



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION IV  
1600 E. LAMAR BLVD.  
ARLINGTON, TX 76011-4511

October 16, 2020

EA-20-050

Ms. Kelly Hefti, Executive Director  
Heart & Vascular  
Sanford Medical Center  
dba Sanford USD Medical Center  
P.O. Box 5039  
Sioux Falls, SD 57117-5039

**SUBJECT: NOTICE OF VIOLATION, NRC INSPECTION REPORT 030-03249/2020-001**

Dear Ms. Hefti:

This letter refers to the routine unannounced inspection conducted on February 3-4, 2020, at your facility in Sioux Falls, South Dakota, with continued in-office review through June 9, 2020. 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 on July 1, 2020, and the details regarding the four NRC-identified apparent violations were provided in NRC Inspection Report 030-03249/2020-001, dated July 13, 2020, NRC's Agencywide Documents and Management System (ADAMS) Accession No. ML20195B114.

In the NRC letter transmitting the inspection report, the NRC provided you the opportunity to address the apparent violations identified in the inspection report by either attending a predecisional enforcement conference, requesting alternative dispute resolution, or providing a written response before we made our final enforcement decision. In a letter received August 25, 2020 (ADAMS Accession No. ML20238C063), you provided a written response to the apparent violations.

Based on the information developed during the inspection and the information that you provided in your response to the inspection report dated July 13, 2020, the NRC has determined that four 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 failure to: (A) monitor exposures from unlicensed sources to one authorized user; (B) develop and implement procedures to address unexpected low doses reported by dosimetry providers; (C) provide instructions regarding the monitoring of exposures from unlicensed sources; and (D) submit a written report to the NRC when an individual's recorded dose exceeded 5 rem.

The NRC considers Violations A, B, and C 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. Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity

Level III problem. The NRC Enforcement Policy can be found at the NRC's web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The NRC considers Violation D above to be of low safety significance and thus has categorized it in accordance with the NRC Enforcement Policy as Severity Level IV. This violation is being formally cited as Severity Level IV rather than as a non-cited violation because it was identified by the NRC during an inspection.

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 two inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process described 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) provide training to your staff on the proper use of dosimetry; (2) conduct random audits to verify proper dosimetry use; and (3) revise your policies and procedures related to these violations.

Therefore, to encourage prompt and comprehensive corrective actions to address 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 an escalated enforcement action that may subject you to increased NRC inspection activities.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report 030-03249/2020-001 and in your letter received on August 25, 2020. 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* (CFR) 2.390 of the NRC's "Rules of Practice and Procedure," 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 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 web site 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,

John D. Monninger  
Deputy Regional Administrator

Docket No. 030-03249  
License No. 40-12378-01

Enclosure: Notice of Violation

cc w/enclosure:  
John Priest, Sr. Health Facilities  
Surveyor-radiation  
South Dakota Dept. of Health

NOTICE OF VIOLATION AND NRC INSPECTION REPORT 030-03249/2020-001 - DATED OCTOBER 16, 2020

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Cvr Ltr & All Encl: ADAMS ACCESSION NUMBER: **ML20289B061**

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

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NAME	MMuessle	JMonninger				
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DATE	10/08/2020	10/16/20				

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## NOTICE OF VIOLATION

Sanford Medical Center  
dba Sanford USD Medical Center  
Sioux Falls, South Dakota

Docket No.: 030-03249  
License No.: 40-12378-01  
EA-20-050

During an NRC inspection conducted on February 3-4, 2020, four 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. At a minimum, each licensee shall monitor 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 January 1, 2013, to February 3, 2020, the licensee failed to monitor an individual's occupational exposure to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of 10 CFR Part 20. Specifically, for one authorized user, the licensee failed to monitor the occupational exposure to radiation from unlicensed radiation sources under the licensee's control and failed to require the use of individual monitoring devices by the authorized user, who received, 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).

- B. 10 CFR 20.1101(a) requires, in part, that each licensee shall implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20.

Contrary to the above, from January 1, 2013, to February 3, 2020, the licensee failed to implement a radiation protection program commensurate with the scope and extent of licensed activities sufficient to ensure compliance with 10 CFR Part 20. Specifically, the licensee failed to provide instructions for further investigation and other actions to be taken when dosimeter readings were zero or less than what the licensee would expect given the likely exposure from monitored activities.

- C. 10 CFR 19.12(a)(3) requires, in part, that all individuals who in the course of employment are likely to receive in a year an occupational dose in excess of 100 mrem shall be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material.

Contrary to the above, from April 28, 2013, to February 3, 2020, the licensee failed to require that an individual who in the course of employment was likely to receive in a year an occupational dose in excess of 100 mrem be instructed in, and required to observe, to the extent within the worker's control, the applicable provisions of Commission regulations and licenses for the protection of personnel from exposure to radiation. Specifically, the licensee failed to provide adequate instructions regarding the proper use

Enclosure

of personnel dosimeters to an authorized user who was likely to receive in a year an occupational dose in excess of 100 mrem.

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

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

Contrary to the above, from January to February 2014, 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, an authorized user's deep dose equivalent exceeded 5 rem and a written report was not submitted to the NRC.

This is a Severity Level IV Violation (NRC Enforcement Policy, Section 6.9.d.8).

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report 030-03249/2020-001 and in your letter received on August 25, 2020. 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-20-050," and send it 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 E. Lamar Blvd, Arlington, Texas 76011-4511, and emailed to [R4Enforcement@nrc.gov](mailto:R4Enforcement@nrc.gov) 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 made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, 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. If personal privacy or proprietary information is necessary to provide an acceptable response, 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 information, 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 are required to post this Notice within 2 working days of receipt.

Dated this 16th day of October 2020