

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: McLaren - Flint 401 S. Ballenger Hwy. Flint, MI 48532 REPORT NUMBER(S) 2021001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
3. DOCKET NUMBER(S) 030-02048	4. LICENSE NUMBER(S) 21-04171-04	5. DATE(S) OF INSPECTION June 23, 2021, with in-office review through June 29, 2021

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)

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			
NRC INSPECTOR	Zahid Sulaiman, Health Physicist	Zahid M. Sulaiman <small>Digitally signed by Zahid M. Sulaiman Date: 2021.07.02 13:35:27 -05'00'</small>	
BRANCH CHIEF	Michael Kunowski, Chief, MIB	Michael A. Kunowski <small>Digitally signed by Michael A. Kunowski Date: 2021.07.06 06:17:56 -05'00'</small>	



Materials Inspection Record

1. Licensee Name: McLaren - Flint		2. Docket Number(s): 030-02048		3. License Number(s) 21-04171-04	
4. Report Number(s): 2021001			5. Date(s) of Inspection: June 23, 2021, with in-office review through June 29, 2021		
6. Inspector(s): Zahid Sulaiman, Health Physicist		7. Program Code(s): 02230		8. Priority: 2	9. Inspection Guidance Used: 87131, 87132
10. Licensee Contact Name(s): Christopher Conlin, MD - RSO		11. Licensee E-mail Address: Christopher.CONLIN@mclaren.org		12. Licensee Telephone Number(s): (810) 342-3830; (810) 342-2768	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input checked="" type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input type="checkbox"/> Unannounced		14. Locations Inspected: <input checked="" type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 06/23/2023 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was an announced remote routine inspection of a 378-bed hospital authorized to use byproduct materials for medical purposes permitted by 10 CFR 35.100, 35.200, 35.300, 35.400, 35.600, and 35.1000. The nuclear medicine department at the main hospital was staffed with a full-time and two part-time nuclear medicine technologists (NMTs). The NMTs performed approximately 160 diagnostic doses monthly. The outpatient imaging center was staffed with a full-time NMT, performed approximately 120 diagnostic doses monthly. The diagnostic administrations included a variety of imaging procedures using technetium-99m (Tc-99m), primarily cardiac stress test, bone scans, HIDA, gall bladder, and MUGA. The licensee retained the services of a medical physics consultant to conduct audits of the program on a quarterly basis.

The cancer center was staffed with four oncologists, six authorized medical physicists (AMPs), five dosimetrists, and 10 therapists. The cancer center performed approximately 24 Iodine-131 hyperthyroid and thyroid ablation, 1-2 radium-223 Xofigo therapy procedures annually, and approximately 30-40 high dose-rate remote afterloader (HDR) treatments primarily skin cancer, gynecological, breast, and occasionally prostate monthly. Licensee performed one permanent seed implant and no liquid Iodine-125 GliaSite radiation therapy procedures since the last inspection.

PERFORMANCE OBSERVATIONS

This inspection was conducted virtually through the Microsoft Team meeting, and consisted of interview with select licensee personnel, a review of select records, and an observation of security of the materials. Through Microsoft Team, the inspector observed the NMT conduct a physical inventory of sealed sources, and all sources were accounted for. The inspector had the NMT demonstrate and discuss about the dose calibrator constancy check, package receipt procedures, the end of the day daily and weekly area surveys, proper handling of radioactive waste and disposal procedures, and spill response, with no issue noted. The inspector had the AMP demonstrate and discuss the HDR unit's: (1) security, (2) daily spot checks, (3) emergency equipment and procedures, (4) safety procedures and instructions, (5) door interlock system, and (6) radiation monitoring equipment checks. The inspector also reviewed the HDR unit full calibration procedures.

The inspector reviewed selected written directives and treatment plans for various brachytherapy and radiation therapies procedures. Through these demonstrations and other discussion, the inspector found that the licensee personnel was knowledgeable of radiation protection principles, licensee procedures, and regulatory requirements.

The inspector reviewed the following records: radiation safety committee minutes, quarterly program audits, package

Materials Inspection Record (Continued)

receipts, waste disposal records, radiation safety and DOT Hazmat training, linearity and accuracy of the dose calibrator, instrument calibration, sealed source leak tests and inventory, daily area surveys, and weekly wipe tests. The inspector reviewed dosimetry records for 2019 through December 31, 2020, indicating the maximum annual dose to be 244 mrem - DDE, and 2,507 mrem - SDE.

The inspector closed the previous violation where licensee failed to perform proper timer accuracy of the HDR unit prior to patient treatment. The inspector reviewed and confirmed the licensee's corrective action in which the licensee updated its HDR start-up checklist to include the timer accuracy check and trained the therapists to perform the timer accuracy check prior to the first use of the HDR.

No violations of NRC requirements were identified as a result of this inspection.