

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Spectron mrc, LLC 17490 Dugdale Drive South Bend, IN 46635</p> <p>REPORT NUMBER(S) 2018001, 2018001</p>	<p>2. NRC/REGIONAL OFFICE</p> <p>Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352</p>
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<p>3. DOCKET NUMBER(S)</p> <p>030-38044, 030-38045</p>	<p>4. LICENSE NUMBER(S)</p> <p>13-32726-01MD, 13-32726-02</p>	<p>5. DATE(S) OF INSPECTION</p> <p>August 28, 2018</p>
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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	Jason Draper / Ryan Craffey	<i>[Signature]</i>	8/28/18
BRANCH CHIEF	Geoffrey Warren, Acting Chief	<i>[Signature]</i>	9/11/18

Docket File Information

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6. INSPECTION PROCEDURES USED 87127, 87125	7. INSPECTION FOCUS AREAS 03.01-03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500, 03120	2. PRIORITY 2	3. LICENSEE CONTACT Gregory S. Hiatt, RSO	4. TELEPHONE NUMBER (574) 271-2800
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Main Office Inspection Next Inspection Date: 08/28/2020

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a radiopharmacy and cyclotron in South Bend, IN. The licensee operated a cyclotron for production of fluorine-18 (F-18) and copper-64 (Cu-64). The licensee used the radiopharmacy to prepare and distribute lutetium-177 (Lu-177) dotatate and F-18 FDG; however, the Lu-177 use was infrequent and the licensee had not prepared any FDG since 2017. As a result, the licensee's facility did not open until 8:00am on weekdays. The licensee also used the radiopharmacy to redistribute strontium-82/rubidium-82 generators, which it was still doing periodically. The licensee still occasionally operated the cyclotron to produce F-18 and Cu-64, and it was last operated in August 2018. The licensee indicated that they are looking to redesign their facility around the production and distribution of iodine-131, lutetium-177, and actinium-225, and they have submitted a license amendment request to support these activities. The licensee employs two radiopharmacists, one radiochemist, one cyclotron engineer, and two part-time drivers.

PERFORMANCE OBSERVATIONS

The inspectors toured the cyclotron room and the radiopharmacy, however there were no principal activities ongoing at the time of the inspection. The inspectors interviewed the licensee's staff regarding radiation safety practices for the cyclotron and the radiopharmacy, specifically regarding handling of F-18 and Cu-64 and preparation of the Lu-177 doses. The inspectors also interviewed the staff regarding shipping and receiving practices and waste storage and handling. The inspectors performed independent surveys of the areas and did not identify any residual contamination or any exposure rates of concern. The inspectors also reviewed licensee records regarding calibration of instruments, shipping and receiving, inventory, leak tests, gaseous effluent, and dosimetry, and identified no concerns with regard to this documentation. The highest whole body and extremity doses received by workers were 691 mrem and 5,056 mrem for 2016 and 604 mrem and 3,762 mrem for 2017.

No violations were identified as a result of this inspection.

GW
9/11/18