

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Spectron mrc, LLC
17490 Dugdale Drive
South Bend, IN 46635

REPORT NUMBER(S) 2016-001

2. NRC/REGIONAL OFFICE

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

3. DOCKET NUMBER(S)

030-38045

4. LICENSE NUMBER(S)

13-32726-02

5. DATE(S) OF INSPECTION

February 17, 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:

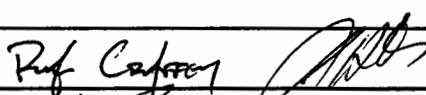
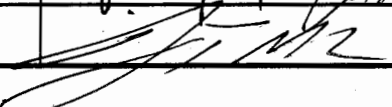
- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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 / Luis Nieves Folch		2/17/16
BRANCH CHIEF	Aaron T. McCraw		2/26/16

Docket File Information

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Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-38044, 030-38045

4. LICENSE NUMBER(S)

13-32726-01MD, 13-32726-02

5. DATE(S) OF INSPECTION

February 17, 2016

6. INSPECTION PROCEDURES USED

87127, 87125

7. INSPECTION FOCUS AREAS

03.01-03.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)

02500, 03120

2. PRIORITY

2

3. LICENSEE CONTACT

Kirk Rozycki, R.Ph. - RSO

4. TELEPHONE NUMBER

(574) 271-2800

Main Office Inspection Next Inspection Date: February 17, 2018

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced routine inspection of a cyclotron and radiopharmacy in South Bend, Indiana, licensed for the production of flourine-18 and the distribution of FDG and sodium fluoride doses. This radiopharmacy employed two pharmacists, one cyclotron engineer, and two drivers. The licensee distributed around 20 doses each day. The pharmacy was open weekdays from midnight to 4:00pm. One cyclotron run was scheduled daily, ending at 4:00am. Shipments left the facility by 5:00am, and as needed after then.

PERFORMANCE OBSERVATION

The inspectors toured the facility in South Bend, observed chemistry setup, F-18 receipt from the cyclotron, QC sample collection and evaluation, dose drawing, dose packaging, package preparation and surveys, package labeling, shipping paper preparation and placement, package blocking and bracing, waste handling and daily area surveys. Licensee personnel demonstrated dose calibrator constancy and other routine procedures, and described cyclotron maintenance. The inspectors noted no concerns with these activities. The inspectors observed that the licensee used remote systems and a hot cell for dose preparation and adequate shielding for doses removed from the hot cell. Interviews with licensee personnel indicated adequate knowledge of radiation safety concepts and procedures. The inspectors also reviewed a selection of relevant documents including dosimetry, audits, training, air monitoring, and equipment calibrations. The inspectors performed independent and confirmatory radiation measurements, which indicated results consistent with licensee survey records and postings.

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