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

July 20, 2018

Enid Dohnert, Associate Administrator
Centro de Radioterapia at
Hospital Auxilio Mutuo
Avenida Ponce de Leon, #725
Parada 37 ½
Hato Rey, Puerto Rico 00918

SUBJECT: CENTRO DE RADIOTERAPIA AT HOSPITAL AUXILIO MUTUO, HATO REY, PUERTO RICO - NRC INSPECTION NO. 03036635/2018001 AND NOTICE OF VIOLATION

Dear Ms. Dohnert:

This letter refers to the inspection conducted on February 13, 14, and June 21, 2018, at your Hato Rey, Puerto Rico facility. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

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. The current Enforcement Policy is included on the NRC's Web site at https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The violation is cited in the enclosed Notice of Violation (Notice) because the violation was identified by the NRC.

The NRC has concluded that information regarding: (1) the reason for the violation; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance will be achieved is already adequately addressed on the docket and include: revising procedures, retraining personnel and obtaining new cylinder sets for use. Therefore, you are not required to respond to this letter unless the description herein 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 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 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.

If you have any questions regarding this matter, please contact Shawn Seeley of my staff at 610-337-5102 or via electronic mail at shawn.seeley@nrc.gov.

Thank you for your cooperation.

Sincerely,

Donna M. Janda

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

Docket No. 03036635
License No. 52-30391-01

Enclosures:
1. Notice of Violation
2. Inspection Report No. 03036635/2018001

cc w/ enclosures: Luis Rivera, M.M.Sc., RSO
Commonwealth of Puerto Rico
Douglas Einstein, M.D.

CENTRO DE RADIOTERAPIA AT HOSPITAL AUXILIO MUTUO, HATO REY, PUERTO RICO - NRC INSPECTION NO. 03036635/2018001 AND NOTICE OF VIOLATION DATED July 20, 2018

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NOTICE OF VIOLATION

Centro de Radioterapia at Hospital Auxilio Mutuo
Hato Rey, PR

Docket No. 03036635
License No. 52-30937-01

During an NRC inspection conducted on February 13, 2018, through June 21, 2018, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

> 10 CFR 35.41(a) requires, in part, that the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.
>
> Centro de Radioterapia implementing procedure, "Procedure for Brachytherapy High Dose Rate (HDR) for Gynecological Cancer," revised in June 2016, directed the licensee's process for performing brachytherapy. Section III, "Brachytherapy with Cylinder," Step 2.b required a doctor (the authorized medical user) to place the cylinder utilized for the cancer treatment into the patient.
>
> Contrary to the above, on or about January 11-24, 2018, the licensee did not develop or implement an adequate written procedure to provide high confidence that each administration was in accordance with the written directive. Specifically, during the administration of three treatment fractions, an attending nurse, rather than a doctor, inserted the cylinder into the patient. Although the procedure required verification of placement of the cylinder, the patient's position was changed prior to treatment and the procedure did not require subsequent verification of the placement prior to connecting to the HDR unit. Consequently, the licensee did not identify that the cylinder had moved from its intended location, resulting in the patient not receiving the dose prescribed in the written directive, which the licensee identified on February 8, 2018, constituted a medical event.
>
> This is a Severity Level IV violation (Enforcement Policy 6.3.d.1).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence and the date when full compliance will be achieved is already adequately addressed on the docket. 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, 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 to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary,

or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 20th day of July 2018

U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03036635/2018001
Docket No.	030-36635
License No.	52-30937-01
Licensee:	Centro de Radioterapia at Hospital Auxilio Mutuo
Location:	Avenida Ponce de Leon, #725, Hato Rey, Puerto Rico
Inspection Dates:	February 13 – June 21, 2018

Shawn Seeley, Health Physicist — Date 7/20/18
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

Approved By:

Donna Janda, Chief — Date 7/20/18
Medical and Licensing Assistance Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Centro de Radioterapia at Hospital Auxilio Mutuo
NRC Inspection Report No. 03036635/2018001

A routine, announced inspection was conducted at Centro de Radioterapia (CDR) at Hospital Auxilio Mutuo facilities located in Hato Rey, Puerto Rico on February 13 -14 and June 21, 2018. The inspection was announced due to a medical event that occurred on January 24, 2018. The inspection was performed in accordance with NRC Inspection Procedures 87103, "Inspection of Material Licensees Involved In An Incident Or Bankruptcy Filing," 87132, "Brachytherapy Programs," and Management Directive (MD) Handbook 8.1, "Abnormal Occurrence Reporting Procedure." The inspection also included an independent assessment of the medical event by a consultant physician.

The inspector conducted interviews with CDR personnel, observed day-to-day operations, toured CDR's facilities, and reviewed documents and procedures. Based on the results of this inspection, one apparent violation of NRC requirements was identified. Specifically, the licensee had discovered, and subsequently determined on February 8, 2018, that a medical event had occurred on January 24, 2018, prior to the third fraction of an HDR treatment. The event occurred, in part, as a result of the licensee staff not following their own procedures during either of the first two treatment fractions on January 11 & 19, 2018, respectively.

REPORT DETAILS

1. Organization, Oversight, and Scope of the Program

a. Inspection Scope

A routine, announced inspection was conducted at Centro de Radioterapia (CDR) at Hospital Auxilio Mutuo facilities located in Hato Rey, Puerto Rico on February 13, 2018, through June 21, 2018. The inspection was announced due to a medical event that was reported on February 8, 2018 (occurred on January 24, 2018). The inspection was performed in accordance with NRC Inspection Procedures 87103, "Inspection of Material Licensees Involved In An Incident Or Bankruptcy Filing," 87132, "Brachytherapy Programs," and Management Directive (MD) Handbook 8.1, "Abnormal Occurrence Reporting Procedure." The inspection also included an independent assessment of the medical event by a consultant physician.

The following focus areas were reviewed:

Procedure 87103: guidance elements 04.03 – 04.11;
Procedure 87132 guidance areas 03.01 – 03.08; and
Reporting Guidance in MD 8.1 associated handbook – DH 8.1

The inspector conducted interviews with CDR personnel, observed day-to-day operations, toured CDR's facilities, and reviewed documents and procedures.

b. Observations and Findings

Program Scope

Centro de Radioterapia is authorized for use of a high dose rate remote after loading unit (HDR) permitted by 10 CFR 35.600. The licensee uses a Varian Medical Systems GammaMedplus iX HDR unit. A Varian treatment planning system was part of the upgrade when the licensee upgraded their HDR treatment unit. There are four authorized users (AUs) and two authorized medical physicists (AMPs). The licensee has a very active HDR program and treats 8-10 patients per week. Almost all of the patients are gynecological cases using vaginal cylinders, interstitial applicators, and tandem and ovoids.

The treatment unit is housed in a dedicated treatment room. Preparation for a patient treatment was observed during the onsite inspections on February 14 and June 21. The inspector observed three vaginal cylinder and two tandem and ovoid procedures. CT scans were obtained after the applicators were placed. The CT images were imported into the treatment planning computer and a final treatment plan was generated.

The written directive for each patient was checked for completeness by the AU and the AMP. Both the AU and the AMP were present for treatment planning and subsequent treatment. The daily spot check was performed early in the day, prior to the treatment. There were no issues identified during the observed treatments.

A sampling of the following records was reviewed for compliance: quarterly receipt/transfer, inventory, leak test, annual audits, written directives/patient files, and instrument calibration. No issues were identified during the review of records.

Medical Event Investigation

The inspector reviewed CDR's initial written report of the medical event that had been reported via telephone on February 8, 2018. Specifically, CDR reported that a medical event had occurred as a result of a dose delivered to a patient's thighs during the second of three treatment fractions for cervical cancer.

The patient received three treatment fractions, approximately one week apart on January 11, 19 and 24, 2018. Prior to the treatment on January 24, the attending nurse noticed a bi-lateral redness on the inner thighs 10-12 cm posterior to the vaginal cuff. At this point it was unclear to all involved whether this was radiation related. The third fraction was administered as planned. The patient was placed on observation and returned on February 6, 2018, when it was noticed that the red area had progressed to a moist desquamation stage indicating that it was a possible radiation exposure. The NRC was notified on February 8, 2018, after the radiation safety committee reviewed the event and determined that a medical event had occurred. CDR staff conducted an internal investigation and determined the event had occurred during the first or second (most likely) fraction. The most likely scenario was that the catheter within the cylinder had become loose and fell out of the cylinder prior to the fraction being administered. Therefore the entire dose was delivered to the inner thighs and not the vagina/cervix as intended. This was also consistent with the length and shape of the affected area, approximately 5 cm in length with a center line of 0.5 cm. This was consistent with the intended treatment length of 5 cm.

The inspector reviewed the case file and interviewed the staff directly involved with the setup and handling of the patient during the first two fractions. The attending nurse on duty the day of the second treatment fraction did not recall anything appearing out of the ordinary, i.e., cylinder or catheter out of place. Upon review of the equipment utilized and the pictures of the affected area, the inspector agreed with the licensee's conclusion that the most likely scenario was the cylinder or catheter slid out after the CT scan was taken to verify correct placement when the patient's legs were lowered and secured prior to treatment.

In April 2018, NRC staff contracted with a medical consultant to review the licensee's event and assess CDR's account and cause(s) of the event. On May 28, 2018, the consultant's final report was received confirming the plausible scenario and dose to the unintended area as reported by CDR.

Upon review of CDR's procedures it was discovered that CDR had revised their brachytherapy cylinder procedure in June 2016 to require the physician to assemble and place the cylinder into the patient. Contrary to this on January 11, 19 and 24, 2018, the nurse assembled and placed the cylinder into the patient. After the event, it was decided that the doctor would assemble and place the device before proceeding with the actual treatment. Furthermore, he or she would double check all connections prior to treatment. During the June 21, 2018, inspection, it was determined that the procedure had been updated to require either the doctor or nurse to assemble and place the cylinder. The procedure was also amended to require an additional step for the AU to

double check all connections and device placement prior to treatment. They also began using a tabletop clamping assembly to secure the source/guide tube/wire in place during the treatment. This is uncomfortable for the patient but gives stability to the equipment during treatment.

Based on the results of this review, one apparent violation of NRC requirements was identified. Specifically, the licensee had discovered, and subsequently determined on February 8, 2018, that a medical event had occurred on January 24, 2018, prior to the third fraction of an HDR treatment. The event occurred, in part, as a result of the licensee staff not following their own procedures during either of the first two treatment fractions on January 11 & 19, 2018, respectively. Specifically, during the administration of three treatment fractions, an attending nurse, rather than a doctor, inserted the cylinder into the patient. Although the procedure required verification of placement of the cylinder, the procedure did not require subsequent verification of the placement if the patient's position was changed prior to connecting the guide tube to the HDR unit before treatment. Consequently, the licensee did not identify that the cylinder had moved from its intended location, resulting in the patient not receiving the dose prescribed in the written directive, which the licensee identified on February 8, 2018, as a medical event.

Corrective actions implemented by the licensee included:

1. On or about February 8, 2018, the licensee conducted a review of their procedures and specified that only the AU was to assemble and place the cylinders into the patient until further notice;
2. On March 6, 2018, the licensee retrained all HDR personnel in the use of the segmented cylinder set;
3. On April 9, 2018, the licensee trained all HDR personnel on the use of the revised protocol for HDR cylinder treatments; this included a revised checklist that included designated spaces for personnel to initial when tasks were performed during treatments, and provided a provision for either the nurse or authorized user to assemble and place the cylinder. The revised procedure also included the use of the tabletop clamping device to secure the tubing in place during treatment; and
4. On April 17, 2018, the licensee trained all HDR personnel in the use of a new (different model) segmented cylinder set.

Radiation Surveys

The inspector observed the licensee's proper use of a survey instrument prior to and after treatment for the presence of material left in the patient. Surveys and leak tests are also performed during the quarterly source exchanges performed by Varian.

Confirmatory surveys were performed at the facility. The storage area and room were surveyed. Readings were well below regulatory limits. No issues were identified.

Occupational Exposure

The licensee utilizes the services of Mirion Technologies for their dosimetry. All staff involved with the treatment were wearing dosimeters. The highest personnel exposure was 23 mrem for 2017, and 20 mrem for 2016. No issues were identified.

Posting and Labeling

The inspector toured the radiation oncology department. All areas of use and storage were properly posted and radioactive materials were properly labelled. No issues were identified.

c. Conclusions

Based on the results of this inspection, one apparent violation of NRC requirements was identified. Specifically, on February 6, 2018, the licensee had discovered, and subsequently determined that a medical event had occurred on January 24, 2018, prior to the third fraction of an HDR treatment. The event occurred, in part, as a result of the licensee staff not following their own procedures during the first two treatment fractions on January 11 & 19, 2018.

10 CFR 35.41(a) requires, in part, that the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Centro de Radioterapia implementing procedure, "Procedure for Brachytherapy High Dose Rate (HDR) for Gynecological Cancer," revised in June 2016, directed the licensee's process for performing brachytherapy. Section III, "Brachytherapy with Cylinder," Step 2.b required a doctor (the authorized medical user) to place the cylinder utilized for the cancer treatment into the patient.

Contrary to the above, on or about January 11-24, 2018, the licensee did not develop or implement an adequate written procedure to provide high confidence that each administration was in accordance with the written directive. Specifically, during the administration of three treatment fractions, an attending nurse, rather than a doctor, inserted the cylinder into the patient. Although the procedure required verification of placement of the cylinder, the patient's position was changed prior to treatment and the procedure did not require subsequent verification of the placement prior to connecting to the HDR unit. Consequently, the licensee did not identify that the cylinder had moved from its intended location, resulting in the patient not receiving the dose prescribed in the written directive, which the licensee identified on February 8, 2018, constituted a medical event.

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

Corrective actions were taken by CDR as documented above.

2. Exit Meeting

At the conclusion of the onsite inspection on June 21, 2018, the inspection findings were discussed with CDR's senior management.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

+*Enid Dohnert, Associate Administrator
+*Luis Rivera, AMP
*Dr. Lawrence Sheplan, MD
Kritsia Rodriguez, RN
Dr. Roberto Santiago, MD
Anais Calero Gonzalez, RN

+Present at entrance meeting
*Present at exit meeting