



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

September 15, 2020

EA-20-065

Jodi Vanderpool, Vice President
Quality Operations and Patient Safety
St. Luke's Regional Medical Center
190 East Bannock Street
Boise, ID 83712

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$7,500, NRC INSPECTION REPORT 030-32196/2020-001

Dear Ms. Vanderpool:

This letter refers to the unannounced inspection conducted on February 24-28, 2020, at your facilities in Boise and Meridian, Idaho, with continued in-office review through April 20, 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 with you and staff representatives on June 25, 2020, and the details regarding three NRC-identified violations were provided in NRC Inspection Report 030-32196/2020-001, dated June 26, 2020, NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML20178A646.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations 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 dated July 7, 2020 (ADAMS Accession No. ML20219A337), you provided a written response to the apparent violations.

Based on the information developed during the inspection and the information you provided in your written response dated July 7, 2020, the NRC has determined that three violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved the failure to: (A) monitor occupational exposure of workers from licensed and unlicensed sources of radiation; (B) implement certain elements of your radiation protection program sufficiently to ensure compliance with the provisions of 10 CFR Part 20; and (C) provide instructions to occupational workers regarding radiation safety, specifically involving the proper use of dosimeters.

The NRC considers the violations above to be significant violations because of the programmatic failures associated with your dosimetry program, and because interventional radiology physicians had a substantial potential to exceed NRC occupational exposure limits.

Therefore, these violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem. The Enforcement Policy can be found on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

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 been the subject of an escalated enforcement action within the last two routine inspections (a Severity Level III problem was issued on March 29, 2018 (EA-17-181)), the NRC considered whether credit was warranted for *Identification* and *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 *Identification* credit is not warranted because the NRC inspector identified the violations during an inspection. However, the NRC has determined that *Corrective Action* credit is warranted based on the prompt and comprehensive corrective actions you implemented. Your corrective actions to address the violations are documented in your letter dated July 7, 2020, and NRC Inspection Report 030-32196/2020-001.

Therefore, to emphasize the importance of the dosimetry program in your licensed activities, the NRC identification of violations, credit for corrective actions, and in recognition of your previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$7,500 for the Severity Level III problem described in the enclosure. In addition, issuance of this Notice constitutes an escalated enforcement action that may subject you to increased inspection in the future.

The NRC recognizes that many of its licensees have been adversely impacted financially by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). Consequently, as described in the enclosed Notice, the NRC is extending by 30 days the period of time by which the civil penalty must be paid (i.e., extending the deadline from 30 days to 60 days from the date of this Notice), and the NRC would consider a request for additional time, if appropriate. Please refer to the enclosed Notice for further instructions.

If you disagree with this enforcement sanction, you may deny the violation, as described in the Notice, or you may request alternative dispute resolution (ADR) mediation with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be found at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>.

The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the Institute on Conflict Resolution at 877-733-9415; and (2) Ms. Patricia Silva at 817-200-1455 within 10 days of the date of this letter. Your submitted signed agreement to mediate using the NRC ADR program will stay the 60-day time period for

payment of the civil penalties, as identified in the enclosed Notice, until the ADR process is completed.

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 your letter dated July 7, 2020, and NRC Inspection Report 030-32196/2020-001. 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 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter, the 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 website 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,

Scott A. Morris
Regional Administrator

Docket No: 030-32196
License No: 11-27312-01

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/ enclosure:
Mr. Mark Dietrich
State of Idaho Radiation Control Program

NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$7,500, NRC INSPECTION REPORT 030-32196/2020-001 - DATED SEPTEMBER 15, 2020

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Cvr Ltr & Encl: ADAMS ACCESSION NUMBER: ML

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

OFFICE	SES:ACES	C:MIB	TL:ACES	RC	OE	NMSS
NAME	JKramer	PSilva	JGroom	DCylkowski	JPeralta	RSun
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E
DATE	08/21/20	08/21/20	08/21/20	08/21/20	09/10/20	08/31/20
OFFICE	OGC	D:DNMS	RA			
NAME	LBaer	MMuessle	SMorris			
SIGNATURE	/NLO/ E	/RA/ E	/RA/ E			
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NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

St. Luke's Regional Medical Center
Boise, Idaho

Docket No. 030-32196
License No. 11-27312-01
EA-20-065

During an NRC inspection conducted February 24-28, 2020, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The violations and associated civil penalty are set forth 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 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 January 1, 2012, to February 24, 2020, the licensee failed to monitor individuals' occupational exposure to radiation sources under the control of the licensee and require the use of individual monitoring devices. Specifically, interventional radiology physicians whose occupational exposure exceeded 10 percent of the limits in 10 CFR 20.1201(a) were not monitored over the course of 8 years.

- B. 10 CFR 20.1101(a) requires, in part, that each licensee 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.

Licensee policy EC046 BMW, "Occupational Radiation Exposure Program (ALARA - As Low As Reasonably Achievable)," Revision effective August 2, 2009, Section III.B and licensee policy EC046 SLHS, "Radiation Exposure Monitoring Program (ALARA)," Revisions effective December 12, 2012, through October 15, 2019, Section III.H, state, in part, that for personnel dose less than the Investigational Level: except when deemed appropriate by the radiation safety officer, no further action will be taken in cases where an individual's dose is less than the Table 1 values for the Investigational Level.

Contrary to the above, from January 1, 2012, to February 24, 2020, the licensee failed to 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. Specifically, the licensee's policies EC046 BMW and EC046 SLHS failed to include provisions regarding actions to be taken when individuals' doses were less than the licensee's Investigational Level, such as when dosimeters were returned unused or had unexpectedly low exposures.

- 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 workers' control, the

Enclosure

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 January 1, 2012, to February 24, 2020, the licensee failed to provide instruction to individuals, who in the course of employment were likely to receive in a year an occupational dose in excess of 100 mrem, on the applicable provisions of the Commission regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material. Specifically, the licensee failed to provide instructions regarding radiation safety involving the proper use and storage of dosimeters to four interventional radiology physicians who were likely to receive an occupational dose in excess of 100 mrem in a year, which resulted in their failure to wear dosimetry to monitor their exposure to occupational radiation.

This is a Severity Level III problem (NRC Enforcement Policy Section 6.7.c.6).
Civil Penalty - \$7,500 (EA-20-065)

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 your letter dated July 7, 2020, and NRC Inspection Report 030-32196/2020-001.

However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-20-065," and send it to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a copy to the Document Control Desk, Washington, DC 20555-0001, and the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV.

You may pay the civil penalty proposed above in accordance with NUREG/BR-0254, "Payment Methods," (NRC's Agencywide Documents Access and Management System (ADAMS) Accession ML19163A244), and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. However, in recognition of the financial impact to licensees by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19), the NRC is extending the period of time by which the civil penalty must be paid from 30 days to 60 days from the date of this Notice. Should you fail to pay the civil penalty within 60 days of the date of this Notice, the NRC may issue an order imposing the civil penalty.

Should you elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation; EA-20-065" and may: (1) deny the violations listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty. Separately, you may request an additional extension of time to pay the civil penalty as a result of impacts to the licensee from COVID-19. Such an extension request must be in writing and should explain the basis for the request and should specify the amount of additional time being requested.

This extension request must be submitted to the NRC no later than 50 days from the date of this Notice (i.e., at least 10 days before the initial 60-day deadline to pay the civil penalty).

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. Your attention is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (i.e., Reply to Notice of Violation, Extension of time to pay the civil penalty request, Statement as to payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, and the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511. In addition, email a copy of all correspondence to R4Enforcement@nrc.gov.

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 website at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the 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, 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 that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (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 2 working days of receipt.

Dated this 15th day of September 2020