



Materials Inspection Report

1. Licensee/Location Inspected: Advanced PET Imaging Network 4000 Wellness Drive Midland, MI 48670 Report Number(s) 2023-001	2. NRC/Regional Office Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352
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3. Docket Number(s) 030-38146	4. License Number(s) 21-32763-01	5. Date(s) of Inspection 06/22/23; exit 08/04/23
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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 20.1802, on June 22, 2023, Advanced PET Imaging Network did not control and maintain constant surveillance of approximately 660 millicuries of fluorine-18 located in an area at a client facility in Alpena, Michigan, which was an unrestricted area.

As corrective action, the licensee retrained all staff and involved management on security requirements, and committed to additional periodic audits of staff compliance with security procedures and requirements at the Alpena facility.

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		James M. Botti Digitally signed by James M. Botti Date: 2023.09.21 10:59:10 -04'00'
NRC INSPECTOR	Ryan Craffey	 Digitally signed by Ryan J. Craffey Date: 2023.08.07 15:50:39 -04'00'
BRANCH CHIEF	Rhex Edwards	 Digitally signed by Rhex A. Edwards Date: 2023.08.23 11:29:33 -05'00'



Materials Inspection Record

1. Licensee Name: Advanced PET Imaging Network	2. Docket Number(s): 030-38146	3. License Number(s) 21-32763-01
4. Report Number(s): 2023-001	5. Date(s) of Inspection: June 22, 2023; exit August 4, 2023	
6. Inspector(s): Ryan Craffey	7. Program Code(s): 02220	8. Priority: 3
9. Inspection Guidance Used: IP 87130		
10. Licensee Contact Name(s): Jim Botti - RSO	11. Licensee E-mail Address: jbotti@mpcphysics.com	12. Licensee Telephone Number(s): 734-662-3197

13. Inspection Type: <input type="checkbox"/> Initial <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced	14. Locations Inspected: <input type="checkbox"/> Hybrid <input type="checkbox"/> Main Office <input type="checkbox"/> Field Office <input checked="" type="checkbox"/> Temporary Job Site <input type="checkbox"/> Remote	15. Next Inspection Date (MM/DD/YYYY): 6/22/2026 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change
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16. Location(s) Inspected List:

1501 West Chisholm Street, Alpena, MI

17. Scope and Observations:
Advanced PET Imaging Network (APIN) is a mobile imaging services provider authorized to use byproduct material for diagnostic medical purposes at temporary job sites in NRC jurisdiction. At the time of the inspection, the licensee operated one PET trailer which traveled between various MyMichigan Health medical facilities in central and northern Michigan. Technologists employed by the licensee and/or its clients performed up to thirteen PET scans per day, using unit doses produced by a cyclotron in Royal Oak, Michigan. The licensee retained the services of a medical physics consultant to serve as RSO and audit the radiation protection program quarterly.

The inspector visited the licensee's trailer parked at a client facility in Alpena. Upon arrival, the inspector was shown through a publicly-accessible hallway to the PET trailer dock. The trailer was open but unoccupied, with five radiopharmaceutical transport cases on the floor of the dock. The cases contained approximately 660 mCi of F-18 (660x the Appendix C quantity) at the time and were not otherwise secured. This was noted as a SLIV violation of 10 CFR 20.1802 (Enforcement Policy Section 6.7). The root cause was human error. Handling practices for licensed material that relied on control and constant surveillance, as well as short staffing on the day of the inspection, were noted as contributing factors. As corrective action, upon returning to the dock and discussing the matter with the inspector, the technologists immediately placed all five transport cases in the trailer's locking hot lab. The licensee thereafter retrained all staff and involved management on proper handling practices and security requirements, and committed to additional periodic audits of staff compliance with security requirements at the Alpena facility.

The inspector continued the inspection with observations of four PET scans using F-18 FDG, demonstrations and discussions with the technologists, and independent surveys in and around the licensee's trailer. The technologists were knowledgeable of radiation protection principles and regulatory requirements, wore personnel dosimetry as assigned, and utilized calibrated and operable radiation detection equipment as well as adequate ALARA measures. The inspector also reviewed a selection of records including consultant audits, instrument calibration records, personnel dosimetry reports, and sealed source return documentation. The inspector also interviewed the licensee's RSO by telephone to discuss the oversight of the licensee's radiation protection program and the above finding.

Materials Inspection Record (Continued)

Signature and Date - Branch Chief

A handwritten signature in black ink, consisting of a stylized 'R' followed by a horizontal line.

Digitally signed by Rhex A. Edwards
Date: 2023.08.23 11:29:08 -05'00'