NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED	2. NRC/REGIONAL OFFICE
Middlesex Health 536 Saybrook Road Middletown, CT **REPORT NUMBER(s) 2021001**	Region 1 2100 Renaissance Blvd Suite 100 King of Prussia, PA 19406-2713

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-01242	06-00649-03	08/05/2021

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 35.40(a) requires, in part, that a written directive be dated and signed by an authorized user before the administration of any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material. Contrary to this, on October 16, 2019, a written directive was not dated and signed by an authorized user before the administration of a therapeutic dosage of unsealed byproduct material or a therapeutic dose of radiation from byproduct material. Specifically, a written directive for a Ra-223 therapy was signed by a physician after the administration.

The licensee identified this violation and implemented corrective actions which included changing the process for ordering Ra-223 so that it cannot be ordered until the written directive is signed by the authorized user, modifying procedure checklist to include a verification step to confirm the written directive is signed prior to administration, and bringing a copy of the signed written directive to the procedure so that the authorized user can perform a final confirmation.

☑ 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 35.24(f) requires, in part, that the membership of the Radiation Safety Committee include an authorized user of each type of use permitted by the license, a Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor the Radiation Safety Officer.

Contrary to the above, as of August 5, 2020, the membership of the licensee's Radiation Safety Committee did not include a representative of the nursing service or an authorized user for 10 CFR 35.1000 Y-90 Microspheres.

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

As a corrective action the licensee appointed a primary representative of the nursing service and a back up representative of the nursing service to the radiation safety committee. Additionally, on September 22, 2021 the licensee submitted an amendment request to remove 10 CFR 35.1000 Y-90 Microspheres from their license.

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B. 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, from 2019 through 2021, the licensee did not ensure that all authorized users and authorized medical physicists participated in drills of emergency procedures for the remote afterloader unit initially and at least annually. Specifically, two of the three of the authorized users and one of the four authorized medical physicist, who were listed on the license and infrequently used the device, did not participate annually in the licensee's emergency procedure drills.

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

As a corrective action the licensee performed training for the two authorized users and one authorized medical physicist on August 24, 2021. The chief physicist will provide the training annually to all authorized users and authorized medical physicists going forward.

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	David Giuffrida		9/27/21
NRC INSPECTOR	Elizabeth Tindle-Engelmann	Elizabeth D. Tindle-Engelmann Digitally signed by Elizabeth D. Tindle-Engelmann Date: 2021.09.22 08:16:33 -04'00'	
BRANCH CHIEF	Tara Weider	Tara L. Weidner Digitally signed by Tara L. Weidner Date: 2021.09.28 16:36:56 -04'00'	