NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Report

1. Licensee/Location Inspected:	2. NRC/Regional Office
McLaren Medical Center Bay Region Nuclear Medicine 1900 Columbus Ave. Bay City, MI 48708 Report Number(s) 2022001	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
030-13900	21-18585-01	March 24, 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. 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)

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		
NRC INSPECTOR	Jason Draper, Health Physicist	Jason D. Draper Digitally signed by Jason D. Draper Date: 2022.04.13 13:28:06 -05'00'
BRANCH CHIEF		Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.04.14 07:55:43 -05'00'

Add Continuation Page

NRC FORM 592M
(10-2020)

U.S. NUCLEAR REGULATORY COMMISSION

Materials Inspection Record

1. Licensee Name:	2. Docket Number(s):	3. License Number(s)
McLaren Medical Center Bay Region	030-13900	21-18585-01

4. Report Number(s):	5. Date(s) of Inspection:
2022001	March 24, 2022

6. Inspector(s):	7. Program Code(s):	8. Priority:	9. Inspection Guidance Used:
Jason Draper	02230	2	IPs 87132 and 87131

10. Licensee Contact Name(s):	11. Licensee E-mail Address:	12. Licensee Telephone Number(s):
Steven Gerhardt, CNMT	steve.gerhardt@mclaren.org	(989) 894-6469

13. Inspection Type:	14. Locations Inspected:	15. Next Inspection Date (MM/DD/YYYY):
☐ Initial		
☑ Routine ☑ Announced	☑ Main Office ☑ Field Office	03/24/2024 ☑ Normal ☐ Extended
☐ Non-Routine ☐ Unannounced	☐ Temporary Job Site ☐ Remote	☐ Reduced ☐ No change

16. Scope and Observations:

This was an announced routine inspection of a community hospital authorized to use licensed material permitted by 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.600 (iridium-192 in a high dose rate remote afterloader (HDR) unit). The licensee conducted activities at three locations. Collectively, the nuclear medicine departments were staffed with five nuclear medicine technologists (NMTs) who performed approximately 25-30 diagnostic procedures per week including primarily cardiac stress tests as well as bone scans, HIDAs, and other occasional studies at the main hospital and approximately 20 cardiac stress tests per week at the West Branch location Monday through Thursday. The NMTs also administered up to 8 iodine-131 capsules per year for hyperthyroid treatment and thyroid ablations and administered radium-223 dichloride (Xofigo) to one patient in 2021. The licensee had not performed any iodine-125 seed implants since 2018 and does not have future plans for implants. At the Jeppeson Radiation Oncology Center, the licensee treated 4-5 gynecological patients per year. At the time of the inspection, the licensee had transferred the iridium-192 source to the manufacturer and disposed of the HDR device as the licensee was in the process of requesting authorization for a new HDR device. The licensee retained the services of a medical physics consultant to perform quarterly audits.

At the main hospital, the inspector toured the nuclear medicine department as well as the stress lab, which included an additional dose preparation area separate from the hot lab. The inspector also performed independent surveys of the preparation and administration areas and found no residual contamination or area radiation levels that could lead to exposure to members of the public in excess of regulatory requirements. The inspector observed the preparation and administration of one rest dosage of technetium-99m and interviewed the NMTs with regard to package receipt procedures daily instrumentation checks, waste disposal, and area radiation and contamination surveys. The inspector also reviewed a selection of records including written directives for I-131 and Xofigo administrations, patient release evaluations, instrumentation checks, surveys, radioactive waste manifests, training, radiation safety committee meeting minutes, and periodic program reviews.

At the licensee's Jeppeson Radiation Oncology Center, the inspector toured the licensee's HDR suite and interviewed the Authorized Medical Physicist regarding the security, handling, and use of the prior HDR device and sources as well as the licensee's plans for the future HDR device. The inspector also reviewed a selection of records including written directives and treatment plans, daily spot checks, and source exchanges and calibrations.

No violation were identified as a result of this inspection.