



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

June 22, 2021

Mr. Ron Frick  
Radiation Safety Officer  
The Cancer Center of Hawaii, LLC  
2226 Liliha Street  
Honolulu, HI 96817

SUBJECT: NRC INSPECTION 030-36775/2021-001 AND NOTICE OF VIOLATION

Dear Mr. Frick:

This letter refers to the remote inspection conducted from April 21, 2021, through June 9, 2021, of licensed activities performed out of 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) rules, regulations, and with the conditions of your license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, and interviews with personnel. The exit meeting with you was held on June 9, 2021.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy, a copy of the Policy can be found on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation involved a failure to develop and implement written procedures, for administrations requiring a written directive, in determining whether medical events occurred and in comparing the post implant source strength to a total source strength administered outside the treatment site. The violation is cited in the enclosed Notice of Violation (Notice) because it was identified by the NRC.

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 9628, "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 or 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.

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 personal privacy or proprietary information is necessary to provide an acceptable response, 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 information, 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 Title 10 of the *Code of Federal Regulations* (CFR) 2.390(b) to support a request for withholding confidential commercial or financial information).

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 the NRC's ADAMS, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Should you have any questions regarding this letter or the enclosed Notice, please contact Jason Dykert at 817-200-1427 or the undersigned by email at [Lizette.Roldan-Otero@nrc.gov](mailto:Lizette.Roldan-Otero@nrc.gov) or at 817-200-1455.

Sincerely,



Gaddy, Vincent signing on behalf  
of Roldan-Otero, Lizette  
on 06/22/21

Lizette Roldan-Otero, Ph.D., Chief  
Materials Licensing and Inspection Branch  
Division of Nuclear Materials Safety

Docket No. 030-36775  
License No. 53-27797-01

Enclosure:  
Notice of Violation

cc w/ Enclosure:

Daryn A. Yamada  
State of Hawaii Department of Health  
Indoor & Radiological Health Branch

SUBJECT: NRC INSPECTION 030-36775/2021-001 AND NOTICE OF VIOLATION DATED  
JUNE 22, 2021

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NRC-002

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## NOTICE OF VIOLATION

The Cancer Center of Hawaii, LLC  
Honolulu, HI

Docket No. 030-36775  
License No. 53-27797-01

During an NRC inspection conducted from April 21, 2021, through June 9, 2021, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 35.41(b)(5) and (b)(6) requires, in part, for any administration requiring a written directive, that the licensee shall develop, implement, and maintain written procedures that must address, at a minimum: (1) Determining if a medical event, as defined by 10 CFR 35.3045, has occurred; and (2) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.

Contrary to the above, since January 14, 2019, the licensee failed to develop and implement written procedures that addressed, at a minimum: Determining if a medical event, as defined by 10 CFR 35.3045, has occurred; and Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented. Specifically, for administrations requiring a written directive, the licensee's procedures did not address: (1) making and documenting the determination if a medical event had occurred; or (2) for permanent implant brachytherapy, a determination documenting the comparison of the documented post-implant total source strength to the total source strength administered outside the treatment site.

This is a Severity Level IV violation (Section 6.3)

Pursuant to the provisions of 10 CFR 2.201, The Cancer Center of Hawaii, LLC 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 Regional Administrator, Region IV, 1600 E. Lamar Blvd., Arlington, Texas 76011, 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 violations, 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 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, an order or a Demand for Information may be issued requiring information as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Enclosure

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 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.

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).

Dated this 21 day of June 2021