

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

MPI Research, Inc.
54943 North Main Street
Mattawan, MI 49071

REPORT NUMBER(S) 2016001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenton Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-08546

4. LICENSE NUMBER(S)

21-11315-02

5. DATE(S) OF INSPECTION

SEPTEMBER 15TH, 2016

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:

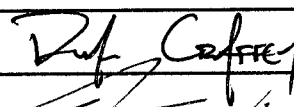
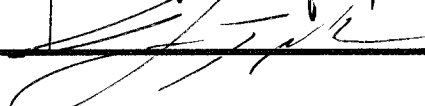
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Ryan Craffey		9/15/16
BRANCH CHIEF	Aaron McCraw		9/23/16

Docket File Information

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1. LICENSEE/LOCATION INSPECTED: MPI Research, Inc. 54943 North Main Street Mattawan, MI 49071 REPORT NUMBER(S) 2016001	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) 030-08546	4. LICENSE NUMBER(S) 21-11315-02	5. DATE(S) OF INSPECTION September 15, 2016
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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS All
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03611	2. PRIORITY 5	3. LICENSEE CONTACT Richard D. Granberg, CHP - RSO	4. TELEPHONE NUMBER (269) 668-3336
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Main Office Inspection Next Inspection Date: 09/15/2021

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a drug development research company authorized to use byproduct materials for research and development, including material from an on-site cyclotron (produced under docket number 030-38755), at its campus in Mattawan, Michigan. At the time of the inspection, the licensee used material primarily for animal studies in two departments. One used material for uptake studies, the other for molecular imaging studies. The licensee performed some synthesis of radiolabeled compounds for its own use when needed. However, the licensee had not operated its cyclotron for several months, as it was no longer involved with the third party who previously provided the staff to operate the unit. Instead, the licensee received accelerator-produced materials from one of two other cyclotrons in the region, though it did intend to resume operations of its own unit in the near future, once it had hired and trained qualified operators. The licensee's RSO was accompanied in his oversight of the program by two radiation technologists, with an additional vacancy (soon to be filled) for a radiation professional. Approximately 300 employees were considered radiation workers, though some of those worked exclusively with radiation-producing machines.

PERFORMANCE OBSERVATIONS: The inspector toured the facilities in Mattawan to evaluate the licensee's measures for materials security, hazard communication and exposure control. The inspector conducted independent surveys of various areas and found no indications of residual contamination or exposure to members of the public in excess of regulatory limits. The inspector observed several in-progress studies, as well as the conduct of area surveys following the conclusion of another. The inspector interviewed several radiation workers to discuss the implementation of licensee procedures and practices for waste handling, area surveys, personnel monitoring and training. The inspector interviewed the RSO and other safety staff to discuss the approval of authorized users and radiation material authorizations, as well as the conduct of quarterly lab surveys by radiation safety staff, and annual audits. The inspector also interviewed shipping and receiving staff to discuss the implementation of procedures and practices for radioactive material receipt and handling. The inspector reviewed a selection of records, including annual audits, ALARA investigations, recent authorized user applications, recently approved laboratory protocols involving the use of radioactive material, dosimetry reports, area survey results, waste handling documents and material accountability tables.

No violations of significance were identified as a result of this inspection.