

December 30, 2009

EA-09-221

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

SUBJECT: NOTICE OF VIOLATION – CARDINAL HEALTH, CHARLOTTESVILLE,
VIRGINIA FACILITY; NRC INSPECTION REPORT 030-36973/2008-001 AND
NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-2008-003

Dear Mr. Coffey:

This refers to the inspection completed on January 23, 2008, at your facility located in Charlottesville, Virginia. The purpose of the inspection was to examine 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. During the inspection, the inspectors confirmed a Cardinal Health audit finding that an individual did not wear ring dosimetry when compounding iodine-131 doses between January and May 2007, as documented in Inspection Report 030-36973/2008-001, dated February 7, 2008. As a result, the U.S. Nuclear Regulatory Commission (NRC) initiated an investigation into the issue. On August 20, 2009, the NRC Office of Investigations (OI) completed its investigation into the circumstances surrounding the failure to wear ring dosimetry while compounding iodine-131 doses. In a letter dated October 26, 2009, the NRC provided you a synopsis of the OI investigation and identified an apparent violation of a license condition.

In the letter transmitting the inspection report, we offered you the opportunity to address the apparent violation identified in the report by either attending a Predecisional Enforcement Conference or by providing a written response before we made our final enforcement decision. In a letter dated December 1, 2009, you provided a response to the apparent violation which outlined your corrective actions.

Based on the information developed during the inspection, the investigation, and the information that you provided in your December 1, 2009, response to our October 26, 2009, letter, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it were described in detail in Inspection Report 030-36973/2008-001 and NRC letter dated October 26, 2009. The violation involved a former member of your staff deliberately failing to wear ring dosimetry on several occasions while compounding iodine-131 doses, contrary to a requirement in your

Radiation Safety Manual, a document incorporated into your NRC license. The NRC determined that the root cause of the violation was the individual's deliberate action to perform an unauthorized experiment to determine the cause of high dosimetry readings that the individual experienced during the previous year.

The violation is of concern to the NRC because the failure to wear dosimetry could have resulted in the individual receiving a radiation dose to their hands that exceeded regulatory limits. Therefore, the violation has been categorized, in accordance with the NRC Enforcement Policy, as a Severity Level III violation.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$3500 is normally considered for a Severity Level III violation. Because there were willful aspects to the violation, the NRC considered whether credit was warranted for both *Identification* and *Corrective Action*, in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. The NRC determined that credit was warranted for *Identification* because the individual self-reported not wearing the dosimetry during an audit of the nuclear pharmacy program and your staff took immediate corrective actions. Credit was also warranted for *Corrective Action*. As an immediate corrective action, the individual was reprimanded and removed as the pharmacy's radiation safety officer. The long-term corrective action to prevent recurrence included development of two new programs which employees can use in order to determine sources of extremity exposures. The first program provides employees with resources to monitor their day to day radioactive material handling duties with a live-time radiation exposure rate and dose assessment instrument. The second program will allow employees to request additional extremity dosimeters to be worn during different nuclide handling activities.

Therefore, to encourage prompt and comprehensive correction of violations, and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and to prevent recurrence, and the date when full compliance was achieved was already adequately addressed in your reply dated December 1, 2009. Therefore, you are not required to respond to this letter unless the description therein 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.

In accordance with Title 10 of the Code of Federal Regulations (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's 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. If personal privacy or proprietary information is necessary to provide an acceptable response, 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 information, 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). The NRC also includes significant enforcement actions on its Web site at www.nrc.gov/about-nrc/regulatory/enforcement.html.

Sincerely,

/RA by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

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

Enclosure:
Notice of Violation

cc w/encl: State of Ohio
Commonwealth of Virginia

Letter to John Coffey from Mark A. Satorius dated December 30, 2009

SUBJECT: NOTICE OF VIOLATION – CARDINAL HEALTH, CHARLOTTESVILLE,
VIRGINIA FACILITY; NRC INSPECTION REPORT 030-36973/2008-001 AND
NRC OFFICE OF INVESTIGATIONS REPORT NO. 3-2008-003

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NOTICE OF VIOLATION

Cardinal Health
Dublin, Ohio

Docket No. 030-36973
License No. 34-29200-01MD
EA-09-221

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on January 23, 2008, and an investigation completed on August 20, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Condition 24 of NRC License 34-29200-01MD, Amendments 10 and 11, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application, dated March 29, 2001.

Item 10.18 of the licensee's application states, in part, that the licensee will establish and implement written personnel monitoring procedures. The licensee's Radiation Safety Manual provides the written personnel monitoring procedures.

Section 7.2.1.b, "Dosimetry and Exposure Monitoring," of the licensee's Radiation Safety Manual, requires, in part, that ring dosimeters be issued to all employees with a task assignment classification of either dispenser or handler and that dispensers wear one finger dosimeter on the index finger of each hand. Section 7.1 of the Radiation Safety Manual states that a dispenser is an employee who compounds radiopharmaceuticals, elutes generators, or dispenses doses, either occasionally or on a regular basis.

Contrary to the above, on several occasions between January and May 17, 2007, a licensee employee, who was a dispenser and the local radiation safety officer, deliberately failed to wear finger ring dosimeters on the index finger of each hand when compounding iodine-131 doses, a radiopharmaceutical.

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

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to be taken to correct the violation and to prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report 030-36973/2008-001(DNMS), dated February 7, 2008, and in a letter from the licensee dated December 1, 2009. However, you are required to submit a written statement or explanation pursuant to Title 10 of the Code of Federal Regulations (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 EA-09-221," 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, 2443 Warrenville Road, Suite 210, Lisle, IL 60532, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

ENCLOSURE

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.

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's 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.

Dated this 30th day of December 2009

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 information, 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). The NRC also includes significant enforcement actions on its Web site at www.nrc.gov/about-nrc/regulatory/enforcement.html.

Sincerely,

/RA by Cynthia D. Pederson Acting for/

Mark A. Satorius
Regional Administrator

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

Enclosure:
Notice of Violation

cc w/encl: State of Ohio
Commonwealth of Virginia

DISTRIBUTION:
See next page

*See previous concurrence

FILE NAME: G:\EICS\ENFORCEMENT\Enforcement Cases 2009\EA-09-221 Cardinal Health\EA-09-221 Cardinal Health Draft Final Action.doc

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OFFICE	RIII	RIII	RIII	RIII	RIII
NAME	Lougheed*	Bloomer	Louden for Reynolds	Heller for Orth	Pederson for Satorius
DATE	12/24/09	12/30/09	12/30/09	12/30/09	12/30/09
OFFICE	D:OE	D:OGC	D:FSME		
NAME	Day for Zimmerman ¹	Barkman for Scott ²	White for Miller ³		
DATE	12/24/09	12/15/09	12/24/09		

OFFICIAL RECORD COPY

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1. OE concurrence received via e-mail from K. Day on December 24, 2009.
 2. OGC "No Legal Objection" received via e-mail from M. Barkman on December 15, 2009.
 3. FSME concurrence received via e-mail from D. White on December 24, 2009.