



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

October 21, 2024

Jose-Louis A. Cueva, Radiation Safety Officer
Providence Alaska Medical Center
3200 Providence Drive
Anchorage, AK 99519-6604

SUBJECT: PROVIDENCE ALASKA MEDICAL CENTER, NRC INSPECTION REPORT
030-13426/2023-001, NOTICE OF VIOLATION

Dear Jose-Louis Cueva:

This letter refers to the routine announced inspection that was conducted on April 5, 2023, at your facility in Anchorage, Alaska. The inspection was performed 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 the conditions of your license. Additionally, the inspectors reviewed licensed activities pertaining to open violations from previous NRC Inspection Reports (IR). Within these areas, the inspection consisted of an examination of selected procedures and representative records, observation of licensed activities, independent radiation measurements, and interviews with personnel.

The inspectors discussed the preliminary inspection findings with Mark Winslow, PhD, temporary Radiation Safety Officer, at the conclusion of the onsite portion of the inspection. On October 11, 2024, a final exit briefing was conducted via telephone with you to discuss the results of the inspection.

Based on the results of this inspection, one Severity Level IV violation of NRC requirements was identified. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation is cited in the enclosed Notice of Violation (Notice) because it was identified by the NRC during the inspection. The violation involved failure to have written directives for sodium iodide I-131 be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries, and failure to assure that written directives contained the dosage to be administered.

The inspectors also reviewed open violations from previous NRC inspections, which consisted of two violations from IR 030-13426/2017-001, two violations from IR 030-13426/2018-001, and four violations from IR 030-13426/2018-002. The inspectors' review of these violations is summarized as follows:

- IR 030-13426/2017-001: Violation A and Violation B were related to the former yttrium-90 administration program, which was subsequently discontinued, and the authorization removed from your license. As a result, these violations are considered closed.

- IR 030-13426/2018-001: Violation A was related to written directives for sodium iodide I-131 administrations. There was a recurrence of this violation that is described in the attached Notice. Accordingly, the violation remains open.
- IR 030-13426/2018-001: Violation B was related to not equipping the high dose rate remote afterloader (HDR) with a treatment room door. The licensee subsequently requested an exemption from Title 10 of the *Code of Federal Regulations* (10 CFR) 35.615(a) and (b). The NRC granted the exemption request and imposed a license condition regarding the actions required to be taken by the licensee in lieu of having a physical door at the entrance to the HDR treatment room. The inspectors found that the licensee was implementing the license condition as required. As a result, this violation is considered closed.
- IR 030-13426/2018-002: Violations A, B, C, and D were related to the licensee's implementation of various requirements regarding its personnel monitoring program. At the time of the inspection, the temporary Radiation Safety Officer did not have access to the personnel monitoring program records. As a result, these violations were not able to be adequately reviewed during the inspection and remain open.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice on the NRC website at: <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. Information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be (was) achieved should be addressed. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Agency 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's 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.

If you have any questions concerning this matter, please contact Dr. Janine F. Katanic, CHP, of my staff at 817-200-1151.

Sincerely,



Signed by Roldán-Otero, Lizette
on 10/21/24

Lizette Roldán-Otero, PhD, Branch Chief
Materials Inspection Branch
Division of Radiological Safety and Security

J. Cueva

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Docket No. 030-13426
License No. 50-17838-01

Enclosure:
Notice of Violation (Notice)

cc w/Enclosure:
Irene Casares
Radiological Health Physicist
Alaska State Public Health Laboratories
5455 Dr. Martin Luther King Jr. Avenue
Anchorage AK 99507

PROVIDENCE ALASKA MEDICAL CENTER, NRC INSPECTION REPORT 030-13426/2023-001, NOTICE OF VIOLATION – DATED OCTOBER 21, 2024

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DOCUMENT NAME: PROVIDENCE ALASKA MEDICAL CENTER, NRC INSPECTION REPORT 030-13426/2023-001, NOTICE OF VIOLATION

ADAMS ACCESSION NUMBER: **ML24295A347**

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NOTICE OF VIOLATION

Providence Alaska Medical Center
Anchorage, AK

Docket No.: 030-13426
License No.: 50-17838-01

During an NRC inspection that was performed on April 5, 2023, at the licensee's facility in Anchorage, Alaska, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

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 I-131 sodium iodide greater than 30 microcuries.

10 CFR 35.40(b)(1) requires, in part, that the written directive must contain the patient or human research subject's name, and for any administration of quantities greater than 30 microcuries of sodium iodide I-131, the dosage.

Contrary to the above, from January 31, 2021- April 5, 2023, the licensee failed to have written directives dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 30 microcuries, and failed to have a written directive for I-131 sodium iodide contain the dosage, as evidenced by the following two examples:

- (1) One written directive for an administration of I-131 sodium iodide that was signed and dated by an authorized user on July 6, 2021, did not have the units of activity to indicate the dosage.
- (2) One written directive for an administration of 18 millicuries of I-131 sodium iodide was signed and dated by an authorized user on October 11, 2021, but the administration was performed on October 9, 2021.

This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3.d.1).

Pursuant to the provisions of 10 CFR 2.201, Providence Alaska Medical Center, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Director, Division of Radiological Safety and Security, U.S. Nuclear Regulatory Commission Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011, and emailed to Lizette.Roldan-Otero@nrc.gov within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (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 was or will be achieved.

Your response may reference or include previous 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.

Attachment

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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 withholding of such material, 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 may be required to post this Notice within 2 working days of receipt.

Dated this 21 day of October 2024