

January 9, 2014

Mr. Gary Bosgraaf
Radiation Safety Officer
Mallinckrodt, LLC
2703 Wagner Place
Maryland Heights, MO 63043

SUBJECT: NRC SPECIAL INSPECTION REPORT NO. 03000001/2013002(DNMS) AND
NOTICE OF VIOLATION – MALLINCKRODT, LLC

Dear Mr. Bosgraaf:

In a letter, dated October 31, 2013, the U.S. Nuclear Regulatory Commission (NRC) requested information regarding activities associated with maintenance work in a cyclotron target bunker that occurred on September 17, 2013. Mallinckrodt, LLC, provided responses to the NRC request in letters, dated November 15 and 27, 2013, and e-mails, dated December 12 and 17, 2013. A final exit meeting was held between you and Mr. Lambert of my staff by telephone on December 18, 2013, to discuss the findings of our review.

During the review of information provided in your letters and e-mails, 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>. The violation concerned Mallinckrodt's failure to ensure that a cyclotron target bunker had radiation cooling for one week before unscheduled maintenance activities were performed in the bunker in accordance with procedure 36-48, "Entrance to and Departure from Cyclotron Bunkers." The violation is cited in the enclosed Notice of Violation (Notice). The NRC is citing the violations in the Notice, because the inspector identified the violations.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be useful in preparing your response. You can find the Information Notice on the NRC's website at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html>. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with Title 10 of the *Code of Federal Regulations* (CFR) 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, 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 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 Ken Lambert of my staff if you have any questions regarding this inspection. Mr. Lambert can be reached at 630-829-9633.

Sincerely,

/RA/

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

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

Enclosure:
Notice of Violation

G. Bosgraaf

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Please feel free to contact Ken Lambert of my staff if you have any questions regarding this inspection. Mr. Lambert can be reached at 630-829-9633.

Sincerely,

/RA/

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

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

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

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| NAME | KJLambert:ps*KJL | | ATMcCraw*ATM | | | | |
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NOTICE OF VIOLATION

Mallinckrodt, LLC
Maryland Heights, MO

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

During a U.S. Nuclear Regulatory Commission (NRC) review of documents submitted in response to a request for information, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License Condition 24 of NRC License Number 24-04206-01, Amendment Number 86, requires, in part, that the licensee conduct its program in accordance with the statements, representation, and procedure contained in a letter, dated November 26, 2001.

Letter, dated November 26, 2001, Section 1, Radiation Safety Program: Procedure Development, Implementation and Maintenance requires, in part, that the licensee commits to developing, implementing and maintaining necessary procedures for program areas of Operating Procedures and Maintenance of Devices, Facilities and Equipment.

Section I.C.4.a. of the licensee's Standard Operating Procedure 36-48, "Entrance to and Departure from Cyclotron Bunkers," dated October 25, 2010, requires, in part, that for unscheduled emergency repairs of the IBA cyclotron involving rebuild of target stations, remove and install, header, and collimators the radiation cooling is 1 week minimum.

Contrary to the above, on September 17, 2013, the licensee failed to ensure radiation cooling of 1 week before an individual entered IBA cyclotron target bunker 1.2 for unscheduled emergency repairs of the target header. Specifically, the individual entered IBA target bunker 1.2 with radiation cooling of only 5 days.

This is a Severity Level IV violation (Section 6.3).

Pursuant to the provisions of Title 10 of the *Code of Federal Regulations* (CFR) 2.201, Mallinckrodt, LLC is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or, if contested, the basis for disputing the violation or its severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken, and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Enclosure

Your response 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>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 9th day of January 2014.