



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

June 30, 2020

EA-20-010

Julio Diaz Padilla, M.D., RSC Chair
Centro Comprensivo de la Cancer de la UPR
P.O. Box 363027
San Juan, Puerto Rico 00936-3027

SUBJECT: CENTRO COMPRESIVO DE CANCER DE LA UPR (CCCUPR) - NOTICE OF VIOLATION - NRC INSPECTION REPORT NO. 03038890/2019001

Dear Dr. Diaz:

This letter refers to the inspection conducted on November 21, 2019, and February 27, 2020, at the Centro Comprensivo de Cancer de la UPR (CCCUPR) facility in San Juan, Puerto Rico, with continued in-office review through April 30, 2020. The purpose of the inspection was to examine CCCUPR's licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the conditions of CCCUPR's license.

Based on the results of the inspection, two apparent violations (AVs) were identified. The AVs were discussed in the U.S. Nuclear Regulatory Commission (NRC) letter sent to you on May 5, 2020, (ML20126G437).¹ The first AV (AV1) involved CCCUPR's failure to maintain or adequately control a high dose rate remote afterloader (HDR) unit, the HDR console, the console keys, and the HDR treatment room when it was not in use or was unattended. Specifically, on November 21, 2019, a CCCUPR medical physicist left the treatment room area for 5-10 minutes and, during that time, inadvertently left the HDR console keys in the console and the key securing the HDR unit, as well as the key and keycard used to access the outer door of the HDR unit room/vault, unsecured on the desk. The second AV (AV2) involved the resultant failure by CCCUPR to secure from unauthorized removal or access licensed material that was stored in a controlled or unrestricted area when the HDR unit (containing licensed material), and the key and keycard to access the room in which the unit was stored, were left unsecured.

In the NRC letter dated May 5, 2020, we requested that you provide a written response with information about CCCUPR's corrective actions for the AVs before we made our final enforcement decision. We also provided you the opportunity to alternatively address the AVs by attending a pre-decisional enforcement conference or requesting Alternative Dispute Resolution. In a letter dated May 29, 2020 (ML20155K869), Dr. Marcia Cruz Correa, CCCUPR's Executive Director, provided a response to the apparent violations and described the actions taken and planned by CCCUPR in response to these issues, as further described below.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS.

Based on the information developed during the inspection, and the information provided in your May 29, 2020, response, the NRC has determined that the violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them were described in detail in the subject inspection report.

As described above, the first violation involved CCCUPR's failure to secure an HDR unit, the console, the console keys, and the treatment room when not in use or unattended. This violation has been categorized at Severity Level (SL) III in accordance with the NRC's Enforcement Policy because the HDR contains a significant quantity of radioactive material, and failure to secure the unit and the controls used to operate it could have resulted in unqualified or unauthorized individuals accessing or utilizing the device and, potentially, exposing themselves or others to radiation. The second violation involved CCCUPR's failure to secure licensed material from unauthorized removal or access when the HDR was left unsecured. This violation has been similarly categorized at SL III based on consideration of the amount of radioactive material within the HDR, which could have presented a security or safety concern if the material or unit had been removed by unauthorized individuals.

Because these two violations are related, they have been categorized collectively as a single SL III problem. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$7,500 is considered for a SL III problem. Because your facility has not been the subject of escalated enforcement actions within the last two 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 Enforcement Policy. The NRC determined that corrective action credit was warranted for CCCUPR's actions taken to address the problem. These actions included retraining staff on security requirements for the HDR and instituting more stringent requirements for the security of the HDR keys and the keycard. The licensee also revised its procedure to document the revised controls and committed to increase inspection of the program by the Radiation Safety Officer.

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 SL III problem violation constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

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 Inspection Report No. 03038890/2019001 and in the letter from CCCUPR dated May 29, 2020. 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 "Rules of Practice," 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 from the NRC's document 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, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Please feel free to contact Mr. Shawn Seeley of my staff at shawn.seeley@nrc.gov if you have any questions.

Sincerely,

David C. Lew
Regional Administrator

Docket No.: 03038890
License No.: 52-35242-02

Enclosure:
Notice of Violation

Cc w/ encl:
Carmelo Perez, RSO
Commonwealth of Puerto Rico

SUBJECT: CENTRO COMPRENSIVO DE CANCER DE LA UPR CCCUPR) - NOTICE OF VIOLATION - NRC INSPECTION REPORT NO. 03038890/2019001 DATED: JUNE 30, 2020

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ML20156A327

DOCUMENT NAME: [https://usnrc-my.sharepoint.com/personal/mmm3_nrc_gov/Documents/MMM3/Shared Enforcement/Final Actions/CCCUPR NOV-III EA-20-010 ML20156A327.docx](https://usnrc-my.sharepoint.com/personal/mmm3_nrc_gov/Documents/MMM3/Shared%20Enforcement/Final%20Actions/CCCUPR%20NOV-III%20EA-20-010%20ML20156A327.docx)

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ENCLOSURE 1

NOTICE OF VIOLATION

Centro Comprensivo de Cancer de la UPR
San Juan, Puerto Rico

Docket No. 03038890
License No. 52-35242-02
EA-20-010

During an NRC inspection conducted on November 21, 2019, and February 27, 2020, with continued in-office review through April 30, 2020, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.610(a)(1) requires that for remote afterloader units, licensees must secure the unit, the console, the console keys, and the treatment room when not in use or unattended.

Contrary to the above, on November 21, 2019, Centro Comprensivo de Cancer de la UPR (CCCUPR) did not secure the unit, the console, the console keys, and the treatment room when not in use or unattended. Specifically, a CCCUPR medical physicist left the high dose rate remote afterloader (HDR) treatment room area for 5-10 minutes and left the HDR unit console keys in the console and the key securing the HDR unit, as well as the key and keycard used to access the outer door of the HDR unit room/vault, unsecured on the desk.

- B. 10 CFR 20.1801 requires that licensees secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, on November 21, 2019, CCCUPR did not secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas. Specifically, a high dose rate remote afterloader (HDR) unit containing licensed material was stored in the HDR unit room/vault, which was a controlled area. A CCCUPR medical physicist left the area for 5-10 minutes and left the key securing the HDR unit as well as the key and keycard used to access the outer door of the HDR unit room/vault unsecured on the desk where they could have been retrieved and used to access and remove the material.

This is a Severity Level III problem (Enforcement Policy Section 6.7)

The NRC has concluded that information regarding the reasons for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report No. 03038890/2019001 and in the letter from CCCUPR dated May 29, 2020. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation (EA-20-010)," 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 I, 2100 Renaissance Blvd. King of

Prussia, PA 19406, and a copy to the Document Control Desk, Washington, DC 20555-0001 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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.

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 Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 30th day of June, 2020.