

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Mercy Health Services Warde Medical Laboratory 300 West Textile Road Ann Arbor, MI 48108 REPORT NUMBER(S) 2019001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
3. DOCKET NUMBER(S) 030-18680	4. LICENSE NUMBER(S) 21-24614-01	5. DATE(S) OF INSPECTION August 26, 2019; Exit 9/13/2019

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:

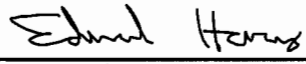
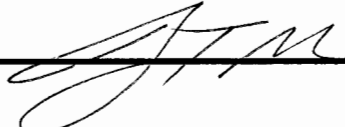
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was 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	Edward F. Harvey		09/16/2019
BRANCH CHIEF	Aaron T. McCraw		9/17/19

Docket File Information

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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS All		

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02410	2. PRIORITY 5	3. LICENSEE CONTACT Krista Byberg, RSO	4. TELEPHONE NUMBER (517) 432-8334
<input checked="" type="checkbox"/> Main Office Inspection Next Inspection Date: August 26, 2024			
<input type="checkbox"/> Field Office Inspection _____			
<input type="checkbox"/> Temporary Job Site Inspection _____			

PROGRAM SCOPE

This was a routine, unannounced inspection of a medical diagnostic services laboratory authorized to use iodine-125 (I-125) in prepackaged kits for in-vitro laboratory studies in Ann Arbor, Michigan. The in-office review consisted of a review of incoming package labeling received by the licensee that was unavailable at the time of the inspection. The licensee authorized approximately eight individuals to use the I-125 prepackaged kits to perform hormonal testing services for medical clients. These studies typically began around 2:00 p.m. and continued through the evening.

The inspector toured the facility in Ann Arbor to evaluate the licensee's measures for material security, hazard communication, and exposure control. There were no work activities being performed with licensed material at the time of the inspection. The inspector interviewed the RSO to discuss the licensee's policies and procedures for package receipt, authorized user training, personal protective equipment use, waste handling, and dosimetry, and material security. Through these discussions, the inspector found the RSO knowledgeable of radiation safety principals and regulatory requirements.

The inspector reviewed pertinent licensee records, including package receipt surveys, survey meter calibrations, waste disposal records, and dosimetry with no issues noted. Independent surveys performed within restricted and unrestricted areas indicated readings below regulatory limits.

No violations of NRC requirements were identified during this inspection.