NRC FORM 591M PART 1
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:	2. NRC/REGIONAL OFFICE
Mallinckrodt, LLC Imaging Research and Development 675 McDonnell Blvd. Hazelwood, Missouri REPORT NUMBER(S) 2015-001	Region III U. S. Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, IL 60532-4352

3. DOCKET NUMBER(S)	4. LICENSE NUMBER(S)	5. DATE(S) OF INSPECTION
030-12559	24-17450-01	1/14&16/15, with in-office review through 2/24/15

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 violations(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.

1 Non-cited violation(s) were discussed involving the following requirement(s):

10 CFR 20.2006(d) and Section G.III.E.1. of Appendix G to 10 CFR Part 20 (failure to investigate radioactive waste shipments that were made after staff had not received acknowledgment of receipt from the recipient within 20 days after the transfer)

☐ 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	Robert G. Gattone, Jr.	Robert G. Gattone, Jr.	3/20/15
BRANCH CHIEF	Aaron T. McCraw		3/20/15

NRC FORM 591M PART 3
(07-2012)
10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

Docket File Information

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6. INSPECTION PROCEDURES USED	7. INSPECTION FOCUS AREAS
87126	02.01 through 02.07

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S)	2. PRIORITY	3. LICENSEE CONTACT	4. TELEPHONE NUMBER
03610	3	Jim Schuh, Director, EH&S, Nuc. Ops.	(314) 654-7981

☑ Main Office Inspection Next Inspection Date: 01/14/2018

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

The licensee used microcurie to curie quantities of molybdenum-99 for Moly/Tech generator product line support; microcurie to curie quantities of molybdenum-99 for for research and development (R&D), technical support, and improvement of its Moly/Tech generator product; low millicurie quantities of technetium-99m and indium-111 for imaging R&D; and microcurie quantities of phosphorus-32, carbon-14, and iodine-125 for tracer studies and animal studies. The licensee had 6 authorized users.

Performance Observations

The inspector: (1) noted that the licensee self-identified a violation of 10 CFR 20.2006(d) and Section G.III.E.1. of Appendix G to 10 CFR Part 20 (failure to investigate radioactive waste shipments that were made after staff had not received acknowledgment of receipt from the recipient within 20 days after the transfer) and implemented corrective actions to prevent occurrence; (2) observed that licensed material was secured as required during the onsite inspection; (3) observed a research scientist demonstrate how he used about 80 millicuries of technetium-99m which included use of whole body and extremity dosimeter badges, safety glasses, lab coat, absorbent paper, fume hood, shielding, remote handling tools, gloves, a survey instrument that was calibrated by an authorized firm, and proper radioactive waste disposal techniques; (4) observed a radiation worker demonstrate how he had done survey instrument operability checks, would respond to a radioactive spill scenario posed by the inspector, would respond to a skin contamination event scenario posed by the inspector, would respond to a skin fixed-contamination event scenario posed by the inspector, and had conducted whole body personnel surveys when leaving the restricted area; (5) reviewed selected records associated with Radiation Safety Committee (RSC) approvals of authorized users; (6) observed that selected fire extinguishers were checked and charged per the affixed tags; (7) observed an authorized user demonstrate how she used iodine-125 while using a lab coat, gloves, whole body and extremity dosimetry badges, absorbent paper, shielding, and tongs; (8) observed an authorized user demonstrate how she would respond to a radioactive spill scenario posed by the inspector; (9) observed the Radiation Safety Officer demonstrate how he would respond to a radioactive spill scenario posed by the inspector; (10) observed the Radiation Safety Officer demonstrate how he would use VARSKIN to calculate skin dose; (11) used a calibrated, NRC-owned survey instrument to measure 0.4 milliroentgens per hour at the surface of a shielded Moly/Tech generator; (12) noted that dosimetry records showed that the annual, maximum whole body and extremity doses for 2011 through November 30, 2014 were 495 millirem and 5039 millirem, respectively; and (13) reviewed selected air sampling records showing compliance with the constraint on air emissions.