



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

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

July 19, 2023

EA-23-012

Dave McFadyen, CEO  
Saint Alphonsus Health System  
1055 North Curtis Road  
Boise, ID 83706

SUBJECT: SAINT ALPHONSUS HEALTH SYSTEM - NOTICE OF VIOLATION, NRC  
INSPECTION REPORT 030-32263/2022-001

Dear Dave McFadyen:

This letter refers to the announced routine inspection that was performed on October 19-21, 2022, at your facilities in Boise, Idaho, with continued in-office review through March 20, 2023. The inspection was conducted 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 (NRC) rules and regulations and with the conditions of your license. A final exit meeting was conducted with members of your staff on April 13, 2023. The results of the inspection and three apparent violations were provided to you in the subject inspection report, dated April 25, 2023, Agencywide Documents Access and Management System (ADAMS) Accession No. ML23087A302.

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 mediation, or providing a written response before we made our final enforcement decision. In a letter dated May 22, 2023 (ML23158A126), you provided a written response to the apparent violations. In a letter dated June 2, 2023 (ML23172A297), you provided a supplemental written response.

Based on the information developed during the inspection and the information you provided in your May 22 and June 2, 2023, written responses to the inspection report, the NRC has determined that three violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding the violations are described in detail in the subject inspection report. The violations involve the failure to: (A) ensure that written directives for permanent implant brachytherapy contained the information required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40(b)(6); (B) implement a radiation protection program commensurate with the scope and extent of licensed activities required by 10 CFR 20.1101(a); and (C) submit a written report within 30 days after learning of doses in excess of the occupational dose limits for adults as required by 10 CFR 20.2203(a)(2)(i).

The NRC considers Violation A to be a significant violation because the failure to ensure that written directives for permanent implant brachytherapy contained all the required information could have resulted in an adverse medical event. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. 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 \$8,750 is considered for a Severity Level III violation.

Because your facility has not been the subject of an escalated enforcement action within the last two routine 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 the prompt and comprehensive corrective actions you implemented. Your corrective actions to address the violation are documented in NRC Inspection Report 030-32263/2022-001 and in your letters dated May 22 and June 2, 2023.

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

The NRC considers Violations B and C to be violations of low safety significance. Therefore, these violations have been categorized in accordance with the NRC Enforcement Policy at Severity Level IV.

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 030-32263/2022-001 and in your letters dated May 22 and June 2, 2023. 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 "Agency 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 and from 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 Dr. Lizette Roldán-Otero of my staff, at 817-200-1455.

Sincerely,



Signed by Lewis, Robert  
on 07/19/23

Robert J. Lewis  
Regional Administrator (Acting)  
Region IV

Docket No. 030-32263  
License No. 11-27306-01

Enclosure:  
Notice of Violation

cc w/enclosure:

Landry Austin  
Radiation Control Program Director  
Idaho Department of Environmental Quality  
900 North Skyline Drive, Suite B  
Idaho Falls, ID 83402  
[Landry.Austin@deq.idaho.gov](mailto:Landry.Austin@deq.idaho.gov)

SAINT ALPHONSUS HEALTH SYSTEM - NOTICE OF VIOLATION, NRC INSPECTION  
 REPORT 030-32263/2022-001 - DATED JULY 19, 2023

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## NOTICE OF VIOLATION

Saint Alphonsus Health System  
Boise, Idaho

Docket No. 030-32263  
License No. 11-27306-01  
EA-23-012

During an NRC inspection conducted on October 19-21, 2022, with continued in-office review through March 20, 2023, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.40(b)(6) requires, in part, that the written directive for permanent implant brachytherapy must contain the following information: (i) before implantation: the treatment site, the radionuclide, and the total source strength; and (ii) after implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date.

Contrary to the above, between April 26, 2021, and October 19, 2022, the licensee failed to ensure that written directives for permanent implant brachytherapy contained the following information: (i) before implantation: the treatment site, the radionuclide, and the total source strength; and (ii) after implantation: the treatment site, the number of sources implanted, the total source strength implanted, and the date. Specifically, for four permanent implant brachytherapy procedures using cesium-131 GammaTile®: (1) four before implantation written directives contained the total source strength based on treatment “expectations” including the planned source strength plus extra sources, rather than the total source strength from the treatment plan; (2) one after implantation written directive contained an incorrect value for total source strength implanted; and (3) one after implantation written directive contained the total source strength implanted in dose-based units of air kerma rather than in units of activity.

This is a Severity Level III Violation (Enforcement Policy Section 6.3.c.2).

- 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 sufficient to ensure compliance with 10 CFR Part 20.

Licensee policy “ALARA (As Low As Reasonably Achievable) – SAHS [Saint Alphonsus Health System],” dated February 5, 2019, Section IV, “Procedure,” Subsection C, “ALARA Program Implementation,” Item 8, “Effective dose in X-ray,” states, in part, that effective dose equivalents may be calculated for exposures received in x-ray and fluoroscopy during which body shielding is worn using Webster’s equation.

Contrary to the above, from December 18, 2020, to October 19, 2022, the licensee failed to implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with 10 CFR Part 20. Specifically, the licensee’s policy “ALARA (As Low As Reasonably Achievable) – SAHS,” did not include adequate provisions for the licensee to identify when or how to apply correction factors to adjust occupational dose for personnel wearing lead shielding.

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

Enclosure

- C. 10 CFR 20.2203(a)(2)(i) requires, in part, that a 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 October 4, 2022, to January 10, 2023, the licensee failed to 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. Specifically, on September 4, 2022, the licensee determined that an individual had received an occupational dose in excess of the occupational dose limits for adults in 10 CFR 20.1201. The licensee was therefore required to submit a written report by October 4, 2022 (within 30 days) but failed to do so until January 10, 2023.

This is a Severity Level IV Violation (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 030-32263/2022-001 and in your letters dated May 22 and June 2, 2023. 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. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-23-012," 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 East Lamar Blvd., Arlington, Texas 76011-4511, and email it to [R4Enforcement@nrc.gov](mailto:R4Enforcement@nrc.gov).

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 Agencywide Documents Access and Management System (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 are required to post this Notice of Violation within 2 working days of receipt.

Dated this 19th day of July 2023