U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03028869/2011001
Docket No.	03028869
License No.	47-15717-03
Licensee:	Charleston Radiation Therapy Consultants, PLLC
Location:	3100 MacCorkle Avenue S.E., Suite B-1 Charleston, West Virginia 25304
Inspection Date:	April 28, and May 16, 2011 (telephonic exit)
Date Follow-up Information Received:	May 4, 2011

Inspectors: ____/RA by Robin Elliott For/_____05/26/2011 ____
Héctor Bermúdez date
Health Physicist

__**/RA/**_____ ____05/26/2011___
Robin Elliott (in-training) date
Health Physicist

Approved By: ___**/RA/**_____ _____05/26/11_____
Marc S. Ferdas, Chief date
Medical Branch
Division of Nuclear Materials Safety

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EXECUTIVE SUMMARY

Charleston Radiation Therapy Consultants, PLLC
NRC Inspection Report No. 03028869/2011001

A routine, unannounced inspection was conducted at Charleston Radiation Therapy Consultants, PLLC (CRTC) in Charleston, West Virginia on April 28, 2011. Additional information, contained in correspondence from CRTC on May 4, 2011, was also reviewed as part of this inspection. The inspection was performed in accordance with NRC Inspection Procedure 87132 and reviewed activities associated with the use of a high dose rate remote afterloader (HDR) unit. The inspectors conducted interviews with CRTC personnel, observed day-to-day operations, toured the facilities, and reviewed documents and procedures related to the HDR program.

Based on the results of this inspection, two apparent violations of NRC requirements were identified. Specifically,

- CRTC personnel did not perform a determination of the timer linearity over the typical range of use with each full calibration of the HDR unit, as required by 10 CFR 35.633(b)(5); and

- CRTC did not ensure that an authorized user (AU) or a physician under the supervision of an AU, that has been trained in the operation and emergency response for the unit, was physically present during the continuation of patient treatments involving the HDR, as required by 10 CFR 35.615(f)(2)(ii).

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

A routine, unannounced inspection was conducted at the Charleston Radiation Therapy Consultants, PLLC (CRTC) facilities located in Charleston, West Virginia on April 28, 2011. Additional information, contained in correspondence from CRTC on May 4, 2011, was also reviewed as part of this inspection. The inspection was performed in accordance with NRC Inspection Procedure 87132. The following focus areas were reviewed: (i) security and control of licensed material; (ii) shielding of licensed material; (iii) comprehensive safety measures; (iv) radiation dosimetry program; (v) radiation instrumentation and surveys; (vi) radiation safety training and practices; and (vii) management oversight.

The inspectors assessed CRTC's performance associated with the use of the HDR unit. The inspection also included a review of CRTC's management of the radiation safety program, including oversight of activities by the Authorized Medical Physicist (AMP)/Radiation Safety Officer (RSO), the Radiation Safety Committee (RSC), and senior management.

The inspectors conducted interviews with CRTC personnel, observed day-to-day operations, toured the facilities, and reviewed documents and procedures related to the HDR program within CRTC.

b. Observations and Findings

The CRTC program is licensed for 10 CFR 35.600 activities involving HDR brachytherapy and a strontium-90 sealed source which is kept in storage. A dedicated facility is used for the treatments which involve approximately 90% gynecologic treatments, with the remainder of the procedures performed being mammosites and a few bronchial treatments. Approximately 30-40 patients are seen per year. The RSO conducts a review of each patient case as part of CRTC's annual audit. The practice is accredited by the American College of Radiation Oncologists (ACRO) which reviews cases during their accreditation process. There are two AMPs, one Medical Physicist in training and two dosimetrists.

The inspectors observed CRTC personnel perform a spot-check (safety system reliability test) for the HDR facility as they would do prior to each day of use. All safety equipment was operational and passed required tests. Radiation level readings taken in the room with the source in the shielded position verified compliance with public dose limits.

During interviews with CRTC personnel and a review of their full calibration procedure, the inspectors noted that the timer linearity over the typical range of use was not being performed at each full calibration of the unit as required by 10 CFR 35.633(b)(5). Specifically, the timer linearity checks were being performed over a range of zero to 3 minutes. However, the typical range of use was 4-5 minutes for vaginal cylinders and 8-9

minutes for mammosites. In addition, the inspectors reviewed CRTC's records associated with a full calibration test performed on April 5, 2011, and noted that timer linearity testing was not conducted over the typical range of use. The inspectors determined that this was an apparent violation of 10 CFR 35.633(b)(5). CRTC took corrective actions to address this issue, which included performing a timer linearity measurement of 10 minutes prior to the next use of the HDR unit. In addition, the CRTC's Quarterly Quality Assurance sheets were modified to prompt the physicist to conduct these measurements up to 10 minutes at each full calibration.

During the course of the inspection the CRTC personnel described the HDR treatment process. For each treatment, a team consisting of the dosimetrist, HDR nurse, AMP, and the AU prepare the patient and initiate the treatment. It was described that the AU routinely leaves the console area after the treatment has started; and visits the adjacent nurses' station to conduct various tasks or to sometimes see patients in rooms within the department. During treatments the door to the console area is closed to maintain patient privacy. The CRTC personnel stated that the AU checks back to monitor the treatment progress and meets with the patient at the conclusion of all procedures. It was also stated that the AU could be summoned by the intercom to return to the treatment area if needed. CRTC personnel confirmed during the inspection exit meeting on May 16, 2011, that AUs leave the console area during the treatment, that they believed the AUs were available if needed, and were within the department during patient treatments.

The inspectors also noted that CRTC's HDR Operating Policy (dated June 12, 2006) which was incorporated in License Condition 17 of CRTC's license stated: "for an AU, physical presence, for this purpose is defined as within audible range of normal human speech." During discussions with CRTC personnel it was agreed that higher than normal human speech would be needed to summon the AU when they were outside of the console area and the door to the area was closed. Therefore, the inspectors concluded that the physical presence requirement was not being met by CRTC on a routine basis as required by NRC requirements. The inspectors determined that this was an apparent violation of 10 CFR 35.615(f)(2)(ii).

CRTC took immediate corrective actions based on the inspector's observations. CRTC convened their RSC on April 28, 2011, discussed the inspection findings, and revised their policy to require an AU to remain in the console area for the duration of the treatment. In correspondence dated May 4, 2011, CRTC stated that they revised their HDR operating policy to further clarify the physical presence requirement and trained all personnel involved with HDR treatments on the policy change.

10 CFR 35.615(f)(2)(ii) requires, in part, that an AMP and either an AU or a physician under the supervision of an AU, who has been trained in the operation and emergency response for the unit, be physically present during the continuation of all patient treatments involving the HDR unit. The term "physically present" has been defined by the NRC in Section V, "Summary of Changes," of the 2002 revised Part 35, as published in the Federal Register on April 24, 2002 (67 FR 20355); and states: "as used in this provision, physically present means to be within hearing distance of normal voice."

The NRC further clarified that the word "normal," as used in this definition, should be given its dictionary meaning of "regular," "average," or "not deviating from an established

rule." Under this definition, a raised voice would not constitute a "normal" voice. In addition, the use of communication devices, such as "walkie-talkies," intercoms, and/or other devices that could be used to amplify the human voice would not be allowed.

c. Conclusions

Based on the results of this inspection, two apparent violations of NRC requirements were identified:

- CRTC personnel did not perform a determination of the timer linearity over the typical range of use with each full calibration of the HDR unit, as required by 10 CFR 35.633(b)(5); and

- CRTC did not ensure that an authorized user (AU) or a physician under the supervision of an AU, that has been trained in the operation and emergency response for the unit, was physically present during the continuation of patient treatments involving the HDR, as required by 10 CFR 35.615(f)(2)(ii).

II. Exit Meeting

At the conclusion of the onsite inspection on April 28, 2011, the inspectors briefed members of CRTC management on the scope of the inspection and the inspectors' preliminary observations. CRTC acknowledged the inspectors' observations and immediately initiated corrective actions. A final exit meeting was held by telephone on May 16, 2011, with Dr. Lewis Whaley, Senior Partner/Owner and Dimitris Mihailidis, Ph.D., RSO, to discuss the results of the inspection.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

** ++Dimitris Mihailidis, PhD. – Radiation Safety Officer/Authorized Medial Physicist
** ++Lewis Whaley, M. D. – Senior Partner/Owner, Authorized User
Teresa Fischer – Authorized Medical Physicist
Various Nurses

** Attended briefing conducted on April 28, 2011
++Attended telephonic exit meeting on May 16, 2011