

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) 030-38755	4. LICENSE NUMBER(S) 21-11315-04	5. DATE(S) OF INSPECTION SEPTEMBER 25 TH 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:

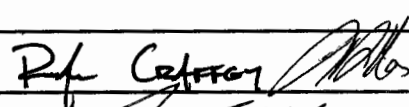
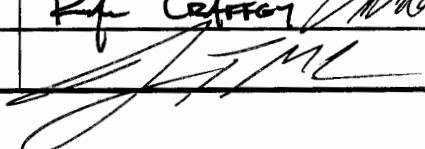
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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		9/25/15
BRANCH CHIEF	Aaron McCraw		9/29/15

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) 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: 09/25/2017

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an announced initial inspection of a drug development research organization authorized for radionuclide production using a refurbished Siemens RDS Eclipse cyclotron recently installed at its campus in Mattawan, Michigan. The licensee owned and maintained oversight of the unit, but relied on another company (who owned and operated a similar facility in Little Rock, Arkansas) to staff and operate the unit in Mattawan. The cyclotron manufacturer performed the majority of service on the unit when required. At the time of the inspection, the unit 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 also intended to produce Cu-64, Zr-89 and In-111 from solid targets in the near future, as it continued to develop this program.

PERFORMANCE OBSERVATIONS

The inspectors toured the new cyclotron facility in Mattawan to evaluate the licensee's measures for materials security, hazard communication and exposure control, and to verify the accuracy of the licensee's representations in its application. The inspectors 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 inspectors were unable to observe any cyclotron operations, as none were scheduled the day of the inspection. However, the licensee's staff were able to demonstrate the implementation of procedures for cyclotron operations and maintenance, area surveys, and waste handling. Through these demonstrations and other discussions, the inspectors found the licensee's staff and the cyclotron operators to be knowledgeable of radiation protection principles and regulatory requirements.

The inspectors 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.