



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

March 11, 2020

EA-19-126

Mr. Todd Forkel, Regional President
and Chief Executive Officer
Avera St. Luke's
dba Avera St. Luke's Hospital
305 South State Street
Aberdeen, SD 57401

SUBJECT: NOTICE OF VIOLATION, NRC INSPECTION REPORT 030-13778/2019-001

Dear Mr. Forkel:

This letter refers to the inspection conducted on July 30-31, 2019, at your facility in Aberdeen, South Dakota. The purpose of the inspection was to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and regulations and with the conditions of your license. A final exit briefing was conducted telephonically with you and members of your staff on December 2, 2019, and the details regarding the apparent violations were provided in NRC Inspection Report 030-13778/2019-001, dated December 17, 2019, NRC's Agencywide Documents and Management System (ADAMS) Accession ML19352D339.

On February 13, 2020, a predecisional enforcement conference was conducted at the Dakota Event Center in Aberdeen, South Dakota with you and members of your staff to discuss the apparent violations, their significance, their root causes, and your corrective actions.

Based on the information developed during the inspection and the information that you provided during the conference, the NRC has determined that three violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved the failures to: (A) monitor occupational exposure of workers from licensed and unlicensed sources of radiation; (B) develop and implement certain elements of your radiation protection program; and (C) submit a written report to the NRC within 30 days of discovery of a situation covered under Title 10 of the *Code of Federal Regulations* (10 CFR) 20.2203; specifically an occupational exposure in excess of the annual limits in 10 CFR 20.1201.

The NRC considers Violations A and B above to be significant violations because they represent a failure to provide adequate oversight for the radiation safety program, specifically in the area of occupational radiation monitoring and dose assessment. Violation C is significant because the failure to submit a written report impedes the NRC's ability to perform its regulatory function. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$7,500 is considered for a Severity Level III problem.

Because your facility has not been the subject of escalated enforcement actions within the last 2 years or last two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the NRC Enforcement Policy. The NRC has determined that *Corrective Action* credit is warranted based on your actions to: (1) recalculate the radiation exposure of the authorized user in question, (2) update policies and procedures to ensure that exposure is monitored accurately, and authorized users wear appropriate dosimetry; and (3) revise policies to include when and how to submit a written report to the NRC. In addition, during the predecisional enforcement conference, you discussed actions planned to evaluate potential dosimetry issues throughout the Avera McKennan health care system to identify any similar problems at other Avera McKennan facilities licensed by the NRC or an Agreement State.

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 problem constitutes escalated enforcement action that may subject you to increased inspection effort.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's 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 or proprietary information so that it can be made available to the public without redaction. The NRC also includes significant enforcement actions on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

If you have any questions concerning this matter, please contact Ms. Patricia Silva of my staff, at 817-200-1455.

Sincerely,

/RA Mark R. Shaffer for/

Scott A. Morris
Regional Administrator

Docket No. 030-13778
License No. 40-18000-01

Enclosure: Notice of Violation

NOTICE OF VIOLATION, NRC INSPECTION REPORT 030-13778/2019-001 - DATED MARCH 11, 2020

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Cvr Ltr & All Encl: ADAMS ACCESSION NUMBER: ML20071J427

SUNSI Review: JGK ADAMS: Non-Publicly Available Non-Sensitive Keyword: By:
 Yes No Publicly Available Sensitive

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NOTICE OF VIOLATION

Avera St. Luke's dba Avera St. Luke's Hospital
Aberdeen, South Dakota

Docket No. 030-13778
License No. 40-18000-01
EA-19-126

During an NRC inspection conducted on July 30-31, 2019, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.1502(a)(1) requires, in part, that each licensee shall monitor exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. As a minimum, each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a).

Contrary to the above, from February 2018, to July 30, 2019, the licensee failed to adequately monitor an individual's occupational exposure to radiation sources under the control of the licensee and require the use of individual monitoring devices. Specifically, a licensee's failure to properly monitor an authorized user's radiation exposure resulted in the authorized user having a significant potential to exceed the NRC's annual limit of 5 rems total effective dose equivalent in 10 CFR 20.1201(a).

- B. 10 CFR 20.1101(a) requires, in part, that each licensee develop and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. Policies and procedures in the Radiation Safety, or "RS" procedures, implement the licensee's radiation protection program.

Policy RS-01 "Radiation Safety Committee," Revision 6-18, Step B.4 requires, in part, that the Radiation Safety Committee will review the occupational radiation dose records of all personnel working with byproduct material. Step B.8, requires, in part, that the Radiation Safety Committee will recommend remedial actions to correct any deficiencies identified in the radiation safety program.

Policy RS-03 "Responsibilities and Authority of Radiation Safety Officer," Revision 9-12, Step 9 requires, in part, that the Radiation Safety Officer will maintain and update the Radiation Safety Manual.

Policy RS-04 "ALARA Program," Revision 9-12, Step II.C.2 requires, in part, that the Radiation Safety Committee will perform a quarterly review of occupational radiation exposures to assess trends in occupational exposure as an index of ALARA program quality. Step VI.E requires, in part, that the Radiation Safety Officer will initiate a review when the whole body external occupational exposure Investigation Levels are exceeded (Level 1: 310 mrem/calendar quarter and Level II: 900 mrem/calendar quarter).

Contrary to the above, from February 2018, to July 30, 2019, the license failed to develop and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions

Enclosure

of 10 CFR Part 20. Specifically, the licensee failed to: (1) review the occupational radiation dose records of all personnel working with byproduct material, (2) recommend remedial actions to correct any deficiencies identified in the radiation safety program, (3) maintain and update the Radiation Safety Manual, (4) perform a quarterly review of occupational radiation exposures to assess trends in occupational exposure as an index of ALARA program quality; and (5) initiate a review when the whole body external occupational exposure Investigation Levels are exceeded (Level I: 310 mrem/calendar quarter and Level II: 900 mrem/calendar quarter).

- C. 10 CFR 20.2203(a)(2)(i) requires, in part, that each licensee shall submit a written report within 30 days after learning of a dose in excess of the occupational dose limits for adults in 10 CFR 20.1201.

Contrary to the above, from November 3, 2018, to July 30, 2019, the licensee failed to submit a written report within 30 days after learning of a dose in excess of the occupational dose limits for adults in 10 CFR 20.1201. Specifically, the licensee was notified by the dosimetry vendor on October 3, 2018, of an exposure exceeding the NRC's annual exposure limits for an authorized user working under the NRC license, and the licensee failed to provide notification to the NRC prior to the NRC's inspection on July 30-31, 2019.

This is a Severity Level III problem (NRC Enforcement Policy Section 6.7.c).

Pursuant to the provisions of 10 CFR 2.201, Avera St. Luke's is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-19-126" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

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.

Your response will be made available electronically for public inspection in the NRC Public Document Room or in 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 or proprietary 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, then 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 material, 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).

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

Dated this 11th day of March 2020