November 9, 2011

EA-11-146

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 PET MANUFACTURING SERVICES; NRC INSPECTION REPORT NO. 03038222/2010-001(DNMS) AND INVESTIGATION REPORT NO. 3-2010-033

Dear Mr. Coffey:

This refers to a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on August 5, 2010, at your facility located in St. Louis, Missouri. The purpose of the inspection was to review the circumstances, root and contributing causes, and corrective actions associated with an event involving an individual who removed a chemical cartridge that contained approximately 4 curies of fluorine-18 from a synthesis unit without using remote handling tools and without wearing extremity dosimetry. As a result of the inspection findings, the NRC initiated an investigation. On June 2, 2011, the NRC Office of Investigations (OI) completed its investigation into the circumstances surrounding the event. In a letter dated August 31, 2011, the NRC provided you a synopsis of the OI investigation and identified an apparent violation of NRC regulations.

In the August 31, 2011, letter, we also provided you with the opportunity to address the apparent violation by attending a Predecisional Enforcement Conference, participating in the Alternative Dispute Resolution process, or providing a written response before we made our final enforcement decision. In a letter dated September 29, 2011, you provided a response to the apparent violation.

Based on the information developed during the inspection, investigation, and the information that you provided in your September 29, 2011, response, 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 are described in detail in NRC Inspection Report No. 03038222/2010-001(DNMS) and in the NRC letter to you dated August 31, 2011. The violation involved your former St. Louis manufacturing/local Radiation Safety Officer deliberately removing his extremity dosimetry on two occasions on June 16, 2010, prior to handling chemical cartridges containing fluorine-18. The individual's actions caused Cardinal Health PET Manufacturing Services to be in violation of the requirements in Title 10 of the Code of Federal Regulations (10 CFR) 20.1502(a)(1) which requires that you monitor an individual's occupational exposure to radiation from licensed and unlicensed radiation sources under your control if the individual was likely to receive a skin dose greater than 5 rem in one year from sources external to the body.

The NRC determined that the root cause of the violation was your local radiation safety officer's deliberate action to remove his extremity (ring) dosimetry. The violation is of concern to the NRC because your local Radiation Safety Officer's deliberate failure to wear assigned extremity dosimetry while handling the chemical cartridge could have prevented identification of the received dose. In addition, willful violations are of particular concern because our regulatory programs are based on licensees, applicants, and their employees acting with integrity and communicating with candor. 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 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 2.3.4 of the Enforcement Policy. The NRC determined that credit was warranted for *Identification* because your staff identified the violation and reported it to the NRC. The NRC also determined that credit was warranted for *Corrective Action* based on your corrective actions which included taking significant disciplinary action against the former employee and retraining all staff at your St. Louis facility. As for your long-term corrective actions to prevent recurrence in the future, your Radiation Safety Committee which met on November 2, 2010, agreed to be more diligent in their review of the individuals appointed to radiation safety officer positions in Cardinal Health facilities. You also revised your Nuclear Pharmacy Services Regulatory Compliance Required Corrective Action Policy (Corrective Action Policy) and Cardinal Health Nuclear Pharmacy Services Personnel Monitoring Policy (Dosimetry Policy Training) by adding a "no tolerance" clause, retrained all individuals who are likely to exceed 10 percent of the annual exposure limit and added the training into the annual training program for employees that have been issued dosimetry. Additionally, the corporate radiation safety officer provided guidance to all local radiation safety officers and operations management on the Corrective Action Policy.

Therefore, to encourage prompt identification and comprehensive correction of violations, 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, which may subject you to increased inspection effort.

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03038222/2010-001(DNMS), in the NRC letter dated August 31, 2011, and in your response dated September 29, 2011. 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 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response, if any, will be made available electronically for public inspection 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. The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/ enforcement/actions.

Sincerely,

/RA by Jennifer L. Uhle Acting for/

Cynthia D. Pederson
Acting Regional Administrator

Docket No. 030-38222

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html. The NRC also includes significant enforcement actions on its Web site at http://www.nrc.gov/reading-rm/doc-collections/ enforcement/actions.

Sincerely,

/RA by Jennifer L. Uhle Acting for/

Cynthia D. Pederson
Acting Regional Administrator

Docket No. 030-38222

Enclosure:
Notice of Violation

cc w/encl: State of Missouri

DISTRIBUTION:
See next page

***SEE PREVIOUS CONCURRENCE**

FILE NAME: G:\ORAIII\EICS\ENFORCEMENT\Enforcement Cases 2011\EA-11-146, 147 Cardinal Health\EA-11-146 Cardinal Health final action.docx
☑ Publicly Available, non-sensitive

OFFICE	RIII	RIII	RIII	RIII	D:OGC
NAME	Lougheed*	Boland for Bloomer*	Boland*	Heck*	Boote for Scott[1]*
DATE	10/24/11	10/24/11	10/24/11	10/25 /11	10/27/11
OFFICE	D:FSME	D:OE	RIII	RIII	
NAME	White for Satorius[2]*	Day for Zimmerman[3]*	Orth	Uhle for Pederson	
DATE	10/28/11	11/01/11	11/08/11	11/09/11	

OFFICIAL RECORD COPY

[1] OGC "No Legal Objection" received via e-mail from K. Day on November 1, 2011.
[2] FSME concurrence received via e-mail from K. Day on November 1, 2011.
[3] OE concurrence received via e-mail from K. Day on November 1, 2011.

Letter to Jack Coffey from Cynthia D. Pederson dated November 9, 2011

SUBJECT: NOTICE OF VIOLATION – CARDINAL HEALTH PET MANUFACTURING SERVICES; NRC INSPECTION REPORT NO. 03038222/2010-001(DNMS) AND INVESTIGATION REPORT NO. 3-2010-033

DISTRIBUTION:

Docket File
RidsSecyMailCenter.Resource
OCADistribution
Bill Borchardt
Michael Weber
Roy Zimmerman
Aida Rivera Varona
Kerstun Day
Mark Satorius
Cynthia Pederson
Marvin Itzkowitz
Catherine Scott
Mark Satorius
Brian McDermott
Michele Burgess
Duane White
Daniel Holody
Scott Sparks
Heather Gepford
Holly Harrington
Hubert Bell
Cheryl McCrary
Mona Williams
Anne Boland
Patrick Louden
Tamara Bloomer
MIB Inspectors
Steven Orth
Robert Goetz
Jared Heck
Allan Barker
Harral Logaras
James Lynch
Viktoria Mitlyng
Prema Chandrathil
Patricia Lougheed
Paul Pelke
Magdalena Gryglak
Sarah Bakhsh
Patricia Buckley
Tammy Tomczak
OEMAIL
OEWEB

NOTICE OF VIOLATION

Cardinal Health PET Manufacturing Services, Inc.
St. Louis, Missouri

Docket No. 030-38222
EA-11-146

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on August 5, 2010 and an investigation completed on June 2, 2011, a 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 (10 CFR) 30.3(c)(1) states, in part, that the requirements specific to licensees in Part 30 and Parts 19, 20, 21, and 71 shall apply to all persons when conducting activities under the authority provided by paragraphs (c)(2) and (c)(3) of Section 30.3.
>
> Title 10 CFR 30.3(c)(3) states, in part, that all persons who possess and use accelerator produced radioactive material for which a specific license is required may continue to use such material for uses permitted under Part 30 provided that the person submits a license application as specified therein.
>
> Title 10 CFR 20.1502(a)(1) requires that the licensee (in this case, an applicant) monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and supply and require the use of individual monitoring devices by adults likely to receive, in one year from sources external to the body, a dose in excess of 10 percent of the limits in 10 CFR 20.1201(a). The extremity limit in 10 CFR 20.1201(a) is 50 rem to the skin of any extremity.
>
> Contrary to the above, on June 16, 2010, Cardinal Health PET Manufacturing Services, an applicant for an NRC license in accordance with 10 CFR 30.3(c)(3), failed to monitor the occupational exposure to radiation from radiation sources under the control of Cardinal Health PET Manufacturing Services and the individual adult was likely to receive, in one year from external sources to the body, an extremity dose in excess of 5 rem. Specifically, on June 16, 2010, a Cardinal Health PET Manufacturing Services employee removed his extremity (ring) dosimetry on two separate occasions prior to handling a chemical (QMA) cartridge containing approximately 4 curies of fluorine-18.

This is a Severity Level III violation (Section 6.7).

The NRC has concluded that information regarding the reasons for the violation, the corrective actions taken and planned to be taken to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in NRC Inspection Report No. 03038222/2010-001(DNMS), in the NRC letter dated August 31, 2011, and in your response dated September 29, 2011.

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, EA-11-146” 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 and the Enforcement Officer, 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).

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 of receipt.

Dated this 9th day of November 2011