

May 28, 2008

Mr. Jack Coffey  
Senior Vice President  
Quality and Regulatory  
Nuclear Pharmacy Services  
Cardinal Health  
7000 Cardinal Place  
Dublin, OH 43017

SUBJECT: NRC INSPECTION REPORT 030-36973/08-08(DNMS) AND NOTICE OF VIOLATION - EAST RUTHERFORD, NEW JERSEY PHARMACY

Dear Mr. Coffey:

This refers to the routine inspection conducted on May 1, 2008, at your East Rutherford, New Jersey facility. The inspection results were discussed with Willie Regits of your staff during a final telephonic exit briefing conducted on May 21, 2008.

This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with 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 this inspection, the NRC has determined that a 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 Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The violation is cited in the enclosed Notice of Violation (Notice) and involves three examples of East Rutherford, New Jersey pharmacy staff's failure to monitor hands and clothing for contamination before leaving the restricted area. The first two examples were identified during a Cardinal Health corporate audit on January 28, 2008, and an East Rutherford pharmacy internal audit on March 27, 2008. The third example was identified during the NRC inspection and involved an individual who monitored his hands and clothing, but rather than exiting the door by the frisking station, walked through the restricted area, exiting through a different door without again monitoring himself. The violation is being cited because, although your staff identified the first two examples, corrective actions implemented to prevent recurrence were not effective, resulting in the third example being identified during our May 1, 2008, inspection.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. For your consideration and convenience, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," is enclosed. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements."

J. Coffey

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document 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.

Sincerely,

*/RA/*

Patrick L. Loudon, Chief  
Materials Inspection Branch

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

Enclosures:

1. Notice of Violation
2. NRC Information Notice 96-28

cc: State of New Jersey

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## NOTICE OF VIOLATION

Cardinal Health Nuclear Pharmacy Services  
Dublin, Ohio 43017

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

During an NRC inspection conducted on May 1, 2008, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

License Condition 24 requires, in part, that except as specifically provided otherwise in this license, the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application dated March 29, 2001, including any enclosures.

Item 10.4.C of the application, dated March 29, 2001, requires that personnel monitor hands and clothing for contamination before leaving the restricted area.

Contrary to the above, on January 28, March 27, and May 1, 2008, personnel failed to monitor their hands and clothing for contamination before leaving the restricted area. Specifically, during audits on January 28 and March 27, 2008, the licensee identified personnel leaving the restricted area without monitoring. In addition, on May 1, 2008, an individual performed the required monitoring, but rather than exiting the door by the frisking station, walked through the restricted area exiting through a different door without again monitoring himself.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Cardinal Health Nuclear Pharmacy Services is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, 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 for the violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid further violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous 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.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> to the extent possible, it should not include any personal privacy, proprietary or safeguards information so that it can be made

Enclosure

available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21. In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 28<sup>th</sup> day of May 2008