UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

May 5, 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 COMPRENSIVO DE CANCER DE LA UPR (CCCUPR) - NRC INSPECTION REPORT 03038890/2019001, SAN JUAN, PUERTO RICO

Dear Dr. Diaz:

On November 21, 2019, and February 27, 2020, with continued in-office review through April 30, 2020, Shawn Seeley and Jonathan Pfingsten of this office conducted a routine inspection of your activities performed under your Nuclear Regulatory Commission (NRC) broad scope license No. 52-35242-02, at your facilities in in San Juan, Puerto Rico. The inspectors discussed the preliminary inspection findings with Carmelo Perez, Radiation Safety Officer, and you at the conclusion of the on-site portion of the inspection on November 21, 2019. A final exit briefing was conducted (telephonically) with you and Carmelo Perez on April 30, 2020.

Based on the results of this inspection, the NRC determined that two apparent violations of NRC requirements occurred related to the failure to secure licensed material from unauthorized removal or access and for failing to secure the keys to access the high dose rate remote afterloader (HDR) console, vault door, and the HDR unit. These apparent violations are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further review. You will be advised by separate correspondence of the results of our deliberations on this matter. The circumstances surrounding the apparent violations, the significance of the issues, and the need for lasting and effective corrective actions were discussed with members of your staff at the inspection exit meeting at the conclusion of the on-site inspection and during the April 30, 2020, telephone call.

Before the NRC makes its enforcement decision regarding the apparent violations, we request that you provide additional information regarding CCCUPR's corrective actions for this event. Although we noted that your immediate corrective actions to control and secure the keys and licensed material appeared to be effective, it is not clear if adequate actions to prevent recurrence have been developed and/or implemented.

The written response should be sent to the NRC within 30 days of the date of this letter. The NRC recognizes that many licensees have been impacted by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). Consequently, you may request an

extension of time to submit the response by contacting Donna Janda, Chief, Medical and Licensing Assistance Branch, via electronic mail at donna.janda@nrc.gov. Such an extension request should explain the basis for the request and should specify the amount of additional time being requested. This extension request must be submitted to the NRC no later than 20 days from the date of this letter (i.e., at least 10 days before the initial 30-day deadline to submit the written response).

Your response should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (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 previously docketed correspondence, if the correspondence adequately addresses the required response. You should clearly mark the response as a "Response to Apparent Violations in NRC Inspection Report No. 03038890/2019001; 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, NRC Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a pre-decisional enforcement conference (PEC).

In lieu of providing this written response, you may choose to provide your perspective on this matter, including the significance, cause, and corrective actions, as well as any other information that you believe the NRC should take into consideration by: (1) requesting a PEC to meet with the NRC and provide your views in person; or (2) requesting Alternative Dispute Resolution (ADR).

If you choose to request a PEC, the meeting should be held within 30 days of the date of this letter, although this timeframe may be extended due to impacts from COVID-19. The conference will include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the PEC may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. "In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. Please note that if a PEC is held, the NRC would issue a press release to announce the conference time and date.

In lieu of a PEC or written response, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation; a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC program as a neutral third party. Please contact ICR

at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. The ADR mediation session should be held within 45 days of the date of this letter, although this timeframe may be extended due to impacts from COVID-19. The mediation session would be closed to public observation, but the time and date would be publicly-announced.

Please contact Ms. Janda at donna.janda@nrc.gov within **10 days** of the date of this letter to notify the NRC which of the above options you choose. If you do not contact the NRC within the time specified, and an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

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 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, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you have any questions concerning this matter, please contact Shawn Seeley of my staff at shawn.seeley@nrc.gov.

Sincerely,

James M. Trapp

Digitally signed by James M. Trapp
Date: 2020.05.05 12:22:40 -04'00'

James M. Trapp, Director
Division of Nuclear Materials Safety

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

Enclosures:
Inspection Report 03038890/2019001
NRC Information Notice 96-28

cc w/Encl: Carmelo Perez, RSO
Commonwealth of Puerto Rico

CENTRO COMPRENSIVO DE CANCER DE LA UPR - NRC INSPECTION REPORT 03038890/2019001, SAN JUAN, PUERTO RICO DATED May 4, 2020 .

ADAMS (PARS)
J Peralta, OE
L Sreenivas, OE
N Hasan, OE
S Rodriguez, OE
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R Sun, NMSS
J Trapp, NMSS, RI
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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03038890/2019001
Docket No.	03038890
License No.	52-35242-02
EA No.	EA-20-010
Licensee:	Centro Comprensivo de Cancer de la UPR (CCCUPR)
Address:	POB 363027 San Juan, PR 00936-3027
Inspection Dates:	November 21, 2019, through April 30, 2020
Exit Meeting:	April 30, 2020

Inspectors:

Shawn Seeley ***/RA/*** 5/1/20

Shawn Seeley — date
Health Physicist
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

Jonathan Pfingsten ***/RA/*** 4/30/20

Jonathan Pfingsten — date
Health Physicist
Commercial, Industrial, R&D
and Academic Branch
Division of Nuclear Materials Safety

Approved By:

Donna M. Janda ***/RA/*** 5/1/2020

Donna M. Janda, Chief — date
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Centro Comprensivo de Cancer de la UPR (CCCUPR)
NRC Inspection Report No. 03038890/2019001

On November 21, 2019, the NRC conducted a routine unannounced inspection to review the organization and scope of activities performed under Centro Comprensivo de Cancer de la UPR's (CCCUPR) NRC License No. 52-35242-02. CCCUPR is a public hospital in San Juan, Puerto Rico. Subsequently, on February 27, 2020, the NRC conducted a follow-up visit to obtain additional information regarding the details of specific sections of the licensee's security procedure under their NRC license. The NRC license, issued in 2016, authorizes the use of radioactive material for activities conducted under 10 CFR Part 35.100, 200, and 300 and use of high dose rate remote afterloader (HDR) and low dose rate remote afterloader (LDR) devices for brachytherapy treatments under 10 CFR Part 35.600.

Two apparent violations of NRC requirements were identified and are being considered for escalated enforcement. 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. Furthermore, 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 the unit, the console, the console keys, and the treatment room when not in use or unattended nor did they secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas. Specifically, a CCCUPR medical physicist left the 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 where they could have been retrieved and used to access and remove the material.

Immediate corrective actions included the authorized medical physicist properly securing all keys prior to exiting the area. Further corrective actions included the review and retraining of all HDR personnel on CCCUPR's expectation for key security.

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

The inspectors reviewed the organization and scope of activities performed under Centro Comprensivo de Cancer de la UPR's (CCCUPR) NRC License No. 52-35242-02. Information was gathered through interviews with licensee staff including selected Radiation Safety Committee members; through reviews of selected records; and through tours of CCCUPR facilities.

b. Observations and Findings

CCCUPR is a public hospital in San Juan, Puerto Rico. The NRC license, issued in 2016, authorizes use of radioactive material for activities conducted under 10 CFR Part 35.100, 200, and 300 and use of HDR and low dose rate remote afterloader (LDR) devices for brachytherapy treatments under 10 CFR 35.600. There are seven authorized medical physicists (AMPs) authorized on the license and three authorized users (AUs) for the HDR and LDR programs. There are two AUs for the 35.100, 35.200 & 35.300 programs. The licensee began performing brachytherapy in late 2018 utilizing a Varian GammaMed Plus iX HDR unit, which uses an Ir-192 sealed source of initially 15 curies. There have been no LDR cases since the license was amended to add this authorization.

CCCUPR has two locations in the greater San Juan area. One is located at Centro Medico de Rio Piedras (HDR & LDR uses) and the other is a short distance away at the intersection of PR Routes 18 & 21 (35.100, 200, and 300 uses).

The Radiation Safety Officer for CCCUPR's license is a consultant who is onsite weekly.

c. Conclusions:

No violations of NRC requirements were identified.

2. Review of Licensed Activities

a. Inspection Scope

The inspectors performed an unannounced routine inspection utilizing NRC Inspection Procedures 87130, "Nuclear Medicine Programs, Written Directive Not Required", 87131, "Nuclear Medicine Programs, Written Directive Required," and 87132, "Brachytherapy Programs," to conduct the inspection. Information was gathered through interviews with cognizant personnel, review of records, tours of the facility, and through the performance of independent radiation surveys.

b. Observations and Apparent violations

The inspectors visited the facility located at the intersection of PR Routes 18 & 21 and inspected the licensee activities conducted under 10 CFR Part 35.100, 200, and 300. These programs are staffed with two certified nuclear medicine technologists (CNMT) and utilize two cameras and a hot lab. The licensee receives unit doses from either Lantheus or Cardinal Health daily. They currently perform 3-4 general nuclear medicine studies daily from 7am – 4pm. Their first patient was October 26, 2018. They performed eight (five therapies, one hyperthyroid, and two whole body scans) I-131 administrations requiring a written directive since the facility opened in October 2018. The therapies are all out-patient. The inspectors observed one CNMT demonstrate the receipt of a package. The consultant RSO visits weekly.

The hot lab included appropriate shielding, waste receptacles and a calibrated radiation survey instrument. The licensee possesses and uses a dose calibrator, which is kept calibrated in accordance with the manufacturer's instructions. All radioactive waste is disposed of by decay in storage. The licensee performs daily radiation level and weekly contamination surveys. Occupational exposures were minimal. No contamination was found in either restricted or unrestricted areas.

The following records were reviewed and found to be acceptable: dose calibrator calibrations, sealed source leak tests, sealed source inventories, daily/weekly surveys, waste disposal, DOT training, radiation safety training, instrument calibrations, and dosimetry reports.

The inspectors visited the main facility at Centro Medico de la UPR and inspected the LDR and HDR programs. No LDR brachytherapy has been performed since license inception, but they are optimistic for starting those procedures sometime in 2020.

The licensee's staff (RSO, three authorized users (AUs), AMP and dosimetrist) attended the manufacturer's training for use of the HDR device and emergency response. In addition, the AMP and dosimetrist attended the manufacturer's training on treatment planning and have practiced treatment planning on several cases. The licensee plans to use electronic signatures with administrative rights limited to AUs and AMP. A username and password are required for access to the system. Also, a proximity card lock provides security for the HDR with access limited to those trained and approved. Dose rates around the HDR were within regulatory limits. Dosimetry is provided and results were minimal for all staff. The inspector observed the AMP perform spot-checks, calibrations, and emergency response. Additionally, the inspectors were able to observe one HDR patient treated during the inspection.

The inspectors observed that after the daily testing and verification of alarms and prior to the patient treatment, the AMP left the HDR treatment room area for 5-10 minutes. He 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 where they could have been retrieved and used to access and remove the material. Two apparent violations of NRC requirements were identified and are being considered for escalated enforcement action. 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. Furthermore, 10 CFR 20.1801 requires that licensees secure from unauthorized removal or access

licensed materials that are stored in controlled or unrestricted areas. These apparent violations are described below.

Summary of Corrective Actions

Immediate corrective action included the authorized medical physicist properly securing all keys and licensed material prior to exiting the area. Further corrective actions included the review and retraining of all HDR personnel on CCCUPR's expectation for key security.

c. Conclusions

Two apparent violations of NRC requirements were identified and are being considered for escalated enforcement action:

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.

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 after loader (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.

3. Exit Meeting

On April 30, 2020, the inspector presented the results of the inspection by telephone. The licensee acknowledged the apparent violations.

ATTACHMENT: SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Licensee
#* Carmelo Perez, Radiation Safety Officer
#* Jose Diaz, MD, Authorized User, Radiation Safety Committee Chair
Zhibin (Jonathan) Huang, Ph.D, Authorized Medical Physicist

#Present at entrance meeting on November 21, 2019
*Present at telephone exit meeting on April 30, 2020

INSPECTION PROCEDURES USED

1) Manual Chapter 2800, “Materials Inspection Program”
2) Inspection Procedure 87131, “Inspection of Nuclear Medicine Programs, Written Directive Required”
3) Inspection Procedure 87132, “Inspection of Brachytherapy Programs”

LIST OF NRC SURVEY INSTRUMENTS USED

1) Ludlum Model 2401-P, serial number 181605 (cal date 9/3/19)

2) Ludlum Model 2401-P, serial number 43571G (cal date 6/21/2019)

LIST OF ACRONYMS USED

AMP	Authorized Medical Physicist
AU	Authorized User
CFR	Code of Federal Regulations
CNMT	Certified Nuclear Medicine Technologist
HDR	High Dose Rate remote afterloader
LDR	Low Dose Rate brachytherapy
NRC	Nuclear Regulatory Commission
mR/h	milliRoentgen per hour
RSO	Radiation Safety Officer