

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**1. LICENSEE/LOCATION INSPECTED**

UConn Health
263 Farmington Avenue
Farmington, CT 06030-3930

2. NRC/REGIONAL OFFICE

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

REPORT NUMBER(S) 2020001**3. DOCKET NUMBER(S)**

030-01295

4. LICENSE NUMBER(S)

06-13022-02

5. DATE(S) OF INSPECTION

12/01/2020 - 3/15/2021

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 violations(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.

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

10 CFR 35.615(f)(2)(i) states, in part, that for high dose-rate remote afterloader units, the licensee shall require an authorized user to be physically present during initiation of all patient treatments involving the unit.

Contrary to the above, on 9/5/2018 and on 5/27/2020, a UConn Health authorized user was not physically present during initiation of patient treatments involving the high dose-rate remote afterloader unit. Specifically, on 9/5/2018 and on 5/27/2020, a physician meeting the requirements to perform the duties of an authorized user was physically present during initiation of patient treatments involving the high dose-rate remote afterloader unit. However, this physician was not an approved authorized user.

The licensee identified this violation and implemented corrective actions which included obtaining authorized user status for the physician, creating a time out procedure to ensure a UConn Health authorized user is physically present during initiation of patient treatments involving the high dose-rate remote afterloader unit, and creating a controlled version of the authorized user list so that the radiation oncology scheduler can schedule an authorized users to be physically present during initiation of patient treatments involving the high dose-rate remote afterloader unit.

- ☒ 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)

A. 10 CFR 35.610(e) requires, in part, that a licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of emergency procedures for the remote afterloader unit, initially and at least annually.

Contrary to the above, since 2018, UConn Health did not ensure that all authorized users participated in drills of emergency procedures for the remote afterloader unit initially and at least annually. Specifically, five of the six of the authorized users who were listed on the license and infrequently used the device did not participate annually in UConn Health's emergency procedure drills. This is a Severity Level IV violation (Enforcement Policy Section 6.3)

Corrective actions include removing all authorized users that have not participated in emergency drills within the last year and committing to performing annual emergency drills for all remote afterloader Authorized Users and Authorized Medical Physicists going forward.

Continued on next page...

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B. 10 CFR 35.633(a)(2)(i) states, in part, that a licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit before medical use following replacement of the source. 10 CFR 35.633(b)(6) states, in part, that to satisfy the requirements of paragraph (a) of this section full calibration measurements must include determination of length of the applicators.

Contrary to the above, prior to March 15, 2021, the licensee was authorized to use a remote afterloader unit for medical use and did not perform full calibration measurements that included determination of length of the applicators. Specifically, the licensee measured the diameter of the applicators for each treatment but failed to determine the length of the applicators as part of their full calibration measurements.

Corrective actions included performing radiographic images of the applicators and then measuring the applicators electronically. These measurements are in progress will be completed within 30 days. Additionally, UConn health will perform these measurements alongside the full calibration procedures in the future.

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	Wesley Byerly	Wesley G Byerly	Digitally signed by Wesley G Byerly Date: 2021.03.31 11:34:10 -04'00'
NRC INSPECTOR	Elizabeth Tindle-Engelmann / Donna M. Janda	Elizabeth D. Tindle-Engelmann Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2021.03.26 12:51:45 -04'00'	Donna M. Janda Digitally signed by Donna M. Janda Date: 2021.03.30 15:19:50 -04'00'
BRANCH CHIEF	Donna M. Janda	Donna M. Janda	Digitally signed by Donna M. Janda Date: 2021.04.02 14:43:32 -04'00'