NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Heart to Heart	030-35352	21-32248-01

4. Report Number(s):	5. Date(s) of Inspection:
2022-001	May 20, 2022; exit June 22, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Ryan Craffey	02121	5	IP 87130

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Laura Luna - Consultant	lluna@mpcphysics.com	734-662-3179 office 810-869-3758 cell

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial ☑ Routine ☑ Announced ☐ Non-Routine ☐ Unannounced	☑ Main Office ☐ Field Office ☐ Temporary Job Site ☐ Remote	06/22/2027 ☑ Normal ☐ Extended ☐ Reduced ☐ No change

16. Scope and Observations:

Heart to Heart is a private cardiology practice authorized to use byproduct material for diagnostic medical purposes at its clinic in Roseville, Michigan. At the time of the inspection, one part-time NMT performed cardiac stress tests on Wednesdays, but only when anticipated workload was sufficient to warrant her presence (currently a minimum of 4-5 patients). The licensee used only unit doses of Tc-99m from a licensed radiopharmacy, and retained the services of a consulting physicist to review the implementation of the radiation safety program quarterly.

The inspector attempted this inspection unannounced on several occasions. However, the clinic was closed each time. The inspector thereafter announced the inspection to the licensee's consultant, who assisted in coordinating the routine inspection with the licensee's NMT.

The inspector toured the clinic in Roseville. All areas were adequately posted, and all licensed material was adequately secured. Independent and confirmatory surveys of the department identified no residual contamination nor exposures to members of the public in excess of regulatory limits. The inspector was unable to observe the conduct of licensed activities, as none were scheduled for the day of the inspection. Instead, the inspection observed demonstrations of the implementation of licensee procedures for instrument quality control, receipt of packages containing licensed material, preparation and administration of doses, handing of radioactive waste, and area surveys. The technologist was knowledgeable of radiation protection principles, regulatory requirements, and licensee procedures, and had appropriate dosimetry available for wear. The inspector reviewed a selection of records, including consultant audits, instrument quality control results, area survey and decay-in-storage waste handling documents, a large sample of dose administration records, worker instruction including hazmat training and testing, and personnel dosimetry reports, which documented occupational exposures that were consistent with licensed activities and well below regulatory limits.

During a review of dose administration records, the inspector identified a SLIV violation of 10 CFR 35.63(d) for administering doses outside of the ranges prescribed by an authorized user. In 2020 (on August 4 and December 9), the licensee's technologist administered two doses (37.5 mCi each) of Tc-99m radiopharmaceuticals for cardiac stress tests that were outside of the directed range of 24-36 mCi, with no residual activity noted post-administration. The root cause of the violation was a lack of attention to detail. As a contributing factor, the technologist commonly performed administrations well before their scheduled time. As corrective action, the inspector discussed the finding and the requirement with the licensee's technologist and 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 discuss the findings, the regulatory requirement, and patient workload with the technologist.