

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED

Charleston Area Radiation Therapy Centers, LLC
3415 MacCorkle Avenue, S.E.
Charleston, WV 25304

2. NRC/REGIONAL OFFICE

Region 1
2100 Renaissance Blvd
Suite 100
King of Prussia, PA 19406-2713

REPORT NUMBER(S) 2021001

3. DOCKET NUMBER(S)

030-28869

4. LICENSE NUMBER(S)

47-15717-03

5. DATE(S) OF INSPECTION

05/17/2021 - 06/30/2021

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

_____ Non-cited violation(s) were discussed involving the following requirement(s):

- 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with the NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11. (Violations and Corrective Actions)

10 CFR 35.633(b)(5) requires, in part, that a licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit to include timer accuracy and linearity over the typical range of use.

Contrary to the above, as of May 17, 2021, the licensee was authorized to use a remote afterloader unit for medical use and did not perform full calibration measurements on the unit to include timer accuracy and linearity over the typical range of use. Specifically, the timer accuracy and linearity was performed from zero to 180 seconds; however, the typical range of use was from zero to 440 seconds.

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

Corrective actions included performing the timer accuracy and linearity from zero to 900 seconds on June 18, 2021.

Continued on page 2.

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10 CFR 20.1101(a) requires, in part, that each licensee implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20.

The licensee developed a policy titled "Radiation Safety Manual" and revised the policy last in August 2020. Page 11 of the policy states, in part, that the licensee will perform an audit of the entire radiation safety program annually and that the review will include, but not be limited to: status of licenses, registrations, any updated regulations, current modalities used, radiation safety oversight and recommendations, personnel dosimetry results with special focus on declared pregnant radiation workers, instrumentation, sealed source inventory, and clinical quality management.


Contrary to the above, as of May 17, 2021, the licensee failed to implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. Specifically, the licensee did not perform an audit of the entire radiation safety program annually that included the status of licenses, registrations, any updated regulations, current modalities used, radiation safety oversight and recommendations, personnel dosimetry results with special focus on declared pregnant radiation workers, instrumentation, sealed source inventory, and clinical quality management.

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

Corrective actions included developing an audit using guidance found in NUREG 1556, Volume 9, Appendix L "Model Medical Licensee Audit". The licensee committed to completing the audit by July 2, 2021 and will complete the audit annually thereafter.

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE <	DATE
LICENSEE'S REPRESENTATIVE	Christine Oskin		6/30/21
NRC INSPECTOR	Elizabeth Tindle-Engelmann	Elizabeth D. Tindle-Engelmann <small>Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2021.06.30 12:55:32 -04'00'</small>	
BRANCH CHIEF	Donna M. Janda		