NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
Karmanos Cancer Center 4100 John R Street Detroit, MI 48201 **Report Number(s)** 2024-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. Docket Number(s)	4. License Number(s)	5. Date(s) of Inspection
030-09376	21-04127-06	January 10-12, 2024

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. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements, and were assessed at Severity Level IV, in accordance with the NRC Enforcement Policy.

A. 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, corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy were satisfied.
(Non-cited violation(s) was/were discussed involving the following requirement(s)

B. The following violation(s) is/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 July 19, 2023, Karmanos Cancer Center administered a diagnostic dosage of technetium-99m (Tc-99m) radiopharmaceutical that differed from the prescribed dosage by more than 20 percent. Specifically, the licensee administered 4.4 millicuries (mCi) of Tc-99m when the prescribed dosage was 3 mCi, and was not otherwise directed by an authorized user to administer this dosage which differed by 47 percent. As corrective action, the licensee committed to reorder the prescribed dosages list, and to post the list in radiology reading rooms for more timely identification and evaluation in the event of any future deviations.

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 AND DATE
LICENSEE'S REPRESENTATIVE	Mara Jelich	2/29/24
NRC INSPECTOR	Ryan Craffey	Digitally signed by Ryan J. Craffey Date: 2024.02.29 10:44:42 -06'00'
BRANCH CHIEF	Rhex Edwards	Digitally signed by RHEX EDWARDS Date: 2024.02.29 10:52:28 -06'00'

Add Continuation Page

NRC FORM 592M
(10-04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
Karmanos Cancer Center	030-09376	21-04127-06

4. Report Number(s):	5. Date(s) of Inspection:
2024-001	January 10-12, 2024; exit February 13, 2024

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Ryan Craffey, Carol Dye (obs.), Laura Dresen (obs.)	02230	2	IP 87130, 87132

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Joe Rakowski PhD - RSO (ret.) Magaraju Mogili - Temp. RSO	rakowski@karmanos.org mogilin@karmanos.org	313-576-9616 313-576-9613

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial	☐ Hybrid	
☑ Routine ☑ Announced	☑ Main Office ☑ Field Office	01/10/2026 ☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Location(s) Inspected List:

4100 John R Street, Detroit, MI
3901 Beaubien Boulevard, Detroit, MI
31995 Northwestern Highway, Farmington Hills, MI

17. Scope and Observations:

Karmanos Cancer Center was authorized to use diagnostic and therapeutic radiopharmaceuticals as well as various sources and devices for brachytherapy, teletherapy, and gamma stereotactic radiosurgery. At the Gershenson Radiation Oncology Center on John R Street in Detroit, the licensee routinely used a Nucletron Flexitron HDR unit for treating gynecological, breast, and prostate cancers, occasionally used a Best Theratronics GammaBeam 500 teletherapy unit for total body irradiations, and occasionally administered Y-90 SIR-Spheres and TheraSpheres. The licensee also routinely administered therapeutic doses of Ra-223 Xofigo and various Lu-177m radiopharmaceuticals, including some for clinical trials. Though authorized for Cs-131 GammaTile treatments, the licensee had not yet performed any, nor had the licensee performed any other manual brachytherapy treatments since the last inspection. The licensee also possessed several sources in storage, including a teletherapy head originally commissioned for research, a Cs-137 instrument calibrator, and a Cu-244 reference source. At the PET Center on Beaubien Boulevard in Detroit, the licensee performed diagnostic administrations daily using an Intego infusion device with F-18 FDG manufactured on-site under Karmanos' cyclotron license (docket no. 030-38328). At the Weisberg Cancer Center in Farmington Hills, the licensee routinely used a Leskell Gamma Knife Icon GSR unit for treating brain tumors and neurologic disorders, and had recently opened a nuclear medicine department for daily diagnostic administrations of radiopharmaceuticals in the form of unit doses.

The inspectors toured the Gershenson Radiation Oncology Center, Weisberg Cancer Center, and the PET Center. All areas were adequately posted, and all licensed material was adequately secured. The inspectors performed independent and confirmatory radiation surveys of these facilities and found no evidence of residual contamination or exposures in unrestricted areas above limits to members of the public. The inspectors observed HDR and GSR unit spot checks, treatment planning and delivery, and the administration of radiopharmaceuticals at the PET Center and Weisberg. The inspectors also observed demonstrations of HDR and teletherapy unit full calibrations, receipt of packages containing radiopharmaceuticals, and radiation detection equipment checks for nuclear medicine. Licensee personnel were knowledgeable of radiation protection principles, wore personnel dosimetry as assigned, used calibrated and operable radiation detection instruments, and implemented effective ALARA measures.

Materials Inspection Record (Continued)

The inspectors reviewed the licensee's procedures for planning and administering HDR, GSR, teletherapy, and Y-90 microspheres treatments, as well as documentation for a selection of these and other treatments involving therapeutic radiopharmaceuticals. All procedures provided high confidence that treatments were performed in accordance with written directives. The inspectors also reviewed program audits, personnel dosimetry reports, routine nuclear medicine records, and additional calibration and quality assurance documentation for the teletherapy unit and the Intego infusion machine.

During a review of dose administration records at the Weisberg nuclear medicine department, the inspectors identified a SLIV violation of 10 CFR 35.63(d) for a diagnostic administration of Tc-99m MAA that differed from the prescribed dosage by more than 20 percent. Specifically, on July 19, 2023, the NMT drew and administered 4.4 mCi for a lung perfusion study when the prescribed dosage was only 3 mCi, a deviation of 47 percent. The root cause was most likely human error. As a contributing factor, the prescribed dosages for lung perfusion studies and for lung shunt studies, which both called for Tc-99m MAA, were listed one after the other on the prescribed dosage list. Their proximity may have led the NMT to mistake the prescribed dosage for a lung shunt study (4 mCi) as the dosage for a lung perfusion study (3 mCi).

The inspectors confirmed that the administration did not meet medical event criteria, as per ICRP Publication 128 the effective dose from this administration was 0.18 rem (threshold is 5 rem) and the maximum organ dose (to the lungs) was 1.07 rem (threshold is 50 rem).

As corrective action, the licensee committed to reorder the prescribed dosages list and to post the list in radiology reading rooms for more timely identification and AU evaluation in the event of any future deviations.

Signature and Date - Branch Chief

Digitally signed by RHEX EDWARDS
Date: 2024.02.29 10:52:06 -06'00'