



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

August 12, 2020

EA-20-003

Mr. David Flicek
President and Chief Executive Officer
Avera McKennan
1325 South Cliff Avenue
Sioux Falls, SD 57117-5045

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$7,500, NRC INSPECTION REPORT 030-11252/2019-002

Dear Mr. Flicek:

This letter refers to the inspection conducted on November 18-22, 2019, at your facilities in Sioux Falls and Mitchell, South Dakota, with in-office reviews through February 27, 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, regulations, and the conditions of your license. A final exit briefing was conducted telephonically with Avera McKennan management and staff representatives on March 12, 2020, and the details regarding six NRC-identified violations were provided in NRC Inspection Report 030-11252/2019-002, dated March 30, 2020, NRC's Agencywide Documents Access and Management System (ADAMS) Accession No. ML20090D288.

On July 15, 2020, a predecisional enforcement conference was conducted 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 six violations of NRC requirements occurred. These violations are cited in Enclosure 1, 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; (C) submit a written report after learning of a dose in excess of the occupational dose limits for adults to the NRC within 30 days; (D) provide instructions to three occupational workers regarding radiation safety, specifically involving the proper use of dosimeters; (E) provide occupational exposure reports to radiation workers; and (F) ensure that an authorized user of each type of use permitted by the license was represented on the radiation safety committee.

The NRC considers Violations A, B, and C above to be significant violations because of the programmatic failures associated with the dosimetry program and because authorized users

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>.

The NRC considers Violations D, E, and F 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 been the subject of an escalated enforcement action within the last two routine inspections (a Severity Level III problem was issued on December 21, 2017 (EA-17-104)), 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 NRC inspectors identified the violations during an inspection. 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 Enclosure 2.

Therefore, to emphasize the importance of the dosimetry program, and in recognition of your previous escalated enforcement action, the NRC identification of violations, and credit for corrective actions, 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 in Enclosure 1. 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) 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.

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.

On March 10, 2020, the NRC issued a license amendment requested by Avera McKennan that separated Avera McKennan's operations into two NRC licenses. Because the violations described in the Notice predated this license amendment, the escalated enforcement action regarding EA-20-003 will be associated with both Avera McKennan dockets 030-11252 and 030-39216.

In accordance with 10 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 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,

Scott A. Morris
Regional Administrator

Docket Nos. 030-11252, 030-39216
License Nos. 40-16571-01, 40-16571-02

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Corrective Actions

cc w/ enclosures:

John Priest
Sr. Health Facilities Surveyor-Radiation
South Dakota Dept. of Health

NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$7,500, NRC
INSPECTION REPORT 030-11252/2019-002 - DATED AUGUST 12, 2020

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Cvr Ltr & All 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: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	07/20/20	07/20/20	07/21/20	07/22/20	07/29/20	07/28/20
OFFICE	OGC	D:DNMS	RA			
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NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Avera McKennan
Sioux Falls, South Dakota

Docket No. 030-11252
License No. 40-16571-01
EA-20-003

During an NRC inspection conducted November 18-22, 2019, six 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 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 2016 to November 22, 2019, 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, two individuals whose occupational exposure exceeded 10 percent of the limits in 10 CFR 20.1201(a) were not monitored over the course of 3 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.

The licensee developed policies S02, "Program for Maintaining Occupational Radiation Exposures [as low as reasonably achievable] ALARA in Diagnostic and Interventional Imaging" and RS-101, "Duties and Responsibilities of the Radiation Safety Officer (RSO)," in part, 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.

Policy S02 requires, in part, that the RSO will: (1) review at least quarterly the external radiation exposures of authorized users and workers (Step 3.a.2); (2) investigate all known instances of deviations from good ALARA practices and, if possible, to determine the causes, and when the cause is known require changes in the program to maintain exposures to ALARA (Step 3.d.1); and (3) investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II (400 mrem/quarter or 200 mrem/month) and, if warranted take action (Step 5.b.3).

Policy RS-101 requires, in part, that the RSO will ensure that if violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented (Step 13).

Contrary to the above, from April 11, 2018, to November 22, 2019, 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 failed to: (1) perform quarterly reviews of external radiation exposures of authorized users and workers; (2) investigate all known instances of deviation from good ALARA practice; (3) investigate in a timely manner the cause of all personnel exposures equaling or exceeding Investigational Level II (400 mrem/quarter or 200 mrem/month); and (4) develop, implement, and document corrective actions for violations of regulations, license conditions, or program weaknesses that were identified.

- 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 September 27 to December 6, 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 its dosimetry vendor on August 27, 2019, of two exposures exceeding the NRC's annual dose limits for an individual and failed to provide notification to the NRC within 30 days (i.e., by September 27, 2019). A dose reconstruction of the affected authorized users was completed and submitted to the NRC on December 6, 2019, demonstrating the authorized users' dose was below the 10 CFR 20.1201 occupational dose limits for adults.

This is a Severity Level III problem (NRC Enforcement Policy Section 6.7.c.6).
Civil Penalty - \$7,500 (EA-20-003)

II. Violations Not Assessed a Civil Penalty

- D. 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 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 2016 to November 18, 2019, 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 of dosimeters to three occupational workers 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 IV violation (NRC Enforcement Policy Section 6.7.d).

- E. 10 CFR 19.13(b)(1) requires, in part, that the licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if the individual's occupational dose exceeds 100 mrem total effective dose equivalent.

Contrary to the above, from January 2016 to November 18, 2019, the licensee failed to provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year when the individual's occupational dose exceeded 100 mrem total effective dose equivalent. Specifically, the licensee failed to provide radiation exposure data to three occupational workers in the course of their employment, who had exceeded 100 mrem total effective dose equivalent.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d).

- F. 10 CFR 35.24(f) requires, in part, that licensees shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The committee must include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO.

Contrary to the above, from January 25, 2018, through October 9, 2019, the licensee's Radiation Safety Committee failed to include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO. Specifically, during the eight quarterly committee meetings between the above dates, there was not an authorized user on the licensee's committee to represent the 10 CFR 35.1000 yttrium-90 microsphere use.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.7.d).

Pursuant to 10 CFR 2.201, Avera McKennan 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-20-003" 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 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-20-003" 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.

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, 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 12th day of August 2020

CORRECTIVE ACTIONS

Avera McKennan's (licensee's) President and Chief Executive Officer, the Chief Medical Officer, and the Radiation Safety Officers presented the licensee's response to the apparent violations documented in NRC Inspection Report 030-11252/2019-002 at a predecisional enforcement conference on July 15, 2020. The licensee's representatives stated that they accepted all the apparent violations, as well as the supporting facts and circumstances, as detailed in the NRC Inspection Report. The corrective actions both completed, and in-process described by licensee representatives included:

1. Revising and updating the radiation protection program policies, as well as the creation of new policies to improve documentation and communication within the licensee's program, including the oversight and execution of the dosimetry and occupational exposure monitoring program;
2. Recalculation of the subject authorized users' occupational radiation exposure for the applicable calendar years and submission of those revised exposures to the third-party dosimetry company for incorporation into the authorized users' records;
3. Improved inter-departmental/inter-license communications, including the development and execution of a Radiation Safety Committee Charter;
4. Conducting observations of radiology activities and creation of a "Physician Champion" for interventional radiology to identify opportunities for process improvement and occupational exposure reduction;
5. Implementation of a dosimetry check in the existing "Time Out" procedure prior to performing interventional radiology procedures;
6. Conducting several training and education sessions with applicable department staff and physicians on new policies and program changes;
7. Creating an Avera system-wide approach to the Radiology Service Line, extending certain actions across and beyond the jurisdiction of the NRC licenses possessed by Avera, including actions to increase consistency in practices and implementation across the Avera system.