

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: MPI Research, Inc. 54943 North Main Street Mattawan, MI 49071 REPORT NUMBER(S) 2017001		2. NRC/REGIONAL OFFICE Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352	
3. DOCKET NUMBER(S) 030-38755	4. LICENSE NUMBER(S) 21-11315-04	5. DATE(S) OF INSPECTION July 24, 2017	

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:

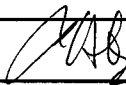

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Luis Nieves Folch		8/2/2017
BRANCH CHIEF	Aaron T. McCraw		8/2/17

Docket File Information
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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01-03.08
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03210	2. PRIORITY 2	3. LICENSEE CONTACT Richard Granberg - RSO	4. TELEPHONE NUMBER (269) 668-3336
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Main Office Inspection Next Inspection Date: July 24, 2019

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a drug development research organization authorized for radionuclide production using a refurbished Siemens RDS Eclipse cyclotron at its campus in Mattawan, Michigan. The licensee owned, maintained, staffed, and operated the cyclotron. The licensee previously relied on another company to staff and operate the unit but that partnership has since dissolved. The cyclotron manufacturer performed the majority of service on the unit when required. At the time of the inspection, the licensee produced C-11 and F-18 in liquid and gaseous forms approximately twice per week during normal business hours for use in animal imaging studies conducted on the premises under a research and development license (030-08546, 21-11315-02). The licensee no longer intended to produce Cu-64, Zr-89 and In-111 from solid targets; they do not have the appropriate equipment to do so.

Performance Observations

The inspector toured the cyclotron facility in Mattawan to evaluate the licensee's measures for materials security, hazard communication, and exposure control. The inspector conducted independent and confirmatory surveys of the facility and found no indications of residual contamination or any exposures to members of the public in excess of regulatory limits. The inspector was unable to observe any cyclotron operations, as none was scheduled the day of the inspection. However, the licensee's staff was able to demonstrate the implementation of procedures for cyclotron operations and maintenance, area surveys, and waste handling. Through these demonstrations and other discussions, the inspector found the licensee's staff to be knowledgeable of radiation protection principles and regulatory requirements.

The inspector reviewed a selection of available records relating to the use of the cyclotron, including area surveys, training documentation, programmatic and cyclotron facility audits, and dosimetry.

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

Nieves Folch, Luis

From: Nieves Folch, Luis
Sent: Thursday, August 03, 2017 8:39 AM
To: 'Richard Granberg'
Subject: Clear 591M report
Attachments: image2017-08-03-093452.pdf

Dear Mr. Granberg,

Attach is the clear 591 report for the inspection conducted on July 24, 2017, no further actions are required at this moment on your part.

In accordance with Title 10 of the Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this message will be available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>.

Please feel free to contact me if you have any questions regarding this correspondence.

Thank you,

Luis Nieves
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
(630) 829-9571