NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Michigan Mobile PET Imaging, LLC 729 West Ann Arbor Trail, Suite 3 Plymouth, MI 48170 Location Inspected: Job Site in Wayne, Michigan REPORT NUMBER(S) 2022-001	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
030-38251	21-32786-01	March 1, 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. The violations(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)

Contrary to 10 CFR 35.63(d), on February 27 and March 1, 2022, Michigan Mobile PET Imaging administered three dosages of fluorine-18 (F-18) radiopharmaceuticals that did not fall within the prescribed dosage range. Specifically, on February 27 the licensee administered 14.45 and 14.6 millicuries (mCi) of F-18 fluorodeoxyglucose when the range was 6 to 14 mCi, and on March 1 administered 10.7 mCi of F-18 piflufolastat when the range was 8 to 10 mCi, and was not otherwise directed to do so by an authorized user.

As corrective action for this Severity Level IV violation, the licensee revised its prescribed dose list and sent all technologists a memo reiterating the requirement in 10 CFR 35.63(d) and requiring them to sign a copy attesting to their understanding.

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	Jennifer Betthauser	Jennifer Betthauser	3/18/22
NRC INSPECTOR	Ryan Craffey	Ryan Craffey Digitally signed by Ryan J. Craffey Date: 2022.03.17 23:01:08 -04'00'	
BRANCH CHIEF	Michael Kunowski	Michael A. Kunowski Digitally signed by Michael A. Kunowski Date: 2022.03.18 07:35:28 -05'00'	