

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

<p>1. LICENSEE/LOCATION INSPECTED:</p> <p>Mallinckrodt, LLC Imaging Research and Development 675 McDonnell Boulevard Hazelwood, MO 63042</p> <p>REPORT NUMBER(S) 2017001</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>	
<p>3. DOCKET NUMBER(S)</p> <p>030-12559</p>	<p>4. LICENSE NUMBER(S)</p> <p>24-17450-01</p>	<p>5. DATE(S) OF INSPECTION</p> <p>December 15, 2017</p>

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:

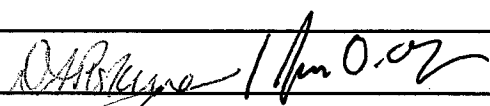

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is 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	Deborah A. Piskura / Jason D. Draper		12/15/17
BRANCH CHIEF	Aaron T. McCraw		12/21/17

Docket File Information

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6. INSPECTION PROCEDURES USED 87126	7. INSPECTION FOCUS AREAS 03.01 - 03.07
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SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 03610	2. PRIORITY 3	3. LICENSEE CONTACT Scott Surovi, RSO	4. TELEPHONE NUMBER (314) 654-7981
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Main Office Inspection Next Inspection Date: December 15, 2020

Field Office Inspection _____

Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced inspection of a pharmaceutical/imaging company authorized to use materials with atomic numbers I through 83 for laboratory research and development, including small animal studies. The licensee operated a type A broad scope program, however the use of RAM had sharply declined over the year due to the sale of the radiopharmaceutical business line. At the time of this inspection, the licensee filed an amendment to its license with its intent to downgrade the program to a type B broad scope; the amendment was pending. Currently, all use of RAM was limited to H-3, Tc-99m, In-111, and I-125 for imaging R&D. The licensee employed 325 individuals at its site, with 5 individuals approved as authorized users of RAM. Twelve individuals worked under the supervision of the authorized users. The RAM use was confined to 5 areas (2 R&D labs, the receiving cage, the HP lab, and the waste processing/storage room) within the licensee's complex. The licensee used its material as needed (at least biweekly) based on the testing schedules. The licensee established an RSC to review and approve all uses and users of RAM.

This inspection consisted of interviews with licensee personnel, a review of select records, a tour of the laboratories, and independent measurements. The inspectors toured the licensee's facility and found that all radioactive material was adequately secured. The inspectors reviewed other aspects of the licensee's radiation protection program, which included audits of the radiation protection program, exposure-rate and wipe-test surveys, rad worker training, survey instrument calibration, physical inventory, waste management, labeling of containers, and postings. The inspectors interviewed selected individuals, toured the licensee's facilities, and reviewed selected records. The laboratory and storage areas were either key or key-card controlled with access granted only to the authorized individuals.

Con't. on NRC Part 2.

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(Continued)

Con't from Part 3

The maximum TEDE and SDE exposures were reported (in millirem) as follows:

	2015	2016	YTD -11/2017
TEDE	140	16	15
SDE	1,589	699	1,409*

*NOTE: The licensee informed the inspectors that this extremity exposure did not appear valid based on the lack of use of RAM for the individuals. The RSO confirmed that all dosimetry was stored in a low background area when not in use. The dosimetry vendor reported extremity exposures for 3 individuals during the February and May 2017 monthly monitoring periods. However the licensee determined that these individuals had not used any RAM during these respective monitoring periods. The licensee noted for each individual, that the dosimetry vendor reported an exposure for only one of the assigned left and right extremity badges. The RSO discussed these exposure reports with the vendor in an attempt to correct the individuals' exposure histories; the vendor asserted that these were real exposures based on the glow curves. The RSO continues to review the licensee's exposure data for similar trends.

No violations of NRC requirements were identified during this inspection.