/2012001(DNMS)

A U.S. Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection on September 13, 2012, with in-office review through October 15, 2012, at the licensee's facility at 1234 Napier Boulevard in Saint Joseph, Michigan, and at the licensee's facility at 31 North Saint Joseph Avenue, Niles, Michigan. The inspection consisted of a review of the licensee's regulated activities in the areas of nuclear medicine and radiation therapy. The in-office review was to review corrective actions.

During the inspection, the inspector identified an apparent violation of Title 10 of the Code of Federal Regulations (CFR) 35.40(a) and License Condition 12.B of NRC License No. 21-04177-01 in which the licensee did not have an authorized user sign three written directives, dated February 28, 2012; February 29, 2012; and March 20, 2012. Specifically, an individual, not authorized on the license for 10 CFR 35.300 medical uses, signed three written directives.

The licensee discussed with the inspector its implemented and planned corrective actions to prevent recurrence by: (1) ensuring that the unauthorized individual does not sign any additional written directives and understands that authorization to sign written directives requires additional training and experience; (2) revising the written directive form to add a checkbox verifying that the physician signing the written directive is authorized on the license for the medical use being administered; (3) instructing nuclear medicine staff on the new requirements for verifying license authorizations; and, (4) adding two new authorized users for 10 CFR 35.300 medical uses to ensure the licensee has adequate coverage of physicians authorized to sign written directives.

Report Details

1 Program Scope and Inspection History

Lakeland Medical Center, Saint Joseph, (licensee) is a hospital authorized by NRC License No. 21-04177-01 to perform activities under 10 CFR 35.100, 200, 300, 400, and 600; which includes administration of radiopharmaceuticals requiring a written directive, permanent implant brachytherapy, and high dose-rate remote afterloader treatments.

During the NRC's last routine inspection conducted on November 29, 2010, with continued in-office review through December 23, 2010, the NRC issued a Non-Cited Violation for the licensee's failure to only hold byproduct material with a physical half-life of less than or equal to 120 days for decay in storage before disposal as non-radioactive material.

During the previous routine inspection conducted on October 27-28, 2008, the inspector identified a Severity Level IV violation regarding the licensee's failure to adhere to its written procedures that were tied down in the licensee. Specifically, the inspector noted that a nuclear medicine technologist was consuming food and drink in a patient treatment area.

2 Radiopharmaceuticals Requiring a Written Directive

2.1 Inspection Scope

The inspector reviewed and evaluated the licensee's use of byproduct material under 10 CFR 35.300. The inspector interviewed nuclear medicine staff and the radiation safety officer and reviewed records of written directives for oral administration of iodine-131 (I-131) sodium iodide.

2.2 Observations and Findings

During a review of the records of the licensee's administration of radiopharmaceuticals requiring a written directive, the inspector identified three written directives that were signed by a physician who was not listed as an authorized user for 10 CFR 35.300 medical uses on NRC License No. 21-04177-01. The physician was an authorized user listed on the license; however, his authorizations were limited to medical uses under 10 CFR 35.100 and 200. The NRC was not afforded an opportunity to review the individual's training and experience as it relates to 10 CFR 35.300 medical uses; therefore, the NRC cannot determine if the individual met the requirements of an authorized user for 10 CFR 35.300 medical uses and could have been authorized on the license.

This is an apparent violation of 10 CFR 35.40(a) and License Condition 12.B of NRC License No. 21-04177-01. Title 10 CFR 35.40(a) requires that a written directive must be signed and dated by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (uCi)). License Condition 12.B, in part, lists the individuals authorized for medical uses under 10 CFR 35.300. The licensee failed to secure the signature of an authorized user listed on the license for 10 CFR 35.300 medical uses on three written directives for the administration of diagnostic dosages of I-131 sodium iodide, dated February 28, 2012;

February 29, 2012; and March 20, 2012. Each administration was a 2-millicurie (mCi) dosage, which requires a written directive.

The root cause of the apparent violation was that the licensee misunderstood the requirements for an authorized user for 10 CFR 35.300 medical uses to sign written directives for the administration of I-131 sodium iodide in any quantity greater than 30 uCi. The licensee believed that, because the physician was an authorized user for diagnostic administrations under 10 CFR 35.100 and 10 CFR 35.200, the physician was authorized to sign written directives for diagnostic administrations of I-131 sodium iodide greater than 30 uCi.

The licensee discussed with the inspector its implemented and planned corrective actions to restore compliance and prevent recurrence which included: (1) ensuring that the unauthorized individual does not sign any additional written directives and understands that authorization to sign written directives requires additional training and experience; (2) revising the written directive form to add a checkbox verifying that the physician signing the written directive is authorized on the license for the medical use being administered; (3) instructing nuclear medicine staff on the new requirements for verifying license authorizations; and, (4) adding two new authorized users for 10 CFR 35.300 medical uses to ensure the licensee has adequate coverage of physicians authorized to sign written directives.

2.3 Conclusion

The inspector identified an apparent violation of 10 CFR 35.40(a) and License Condition 12.B of NRC License No. 21-04177-01, involving the licensee's failure to have an authorized user for 10 CFR 35.300 medical uses sign three written directives, dated February 28, 2012; February 29, 2012; and March 20, 2012.

3 Other Areas of Radiation Safety Program

3.1 Inspection Scope

The inspector reviewed and evaluated a representative sample of the remainder of the licensee's program to determine whether licensed activities were being conducted in accordance with NRC requirements.

3.2 Observations and Findings

The inspector reviewed the licensee's medical uses of byproduct materials under 10 CFR 35.100 and 200. The inspector interviewed selected licensee personnel and determined that each individual was knowledgeable of safe radioactive material handling techniques. The inspector reviewed a selected and representative sample of records that included dosimetry, radiological surveys, administrations of licensed material, transportation, and waste disposal. The inspector did not identify any regulatory or safety issues.

The inspector also reviewed the licensee's radiation oncology program covered under 10 CFR 35.400 for permanent implant brachytherapy and 10 CFR 35.600 for high dose-rate remote afterloader (HDR) brachytherapy. The inspector reviewed the documentation for all permanent implant brachytherapy administrations performed since

the last inspection. All administrations were in accordance with the written directives and treatment plans. The inspector determined that the licensee adequately assessed the quality of the implants at an appropriate interval following the administrations. The inspector observed the physics hot lab where brachytherapy sources are stored and reviewed leak test and source accountability records. The inspector reviewed the written directives and treatment plans for eight HDR administrations, including gynecological cylinder and breast treatments. All administrations were in accordance with the written directives and treatment plans.

3.3 Conclusion

The inspector did not identify any violations in the licensee's use of radioactive materials under 10 CFR 35.100, 200, 400, and 600.

4 Exit Meeting Summary

At the completion of the onsite inspection, the inspector discussed potential issues and findings with the licensee during a preliminary debrief meeting. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature. The inspector conducted an exit meeting with the licensee via telephone on October 17, 2012.

Partial List of Persons Contacted

+^ Angelica Padilla, Director, Imaging Services
+^ Bobbie Reddick, Manager, Diagnostic Imaging
+^ David Sieffert, Radiation Safety Officer
+ Eileen Willits, Vice President for Patient Services
+ Nikol Wolnik, Nuclear Medicine Technologist
^ Kellee Ferry, Lead Nuclear Medicine Technologist

+ Attended the onsite preliminary debrief meeting on September 13, 2012
^ Participated in the telephone exit meeting on October 17, 2012

Inspection Procedures Used

87131	Nuclear Medicine Programs, Written Directive Required
87132	Brachytherapy Programs