

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

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

REPORT NUMBER(S) 2015-001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-08546

4. LICENSE NUMBER(S)

21-11315-02

5. DATE(S) OF INSPECTION

September 25, 2015

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 / Luis Nieves	<i>Ryan Craffey</i>	9/28/15
BRANCH CHIEF	Aaron McCraw	<i>[Signature]</i>	9/28/15

Docket File Information

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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 Granberg - RSO	4. TELEPHONE NUMBER (269) 668-3336
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Main Office Inspection Next Inspection Date: No change

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an announced special inspection of a drug development research organization authorized to use byproduct materials for research and development at its campus in Mattawan, Michigan. The purpose of this inspection was to review the circumstances surrounding an extremity exposure of approximately 43 rem received by a cyclotron operator between March and April 2015 while performing synthesis of cyclotron products which had been transferred to the licensee's hot cells for use under this license. The inspectors noted and reviewed this exposure during the initial inspection of the license (030-38755, 21-11315-04) that MPI Research obtained in September 2014 for radionuclide production using the newly-installed cyclotron.

PERFORMANCE OBSERVATIONS

The inspectors reviewed the licensee's dosimetry records for 2015, a root cause analysis of the exposure, and a series of process improvement evaluations to improve ALARA practices by reducing the need to handle large quantities of cyclotron products (C-11 and F-18 so far). The inspectors interviewed the licensee's radiation safety staff and the cyclotron operator who received the dose, and toured the cyclotron facility to evaluate the implementation of corrective actions in response to these exposures. The inspectors noted the completion of these process and engineering control improvements to almost completely eliminate all handling of radioactive materials during radionuclide synthesis work in the hot cells, and found that while the operator had been prohibited from any further radioactive materials work this year (and her dose reflected as such), her replacement had received much lower extremity doses in the subsequent months. The inspectors also discussed with the licensee its plans to produce solid targets containing Cu-64, Zr-89 and In-111, and in particular the development and implementation of process and engineering controls for the safe handling and use of such products.

No violations of NRC requirements were identified as a result of this inspection.