



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
1600 EAST LAMAR BOULEVARD  
ARLINGTON, TEXAS 76011-4511

October 7, 2020

EA-19-132

Mr. Taylor Rudd, Chief Operating Officer  
St. Joseph Regional Medical Center, Inc.  
504 Sixth Street  
Lewiston, Idaho 83501

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL  
PENALTY - \$7,500, NRC INSPECTION REPORT 030-32211/2019-001

Dear Mr. Rudd:

This letter refers to the inspection conducted on July 8-9, 2019, and October 21, 2019, at your facility in Lewiston, Idaho, with in-office review through December 26, 2019. The purpose of the inspection was to examine activities conducted under your license as they relate to safety and 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 members of your staff on January 21, 2020. The details regarding five apparent violations were provided in NRC Inspection Report 030-32211/2019-001, dated January 30, 2020, NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML19361A162.

On February 14, 2020, the NRC and your staff agreed to pursue an alternative dispute resolution (ADR) mediation session in an attempt to resolve the issues after both parties signed the agreement to mediate. The ADR mediation session was subsequently delayed as a result of the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). On July 23, 2020, the NRC and you agreed to hold a predecisional enforcement conference. On August 25, 2020, the predecisional enforcement conference was conducted virtually by telephone bridge 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 you provided during the conference, the NRC has determined that five 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) prepare written directives that were dated and signed by an authorized user; (B) ensure that written directives contained all required information; (C) develop, implement, and maintain written procedures to provide high confidence that each administration requiring a written directive was in accordance with the written directive; (D) appoint a radiation safety officer, who agreed in writing to be responsible for implementing the radiation protection program; and (E) conduct the program in accordance with the statements, representations, and procedures referenced in the license.

The NRC considers Violations A, B, and C noted above to be significant violations because of the programmatic failures associated with the failure to prepare written directives in accordance with regulatory requirements and the lack of procedures for developing these written directives. 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>.

The NRC considers Violations D and E noted above to be of low safety significance and thus has categorized them in accordance with the NRC Enforcement Policy as Severity Level IV. These violations are being formally cited as Severity Level IV rather than as non-cited violations because they were 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. After the July 2019 inspection, you placed a hold on the iodine-131 sodium iodide administrations that require a written directive until you could implement corrective actions. During the follow-up inspection in October 2019, the NRC inspector learned that the iodine-131 sodium iodide administrations requiring a written directive had resumed at your facility. The inspector identified that your corrective actions were not sufficient to prevent recurrence of another incomplete written directive for an iodine-131 sodium iodide administration. In addition, you had taken no actions to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

When assessing *Corrective Action* credit, the NRC evaluates both the promptness and the comprehensiveness of the licensee's corrective actions. Based on the information developed during the inspection and the information you provided during the predecisional enforcement conference, the NRC determined that *Corrective Action* credit is not warranted because your actions taken after the July 2019 inspection were neither prompt nor comprehensive, resulting in an additional incomplete written directive and continued noncompliance.

Therefore, to emphasize the importance of the need to establish and maintain an adequate program for administrations requiring written directives, and to encourage prompt and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the base amount of \$7,500 for this Severity Level III problem. 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 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 ADR with the NRC 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 ADR 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.

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 should 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 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, the enclosures, and 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>. 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>.

T. Rudd

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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. 030-32211  
License No. 11-27371-01

Enclosure:  
Notice of Violation and Proposed  
Imposition of Civil Penalty

cc w/enclosure:  
Mark Dietrich  
Radiation Control Program Director  
Idaho Department of Environmental Quality  
1410 North Hilton Street  
Boise, ID 83706

NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$7,500, NRC  
INSPECTION REPORT 030-32211/2019-001 - DATED OCTOBER 7, 2020

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Cvr Ltr & Encl: ADAMS ACCESSION NUMBER: **ML20281A460**

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

OFFICE	SES:ACES	C:MLIB	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	09/21/20	09/21/20	09/22/20	09/22/20	09/30/20	09/25/20
OFFICE	OGC	D:DNMS	RA			
NAME	RSusko	MMuessle	SMorris			
SIGNATURE	/NLO/ E	/RA/ E	/RA/ E			
DATE	09/30/20	09/30/20	10/07/20			

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NOTICE OF VIOLATION  
AND  
PROPOSED IMPOSITION OF CIVIL PENALTY

St. Joseph Regional Medical Center, Inc.  
Lewiston, Idaho

Docket No.: 030-32211  
License No.: 11-27371-01  
EA-19-132

During an NRC inspection conducted on July 8-9, 2019, and October 21, 2019, five 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:

I. Violations Assessed a Civil Penalty

- A. 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an authorized user before the administration of iodine-131 (I-131) sodium iodide greater than 30 microcuries or any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

Contrary to the above, between June 1, 2016, and October 21, 2019, the licensee failed to prepare written directives that were dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries or any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material. Specifically: (1) written directives for administrations of I-131 sodium iodide greater than 33 millicuries were dated and signed by an individual who was not authorized under the license as an authorized user for oral administration of I-131 sodium iodide in quantities greater than 33 millicuries; (2) the licensee administered I-131 sodium iodide greater than 30 microcuries and failed to prepare written directives; (3) the licensee administered I-131 sodium iodide greater than 30 microcuries and the written directive was not dated by an authorized user; and (4) the licensee administered 12 therapeutic doses of radiation from byproduct material from palladium-103 and the written directives were not dated by an authorized user.

- B. 10 CFR 35.40(b)(2) requires, in part, that the written directive must contain for an administration of a therapeutic dosage of unsealed byproduct material other than I-131 sodium iodide: the radioactive drug, dosage, and route of administration.

Contrary to the above, between June 1, 2016, and October 21, 2019, the licensee failed to ensure that written directives for the administration of a therapeutic dosage of unsealed byproduct material other than I-131 sodium iodide contained the radioactive drug, dosage, and route of administration. Specifically, for therapeutic dosages of unsealed radium-223 dichloride, 16 written directives did not contain the route of administration and two written directives did not contain the units of activity to specify the dosage.

- C. 10 CFR 35.41(a)(2) requires that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Enclosure

Licensee procedure "Radiopharmaceutical Quality Management Program – Iodine-131," dated March 25, 2013, reviewed January 9, 2017, includes a section titled "Audit Program," which requires, in part, that the radiation safety committee will review all patients who have received I-131 sodium iodide during the previous quarter.

Licensee procedure "Brachytherapy Quality Management Program – Permanent Prostate Seed Implants," dated February 21, 2011, reviewed January 9, 2017, includes a section titled "Audit Program," which requires, in part, that following the completion of each brachytherapy implant there will be a complete audit by the physicist and/or dosimetrist of the implant.

Licensee procedure "Radiopharmaceutical Quality Management Program – Xofigo," dated July 29, 2013, includes a section titled "Audit Program," which requires, in part, that the radiation safety committee will review the treatment records of all patients who have received Xofigo injection during the previous quarter. Further, the section titled "Written Directive" requires, in part, that a written directive for each patient will include dose (1.35 millicuries per kilogram of body weight).

Contrary to the above, between June 1, 2016, and October 21, 2019, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration requiring a written directive was in accordance with the written directive. Specifically, the radiation safety committee did not review all patients who had received I-131 sodium iodide during the previous quarter; there was not a complete audit by the physicist and/or dosimetrist following the completion of each brachytherapy implant; the radiation safety committee did not review all patients who had received a Xofigo injection during the previous quarter; and the Xofigo procedure incorrectly listed the patient dose as 1.35 millicuries per kilogram of body weight, whereas the vendor's prescribing information was 1.49 microcuries per kilogram of body weight.

This is a Severity Level III problem (NRC Enforcement Policy Section 6.3.c.2).  
Civil Penalty - \$7,500 (EA-19-132)

## II. Violations Not Assessed a Civil Penalty

- D. 10 CFR 35.24(b) requires, in part, that a licensee's management shall appoint a radiation safety officer, who agrees in writing, to be responsible for implementing the radiation protection program.

Contrary to the above, from June 1, 2016, to October 21, 2019, the licensee's management failed to appoint a radiation safety officer, who agreed in writing, to be responsible for implementing the radiation protection program.

This is a Severity Level IV Violation (NRC Enforcement Policy Section 6.3.d).

- E. NRC License 11-27371-01, Amendments 11 and 12, Condition 16.C, Amendments 13 and 14, Condition 15.C, and Amendment 15, Condition 14.C require, in part, that the licensee shall conduct its program in accordance with the statements contained in Emails with attachments dated March 18, 2013.

Emails with attachments dated March 18, 2013, Table C.3, "Item 10: Safe Use of Unsealed Licensed Material" contain a statement that was checked by the licensee to

indicate: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."

Contrary to the above, from December 3, 2014, to October 21, 2019, the licensee failed to conduct its program in accordance the statements contained in Emails with attachments dated March 18, 2013. Specifically, the licensee failed to develop, implement, and maintain written procedures for the safe use of unsealed byproduct material that meets the requirements of 10 CFR 20.1101 and 10 CFR 20.1301.

This is a Severity Level IV Violation (NRC Enforcement Policy Section 6.3.d.3).

Pursuant to 10 CFR 2.201, St Joseph Regional Medical Center, Inc. is hereby required to submit a written statement or explanation 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 within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-19-132" 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 previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, the NRC may issue an order or a demand for information requiring you to explain why your license should not be modified, suspended, or revoked or why the NRC should not take other action as may be proper. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

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 No. 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-19-132" and may: (1) deny the violation 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, 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, and emailed to [R4Enforcement@nrc.gov](mailto:R4Enforcement@nrc.gov).

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 be 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 7th day of October 2020