

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED

MidState Medical Center
435 Lewis Avenue
Meriden, CT 06451

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)

030-01257

4. LICENSE NUMBER(S)

06-05686-02

5. DATE(S) OF INSPECTION

09/14/2021 - 09/21/2021

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 35.24(f) states, in part, that licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license.

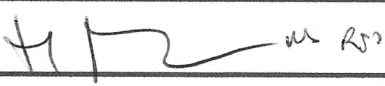
Contrary to the above, from April 2019 to September 2021, the licensee did not include an authorized user of each type of use permitted by the license on the Radiation Safety Committee. Specifically, the license was authorized for 10 CFR 35.1000 Y-90 (TheraSpheres) and did not include representation by a Y-90 (TheraSpheres) authorized user.

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

The licensee identified a Y-90 (TheraSpheres) authorized user for Radiation Safety Committee membership and indicated on September 16, 2021 that they were added to the committee roster.

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	Harry Hajedemos, M.D., RSO		9/22/2021
NRC INSPECTOR	Robin Elliott	Robin L. Elliott <small>Digitally signed by Robin L. Elliott Date: 2021.09.21 17:05:51 -04'00'</small>	
BRANCH CHIEF	Tara Weidner		