

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Heart to Heart
25689 Kelly Road, Suite D
Roseville, MI 48066

REPORT NUMBER(S) 2022-001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-35352

4. LICENSE NUMBER(S)

21-32248-01

5. DATE(S) OF INSPECTION

May 20, 2022
Exit June 22, 2022

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):

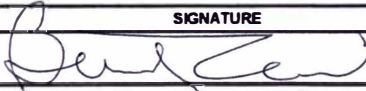
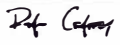
- ☒ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations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

Contrary to 10 CFR 35.63(d), on August 4, 2020 and December 9, 2020, Heart to Heart administered two dosages of technetium-99m (Tc-99m) radiopharmaceuticals that did not fall within the prescribed dosage range. Specifically, on both occasions the licensee administered 37.5 millicuries (mCi) of Tc-99m when the range was 24 to 36 mCi, and was not otherwise directed to do so by an authorized user.

As corrective action for this Severity Level IV violation, the inspector discussed the finding and the requirement with the licensee's technologist and with its consultant. The technologist committed to being more diligent in ensuring that doses fell within the prescribed dosage range prior to administration, and the consultant committed to discussing the findings and the regulatory requirement with the technologist.

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	BEVERLY TOWNER		6/29/22
NRC INSPECTOR	Ryan Craffey	 Digitally signed by Ryan J. Craffey Date: 2022.06.27 10:49:18 -04'00'	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.06.27 10:49:18 -04'00'	