NRC FORM 591M
(04-2022)

U.S. NUCLEAR REGULATORY COMMISSION

# Materials Inspection Report

| 1. Licensee/Location Inspected: | 2. NRC/Regional Office |
|---|---|
| McLaren Port Huron<br>1221 Pine Grove Avenue<br>Port Huron, MI 48061<br><br>Report Number(s) 2023-001 | Region III<br>U. S. Nuclear Regulatory Commission<br>2443 Warrenville Road, Suite 210<br>Lisle, IL 60532-4352 |

| 3. Docket Number(s) | 4. License Number(s) | 5. Date(s) of Inspection |
|---|---|---|
| 030-18005 | 21-20137-01 | 02/03/23 - 04/21/23 |

**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 35.40(a), on 06/15/21 and 08/04/22, McLaren Port Huron administered therapeutic doses of radiation from iodine-125 permanent implant brachytherapy seeds but the authorized user did not sign and date the written directives before each administration. As corrective action, the the licensee committed to discuss the requirement with the authorized user and to create a checklist in their electronic medical records system to confirm the timely completion of all required steps and records in the permanent implant brachytherapy treatment process. The licensee also committed to ensure the network (i.e., McLaren Health Care) procedure for permanent implant brachytherapy would include equivalent verifications.

**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 | Eric Cecava | 11 May 23 |
| NRC INSPECTOR | Ryan Craffey | Digitally signed by Ryan J. Craffey Date: 2023.05.02 10:48:00 -04'00' |
| BRANCH CHIEF | Rhex Edwards | Digitally signed by Rhex A. Edwards Date: 2023.05.05 08:39:39 -05'00' |

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) |
|---|---|---|
| McLaren Port Huron | 030-18005 | 21-20137-01 |

| 4. Report Number(s): | 5. Date(s) of Inspection: |
|---|---|
| 2023-001 | February 3, 2023; exit April 21, 2023 |

| 6. Inspector(s): | 7. Program Code(s): | 8. Priority: | 9. Inspection Guidance Used: |
|---|---|---|---|
| Ryan Craffey | 02120 | 3 | IP 87130, 87132 |

| 10. Licensee Contact Name(s): | 11. Licensee E-mail Address: | 12. Licensee Telephone Number(s): |
|---|---|---|
| Shelli Kritzman - Consultant | mkritzman@mpcphysics.com | 734-662-3197 |

| 13. Inspection Type: | 14. Locations Inspected: | 15. Next Inspection Date (MM/DD/YYYY): |
|---|---|---|
| ☐ Initial | ☐ Hybrid | |
| ☑ Routine | ☑ Main Office | 02/03/2026 |
| ☐ Announced | ☐ Field Office | ☑ Normal |
| ☐ Non-Routine | ☐ Temporary Job Site | ☐ Extended |
| ☑ Unannounced | ☐ Remote | ☐ Reduced |
| | | ☐ No change |

16. Location(s) Inspected List:

1221 Pine Grove Avenue, Port Huron, MI 48061

17. Scope and Observations:

McLaren Port Huron was a 186-bed community hospital and level III trauma center in Port Huron, Michigan, authorized to perform diagnostic and therapeutic administrations of radiopharmaceuticals, as well as permanent implant brachytherapy. At the time of the inspection, three full-time nuclear medicine technologists performed a full spectrum of diagnostic administrations and occasional I-131 therapies. The licensee also performed occasional I-123 prostate seed implants at the on-site Karmanos Cancer Institute. A mobile imaging service provider (Michigan Mobile PET, docket no. 030-38252) performed PET scans on Fridays and occasionally on Saturdays. The licensee retained the services of a medical physics consultant who audited the nuclear medicine program, and maintained an RSC which met quarterly.

The inspector toured the hospital in Port Huron, including the on-site Karmanos Cancer Institute. All areas were adequately posted, and all licensed material was adequately secured. Readings from independent surveys of both areas found no residual contamination or exposures to members of the public in unrestricted areas. The inspector observed several cardiac stress tests and a bone scan, observed radiation detection instrument checks, and interviewed nuclear medicine staff and management. The technologists were knowledgeable of radiation protection principles and regulatory requirements, used calibrated and operable instruments, and implemented adequate ALARA practices. The inspector also reviewed a selection of records related to the nuclear medicine program, including written directives and treatment and release documentation for all therapeutic administrations since the last inspection, personnel dosimetry reports, quarterly consultant audits, RSC meeting minutes, sealed source return documentation, reports of minor spills, and one fetal exposure in October 2021 involving 4.1 mCi of Tc-99m for a HIDA scan that was determined to be well below reporting requirements in 10 CFR 35.3047(a).

The inspector also reviewed both prostate seed implants which had been performed by the licensee since the last routine inspection. This included an evaluation of the pre- and post-implantation written directives and associated planning, treatment, and verification documentation with the licensee's dosimetrist and authorized medical physicist.

## Materials Inspection Record (Continued)

During this review, the inspector identified that the licensee's authorized user for both treatments signed all documentation, including the pre- and post-implantation portions of the written directive, well after the treatment had been completed and the patient had left the post-treatment recovery area, contrary to 10 CFR 35.40(a). The inspector determined that this represented a SLIV violation because the licensee's procedures continued to provide high confidence that the treatment was in accordance with written directives regardless of when they were signed, as the authorized user involved in planning the treatments (as well as preparing and signing the written directives) was the same one who performed them.

The root cause of the violation was an oversight. As corrective action, the licensee committed to discuss the requirement with the authorized user and to create a “process document” (checklist) in their electronic medical records system to confirm the timely completion of all required steps and records in the permanent implant brachytherapy treatment process. The licensee also committed to ensure that the “network” (i.e., McLaren Health Care) procedure for permanent implant brachytherapy, currently under review for ACR accreditation, would include equivalent verifications.

**Signature and Date - Branch Chief**

Digitally signed by Rhex A. Edwards
Date: 2023.05.05 09:08:20 -05'00'

McLaren
PORT HURON

**05/10/2023**

**UNITED STATES NUCLEAR REGULATORY COMMISSION**
**Region III**
**Materials Licensing Branch**
**2443 Warrenville Road Suite 210**
**Lisle, IL 60532-4352**

Re: Materials Inspection Report No. 2023-001 for License No. 21-20137-01

Dear Sirs,

Pursuant to the requirements in 10CFR Part 35.40(a) the following corrective actions have been taken at McLaren Port Huron:

- The AU has been educated on the written directive requirements in 35.40
- The procedure followed at the licensee has been modified to require signed written directive prior to order of Iodine-125 permanent implant brachytherapy seeds
- A checklist has been implemented to ensure that the licensee complies with the timeliness of requirements regarding steps and records in the permanent implant brachytherapy treatment process

Thank you for your time and assistance. If you have any questions, please contact our RSO, John Ference, M.D.

Sincerely,

Eric Cecava
President and Chief Executive Officer
McLaren Port Huron