

June 30, 2011

EA-11-115

Michael B. Harmon, M.D.  
Owner/Senior Partner  
Charleston Radiation Therapy Consultants, PLLC  
3100 MacCorkle Avenue S.E., Suite B-1  
Charleston, WV 25304

SUBJECT: NOTICE OF VIOLATION - NRC INSPECTION REPORT NO. 03028869/2011001

Dear Dr. Harmon:

This refers to the U.S. Nuclear Regulatory Commission (NRC) inspection conducted on April 28, 2011, at the Charleston Radiation Therapy Consultants, PLLC (CRTC) office in Charleston, West Virginia. In addition to the on-site review, the inspection also involved in-office review of additional information CRTC provided the NRC in correspondence dated May 4, 2011. During the inspection, which consisted of an examination of your licensed activities as they relate to radiation safety and to compliance with the NRC's requirements and the conditions of your NRC license, two apparent violations of NRC requirements were identified. Information related to the corrective actions implemented in response to the apparent violations was provided in your May 4, 2011 letter.

The results of the inspection, including the apparent violations, were discussed with Lewis Whaley, M.D., and Dimitris Mihailidis, Ph.D., of your organization by telephone during an exit meeting on May 16, 2011, and were transmitted to you, along with the NRC inspection report in a letter dated May 26, 2011. In a telephone conversation on June 8, 2011, Mr. Marc Ferdas of my staff informed you that the NRC was considering escalated enforcement for one of the apparent violations, and that we had sufficient information regarding that apparent violation and your corrective actions to make an enforcement decision without the need for a pre-decisional enforcement conference (PEC) or a written response from you. In a follow-up telephone conversation on June 9, 2011, you informed the NRC that a PEC would not be necessary, and that CRTC did not plan to submit a written response. Therefore, based on the information developed during the inspection and the information that CRTC provided in the communication noted above, the NRC has determined that violations of NRC requirements occurred.

The violations are cited in the enclosed Notice of Violation (Notice). The circumstances surrounding the violations are described in detail in the inspection report issued on May 26, 2011. The most significant violation involved not having an authorized user (AU), or a physician under the supervision of an AU, physically present during a portion of patient treatments with the high dose rate remote afterloader (HDR). 10 CFR 35.615(f)(2) requires the AU, or a physician under the supervision of the AU, to be physically present during the entire duration of the treatments. 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." In addition, CRTC's HDR Operating Policy, as incorporated into CRTC NRC License as License Condition 17, states that

the AU must be physically present during all HDR treatments, and CRTC's Policy defines physical presence as "within the audible range of normal human speech." During the inspection, CRTC personnel described the HDR treatment process and stated that the AU routinely left the console area after a treatment had started, to perform other tasks at the adjacent nurse's station or to visit other patients in rooms within the department. The CRTC personnel stated that the AU remained within the department area during treatments, and would routinely return to the console area to monitor the treatment progress, and would meet with the patient at the conclusion of the procedure. However, CRTC staff agreed that, during treatments, higher than normal human speech would have been required to summon the AU. As such, the AU was not considered physically present for portions of the treatment, in violation of 10 CFR 35.615(f)(2).

Although the NRC concluded that there were no health or safety consequences to the patients or the public during the time the violation occurred, not having an AU continually present during HDR brachytherapy treatments could have affected patient safety if an emergency medical intervention would have been necessary during the treatment. Therefore, in accordance with the NRC Enforcement Policy, the NRC has categorized this violation at Severity Level (SL) III.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3,500 is considered for a SL III violation. Because CRTC has not been the subject of escalated enforcement actions within the last two years or 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 has concluded that credit is warranted for CRTC's corrective actions taken to address the violation. CRTC convened its radiation safety committee on the day of the inspection and discussed the inspection findings. CRTC additionally revised its HDR policies to require an AU to remain in the console area for the duration of the treatment and trained all CRTC personnel involved with HDR treatment on the policy change.

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 violation constitutes escalated enforcement action that may subject you to increased inspection effort in the future.

One additional violation, also documented in the Notice, has been categorized in accordance with the NRC Enforcement Policy as SL IV. The circumstances surrounding this violation are documented in detail in the above-referenced inspection report.

The NRC has concluded that information regarding the reason for the violations, the corrective action taken to correct the violations and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter, in your electronic mail to the NRC dated May 4, 2011, and in NRC Inspection Report 03028869/2011001. 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, Enclosure 1, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and 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 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 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

*/RA/ Original Signed by David C. Lew for*

William M. Dean  
Regional Administrator

Docket No. 03028869  
License No. 47-15717-03

Enclosure:  
Notice of Violation

cc w/encl:  
Dimitris N. Mihailidis, Ph.D., Radiation Safety Officer  
State of West Virginia

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, Enclosure 1, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room and 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 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 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

*/RA/ Original Signed by David C. Lew for*

William M. Dean  
Regional Administrator

Docket No. 03028869  
License No. 47-15717-03

Enclosure:  
Notice of Violation

cc w/encl:  
Dimitris N. Mihailidis, Ph.D., Radiation Safety Officer  
State of West Virginia

SUNSI Review Complete: MMM

DOCUMENT NAME: S:\Enf-allg\Enforcement\Proposed-Actions\Region1\EA-11-115 Charleston Rad Thrpy NOV III.docx

After declaring this document "An Official Agency Record" it will be released to the Public. ADAMS Accession No.: ML111822614

To receive a copy of this document, indicate in the box: "C"= Copy without attachment/enclosure "E"=Copy with attachment/enclosure "N"=No copy

OFFICE	RI/ORA	RI/DNMS	RI/DNMS	RI/ORA	RI/ORA
NAME	MMcLaughlin/MMM**	M Ferdas/ PAL for**	R Lorson/ RKL**	K Farrar/ KLF**	D Holody/ DJH**
DATE	6/21/11	6/21/11	6/22/11	6/24/11	6/24/11
OFFICE	HQ/OE*	RI/ORA			
NAME	L Sreenivas by email	W Dean/DCL for			
DATE	6/28/11	06/30/11			

OFFICIAL RECORD COPY

\*HQ to perform a quick review. \*\* see previous concurrence page

DISTRIBUTION w/encl:

ADAMS (PARS)

SECY

CA

OEMAIL

OEWEB

W Borchardt, EDO

M Weber, DEDMRT

R Zimmerman, OE

A Campbell, OE

N Hilton, OE

N Riddick, OE

N Hasan, OE

L Sreenivas, OE

C Carpenter, FSME

R Lewis, FSME

T Reis, FSME

J Luehman, FSME

M Burgess, FSME

G Villamar, FSME

D White, FSME

Enforcement Coordinators

RII, RIII, RIV (C Evans; S Orth; W. Jones)

C Scott, OGC

E Hayden, OPA

H Bell, OIG

C McCrary, OI

M Williams, OCFO

S Titherington-Buda, OCFO

R Lorson, DNMS, RI

D Collins, DNMS, RI

M Ferdas, DNMS, RI

H Bermudez, DNMS, RI

R Elliott, DNMS, RI

D Screnci, PAO-RI / N Sheehan, PAO-RI

D Janda, SAO-RI / M Orendi, SAO-RI

K Farrar, RI

D Holody, RI

A DeFrancisco, RI

M McLaughlin, RI

C O'Daniell, RI

S Villar, RI

R1DNMSMailResource

Region I OE Files (with concurrences)

ENCLOSURE 1

NOTICE OF VIOLATION

Charleston Radiation Therapy Consultants, PLLC  
Charleston, West Virginia

Docket No. 030-28869  
License No. 47-15717-03  
EA-11-115

Based on an onsite NRC inspection on April 28, 2011, as well as an in-office review of information provided by Charleston Radiation Therapy Consultants, PLLC (CRTC) in an electronic mail dated May 4, 2011, for which a telephonic exit meeting was held on May 16, 2011, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 35.615(f)(2) states, in part, that for high dose-rate (HDR) remote afterloader units, an authorized medical physicist and either an authorized user (AU) or a physician, under the supervision of an AU, who has been trained in the operation and emergency response for the unit, is required to be physically present during continuation of all patient treatments involving the unit.

Condition 17 of NRC License No. 47-15717-03 states, in part that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the CRTC application for renewal of its NRC license, submitted through a letter dated March 13, 2006.

HDR Operating Policy, Clinical Operations, is a procedure contained in the CRTC license renewal application submitted on March 13, 2006, and states, in part, that physical presence is defined as within audible range of normal human speech.

Contrary to the above, on an indeterminate number of occasions on and prior to April 28, 2011, neither a CRTC AU, nor a physician under the supervision of an AU, was physically present during continuation of patient treatments involving the HDR unit. Specifically, the AU would, at times, leave the console area after a treatment had started, to perform other tasks at the adjacent nurse's station or to visit other patients in rooms within the department, and would not remain within audible range of normal human speech. The AU would routinely return to the console area to monitor the treatment progress, and would meet with the patient at the conclusion of the procedure. However, while the AU was not in the HDR console area during patient treatments, a physician under the supervision of an AU was not physically present, and higher than normal human speech would have been required to summon the AU.

This is a Severity Level III violation (Enforcement Policy Section 6.3).

- B. 10 CFR 35.633(b) states, in part, that full calibration measurements of HDR remote afterloader units must include a determination of timer accuracy and linearity over the typical range of use.

Contrary to the above, on and prior to April 28, 2011, CRTC did not include a determination of timer linearity over the typical range of use in the full calibration measurements of its HDR remote afterloader units. Specifically, CRTC performed timer linearity measurements for three minutes when the typical range of use was five minutes.

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

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 03028869/2011001, in a CRTC electronic mail dated May 4, 2011, and in the letter transmitting this Notice of Violation (Notice). Therefore, no response to this Notice is required. 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-11-115," 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, Region I, within 30 days of the date of the letter transmitting this Notice.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room and 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>. 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 2011.