



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

June 13, 2022

Mr. Gregg Oishi
Senior Vice President
and Chief Administrative Officer
Kuakini Medical Center
347 North Kuakini Street
Honolulu, Hawaii 96817

SUBJECT: NRC INSPECTION REPORT 030-13337/2022-001; AND NOTICE OF VIOLATION

Dear Mr. Oishi:

This letter refers to the announced routine inspection that was performed on April 14, 2022, at your facility in Honolulu, Hawaii. The inspection was an examination of activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observation of licensed activities, independent radiation measurements, and interviews with personnel. The inspector discussed the preliminary inspection findings with Mr. Harold F. Palmer, Radiation Safety Officer (RSO), at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted telephonically with Mr. Chris McIntire, Imaging and Cardiac Catherization Manager, Mr. Palmer, and you on June 8, 2022.

Based on the results of this inspection, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy which can be found at the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violations are cited in the enclosed Notice of Violation (Notice) because they were identified by the NRC during the inspection. The violations involved failures to: (1) ensure that written directives for administrations of sodium iodide iodine-131 contained the required information, and (2) perform a prospective evaluation demonstrating that occupationally exposed individuals were not likely to receive, in 1 year, a radiation dose in excess of NRC's limits, or provide dosimetry to the individuals.

During the inspection, the NRC also reviewed the corrective actions taken to address one violation identified during the NRC inspection conducted at your facility in Honolulu, Hawaii, in May 2018. The violation involved the failure to monitor packages for radioactive contamination before discarding. With respect to this violation, the current inspection determined that compliance was restored and has been maintained. The violation is considered closed.

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, will be made available electronically for public inspection in the NRC Public Document Room or from 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.

Should you have any questions regarding this letter or the enclosed Notice, please contact Dr. Janine F. Katanic, CHP, at (817) 200-1151, or the undersigned at (817) 200-1455.

Sincerely,



Signed by Roldan-Otero, Lizette
on 06/13/22

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

Docket No. 030-13337
License No. 53-17797-01

Enclosure:
Notice of Violation

cc w/Enclosure:
Thomas Lileikis, Chief
Hawaii State Department of Health
Indoor and Radiological Health Branch
99-945 Halawa Valley Street
Aiea, HI 96701

SUBJECT: NRC INSPECTION 030-13337/2022-001; AND NOTICE OF VIOLATION – DATED
JUNE 13, 2022

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ADAMS ACCESSION NUMBER: **ML22164A796**

SUNSI Review: ADAMS: Non-Publicly Available and Sensitive
By: JFK Yes No Publicly Available and non-sensitive

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NOTICE OF VIOLATION

Kuakini Medical Center
Honolulu, HI

Docket No. 030-13337
License No. 53-17797-01

During an NRC inspection that performed on April 14, 2022, at the licensee's facility in Honolulu, Hawaii, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.40(b)(1) requires, in part, that the written directive must contain, for any administration of a quantities greater than 30 microcuries of sodium iodide iodine-131: the dosage.

Contrary to the above, on January 9, 2018, and February 12, 2020, the licensee failed to ensure that written directives for administrations of quantities greater than 30 microcuries of sodium iodide iodine-131 contained the dosage. Specifically, two written directives for administrations of quantities greater than 30 microcuries of sodium iodide iodine-131 did not contain the dosage, in that the written directives did not indicate the units of activity to specify the dosage.

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

- B. License Condition 16 of NRC Materials License No. 53-17797-01, Amendment No. 42, requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, of Application dated March 18, 2014.

Application dated March 18, 2014, Item 10, "Occupational Dose," states, in part, that the licensee will either perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under "Criteria" in NUREG-1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2008.

Contrary to the above, from May 30, 2018, to April 14, 2022, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, of Application dated March 18, 2014. Specifically, for contracted or temporary nuclear medicine and PET/CT technologists, the licensee failed to either: (1) perform a prospective evaluation demonstrating that the individuals were not likely to receive, in one year, a radiation dose in excess of 10 percent of the allowable limits in 10 CFR Part 20, or (2) provide dosimetry that met the requirements listed under "Criteria" in NUREG-1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees," dated October 2008.

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

Pursuant to 10 CFR 2.201, Kuakini Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control

Enclosure

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, 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 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.

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 13th day of June 2022