

June 20, 2012

Willie Regits, Ph.D., Radiation Safety Officer
Cardinal Health Nuclear Pharmacy Services
7000 Cardinal Place
Dublin, OH 43017

SUBJECT: NRC ROUTINE INSPECTION REPORT 030-36973/12-001 & 12-003(DNMS)
AND NOTICE OF VIOLATION – CARDINAL HEALTH NUCLEAR PHARMACY
SERVICES.

Dear Dr. Regits:

On May 14, 2012 through 15, 2012, inspectors from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Highland, Indiana facility, with continuing in-office review through May 30, 2012. In addition, on May 16, 2012 the inspectors conducted a routine inspection at your Fort Wayne, Indiana facility, with continuing in-office review through May 30, 2012. The purpose of the inspections was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. The in-office review included receipt and review of information that was unavailable during the onsite inspections, including information about how dose calibrators were used to measure the radioactivity of beta emitters. A final exit meeting was held between you and Ken Lambert of my staff by telephone on June 8, 2012.

During these inspections, 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.

Based on the results of these inspections, the NRC has determined that two Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The first Severity Level IV violation concerned the failure to stow shipping papers as required by Title 10 of the Code of Federal Regulations (CFR) Part 71.5 and 49 CFR 177.817(e)(2)(ii). Specifically, on several occasions as of May 16, 2012, drivers from the Highland and Fort Wayne, Indiana facilities failed to ensure that, when they were not at the vehicle's controls, the shipping papers were in a holder mounted to the inside of the door on the driver's side of the vehicle or on the driver's seat in the vehicle.

The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in this letter. The violation is being cited in the Notice because it was identified by the inspectors.

The root cause of the shipping paper violation was ineffective training on the regulatory requirement. As corrective action, you committed to promptly train applicable staff on the requirement. In addition, you planned to revise your training program to emphasize the regulatory requirement during future training sessions. As such, you are now in compliance with the NRC requirement.

The NRC has concluded that information regarding the reason for the shipping paper violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

The second Severity Level IV violation concerned the failure to secure licensed material as required by 10 CFR 20.1801. Specifically, on August 25, 2011, a driver from the Highland, Indiana facility stored approximately 73 millicuries of technetium-99m in an unlocked and unattended vehicle that was in an unrestricted area. The violation was identified during an audit conducted by a member of your corporate staff. The root cause of the violation was the driver's lack of attention to details. Based on the inspection, your corrective action to prevent future recurrence was determined to be adequate.

Because this violation was self-identified, non-willful, non-repetitive, and your company took immediate corrective action, it is being treated as a Non-Cited Violation (NCV), consistent with Section 2.3.2 of the Enforcement Policy. If you contest the violation or significance of the NCV, you should provide a response within 30 days of the date of this letter, 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, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site 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 available to the public without redaction.

W. Regits

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If you have any questions concerning this matter, please contact Robert Gattone of my staff at 630-829-9823.

Sincerely,

/RA/

Hironori Peterson, Acting Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-36973
License No. 34-29200-01MD

Enclosure:
Notice of Violation

cc w/encl: State of Michigan

If you have any questions concerning this matter, please contact Robert Gattone of my staff at 630-829-9823.

Sincerely,

/RA/

Hironori Peterson, Acting Chief
Materials Inspection Branch
Division of Nuclear Materials Safety

Docket No. 030-36973
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Enclosure:
Notice of Violation

cc w/encl: State of Michigan

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NOTICE OF VIOLATION

Cardinal Health Nuclear Pharmacy Services
Dublin, OH

Docket No. 030-36973
License No. 34-29200-01MD

During U.S. Nuclear Regulatory Commission (NRC) inspections conducted on May 14 through 15, 2012, and May 16, 2012, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the Code of Federal Regulations (CFR) 71.5(a) requires that a licensee who transports licensed material outside of the site of usage, as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 107, 171-180, and 390-397.

Title 49 CFR 172.602(c) requires, with exceptions not applicable here, that the emergency response information specified in 49 CFR 172.602(a) must be maintained by each carrier who transports hazardous material in the same manner as prescribed for shipping papers. Title 49 CFR 177.817(e) requires, in part, that the driver of a motor vehicle containing hazardous material ensure that the shipping paper is readily available to, and recognizable by, authorities in the event of accident or inspection. Specifically, (i) when the driver is at the vehicle's controls, the shipping paper shall be: (a) within his immediate reach while he is restrained by the lap belt; and (b) either readily visible to a person entering the driver's compartment or in a holder which is mounted to the inside of the door on the driver's side of the vehicle; (ii) when the driver is not at the vehicle's controls, the shipping paper shall be: (a) in a holder which is mounted to the side of the door on the driver's side of the vehicle; or (b) on the driver's seat in the vehicle. Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

Contrary to the above, on several occasions as of May 16, 2012, including May 14 and 15, 2012, the licensee transported licensed material, outside the site of usage, as specified on the NRC license, or on a public highway, and the driver of the vehicle did not ensure that the emergency response information was readily available in the driver's compartment, as required. Specifically, when the drivers were not at the vehicle's controls, the shipping papers were left on the front passenger seat of the vehicle while licensed material was in the vehicle, rather than in a holder mounted to the door on the driver's side of the vehicle or on the driver's seat.

This is a Severity Level IV violation (Section 6.8).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in the letter transmitting this Notice of Violation (Notice). However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, IR 030-36973/12-001 & 12-003(DNMS)," and send it 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.

Enclosure

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

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site 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.

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

Dated this 20th day of June 2012.