



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

March 7, 2018

Mr. Richard Proehl, Site Director
Mallinckrodt Nuclear Medicine, LLC
2703 Wagner Place
Maryland, MO 63043

SUBJECT: NRC ROUTINE INSPECTION REPORTS NO. 03000001/2018001(DNMS),
03038173/2018001(DNMS), AND 03010801/2018001(DNMS) – MALLINCKRODT
NUCLEAR MEDICINE, LLC

Dear Mr. Proehl:

On February 5, 2018, through February 8, 2018, two inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Maryland Heights, Missouri facility. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. This letter presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. The inspectors reviewed four incidents that occurred since the last routine inspection which the licensee investigated and entered into its corrective action program.

Based on the results of this inspection, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. Because Mallinckrodt Nuclear Medicine, LLC identified this violation and entered it into its corrective action program, this violation is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy. The NCV concerned the failure to monitor the external surfaces of a package, received on January 16, 2018, for removable contamination and for radiation levels, no later than three hours after the package was received as required by Title 10 of the *Code of Federal Regulations* (CFR) 20.1906(c). On January 16, 2018, at approximately 10:30 a.m., Mallinckrodt Nuclear Medicine, LLC received a "Radioactive Yellow III" labeled package containing approximately 3,000 curies of molybdenum-99 in normal form. The common carrier delivered the package to your receiving dock and secured the door. After your staff became aware of the delivery at approximately 3:00 p.m., your staff performed surveys of this package for removable contamination and for radiation levels. Your investigation attributed the root cause of the late package surveys to a miscommunication between the licensee's security staff and the courier. As a result, the security staff, in turn, did not notify the health physics (HP) staff of the arrival of the package to prompt the HP staff to perform the required surveys of the

package. Your staff also identified that the courier knew the location of the key that operated the rollup door and proceeded to place the package in the receiving area without the knowledge of the staff. Your corrective actions included securing the keys to the rollup door, reviewing your site access procedures for contractors and couriers, and directing the wiring connection for the blue alarm light to the HP office to alert the staff of any package receipts. If you contest the violation or significance of this NCV, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region III; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response, if you choose to provide one, should not include any personal privacy, proprietary, or safeguards information so that it can be made publicly available without redaction.

Please feel free to contact Ms. Deborah A. Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA/

Aaron T. McCraw, Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-00001
License No. 24-04206-01

cc: Manuel Diaz, Radiation Safety Officer
State of Missouri

Letter to Richard Proehl from Aaron McCraw, dated March 7, 2018

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