NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Henry Ford Hospital	030-02043	21-04109-16

4. Report Number(s):	5. Date(s) of Inspection:
2021-001	May 25 through June 15, 2021

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Ryan Craffey	02110	2	IP 87131, 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Alan Jackson - RSO	alanj@rad.hfh.edu	313-916-2739

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial		
☑ Routine ☑ Announced	☑ Main Office ☑ Field Office	05/25/2023 ☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced hybrid routine inspection of a broad-scope medical institution in Detroit, Michigan, authorized to use byproduct material for diagnostic and therapeutic medical purposes and for research and development at six facilities and at temporary job sites in NRC jurisdiction. At the time of the inspection, the licensee performed diagnostic administrations of radiopharmaceuticals at its main hospital in Detroit (doses were prepared on-site by an authorized nuclear pharmacist using generators), its cancer center across the street (PET scans only), and at satellite facilities in West Bloomfield, Dearborn, and Sterling Heights using unit doses from commercial radiopharmacies. The licensee performed therapeutic administrations of radiopharmaceuticals at its main hospital in Detroit (I-131, Ra-223 Xofigo, and Lu-177 Lutathera), and at its satellite facility in West Bloomfield (I-131 only). The licensee also performed therapeutic administrations of Y-90 microspheres and IVB treatments at its main hospital, and HDR treatments at its cancer center; it had not performed permanent implant brachytherapy since the last routine inspection. The licensee also used a self-shielded irradiator for research at its headquarters building in Detroit at least once a month; one other authorized user possessed C-14 for research but did not actively use it. The licensee has worked at two temporary job sites (both clinics it owned) since receiving authorization to do so in October 2020. It used Co-57 flood sources to confirm the presence of lead shielding in the walls of rooms containing x-ray units. The licensee's RSO, based at the main hospital in Detroit, was assisted in his oversight by two medical physicists, two physics residents, and an administrative assistant, as well as an RSC which met quarterly to review the status of the program and to evaluate applications for authorized users and uses.

The inspector toured the main hospital, cancer center, headquarters building, and satellite facilities in West Bloomfield and Dearborn. All facilities were adequately posted, and all material was adequately secured. The inspector observed numerous diagnostic administrations, as well as therapeutic administrations of Lu-177 Lutathera, Ra-223 Xofigo, Y-90 microspheres, and two treatments with the HDR unit. The inspector also observed the use of generators and preparation of doses at the main hospital, use of the self-shielded irradiator, HDR spot checks, and the receipt of several packages containing licensed material. The inspector reviewed the licensee's practices for waste handling, including a tour and independent surveys of the licensee's waste storage facility at the main hospital. The inspector performed additional surveys at each facility, and found no evidence of residual contamination or exposures above public limits in unrestricted areas. The inspector interviewed the licensee's radiation safety staff, numerous nuclear medicine technologists, authorized medical physicists, physics residents, the authorized user for the irradiator and several medical users, including primary Y-90 and IVB users via video teleconference prior to the on-site inspection. The inspector reviewed the licensee's methods for approving authorized users and uses, radiation exposure monitoring, planning and administering IVB treatments, performing area surveys, ALARA practices for inpatients, and use of material at temporary job sites.

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The inspector also reviewed a selection of records, including RSC meeting minutes, supporting documentation for approving authorized users and uses (both medical and non-medical), personnel dosimetry results, routine nuclear medicine records, HDR source exchange and full calibration documentation, and a sample of written directives, planning and verification documentation and release calculations/evaluations for I-131, Ra-223 Xofigo, Lu-177 Lutathera, Y-90 microsphere, IVB and HDR treatments.

No violations of NRC requirements were identified as a result of this inspection. The inspector held a preliminary on-site exit meeting with licensee staff and management on May 28, and a final exit meeting via telephone with the RSO on June 15 after completing in-office review of a security-related matter.