August 31, 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: RESULT OF NRC INVESTIGATION, REPORT NO. 3-2010-033 – CARDINAL HEALTH PET MANUFACTURING SERVICES – ST. LOUIS, MISSOURI

Dear Mr. Coffey:

On August 5, 2010, the U.S. Nuclear Regulatory Commission (NRC) conducted a reactive inspection at the Cardinal Health PET Manufacturing Services St. Louis, Missouri, facility, to review the circumstances surrounding an individual who handled a chemical cartridge containing approximately 4 curies of fluorine-18 without wearing extremity dosimetry. On June 2, 2011, the NRC Office of Investigations (OI) completed its investigation into the circumstances surrounding the event. Enclosed is a summary of the OI investigation report.

Based on the results of the August 5, 2010, inspection and the OI investigation, one apparent violation was identified and is being considered for escalated enforcement action 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 apparent violation involves an individual's deliberate failure to wear extremity dosimetry while handling a chemical cartridge containing fluorine-18 in accordance with Title 10 of the Code of Federal Regulations (CFR) Sections 30.3(c)(1), 30.3(c)(3), and 20.1502(a)(1). The regulations in 10 CFR Section 20.1502(a)(1) require that individuals likely to receive, in one year from licensed or unlicensed radiation sources, a dose external to the body in excess of ten percent of the limits in 10 CFR 20.1201(a) be provided and required to wear individual monitoring devices. The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective action were discussed with Willie Regits, your corporate radiation safety officer (RSO), during a telephonic exit meeting on August 24, 2010, and documented in detail in Inspection Report No. 030-38222/10-01(DNMS), dated September 22, 2010.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violation addressed herein within 30 days of the date of this letter; (2) request a Pre-decisional Enforcement Conference (PEC); or (3) request Alternative Dispute Resolution (ADR). If a PEC is held, the NRC will issue a press release to announce the time and date of the conference; however, it will be closed to public observation because the apparent violation is based on an NRC OI Report that has not been publicly disclosed and pertains to whether an individual has committed wrongdoing. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter. Please contact Tamara Bloomer at (630) 829-9627 within ten days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a “Response to an Apparent Violation; EA-11-146,” and should include: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent 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. In addition, we request that you include in your response a description of the radiation safety duties and responsibilities of the individual, in his role as the local site RSO. Also, describe the actions you have taken to ensure the other local RSOs have the knowledge and skills necessary to adequately recognize and implement their safety and regulatory responsibilities, considering that, the individual involved in this issue had been in your employ for less than two years and had no previous radiation safety experience. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. The guidance in NRC Information Notice 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” may be helpful. You can find the information notice on the NRC website at: http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1996/in96028.html. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on the apparent violation and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the conference may include the following: (1) information to determine whether a violation occurred; (2) information to determine the significance of a violation; (3) information related to the identification of a violation; (4) information related to any corrective actions taken or planned to be taken; and (5) information to ensure that your local RSOs have the knowledge and skills to implement their safety mission. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation.

In lieu of a PEC, you may also request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a third party neutral. The technique that the NRC has decided to employ is mediation. Mediation is a voluntary, informal process in which a trained neutral (the “mediator”) works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact ICR at (877) 733-9415 within ten days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

In addition, please be advised that the number and characterization of apparent violations may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR Section 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 you have any questions concerning this matter, please contact Tamara Bloomer of my staff at (630) 829-9627.

Sincerely,

/RA by Patrick L. Louden acting for/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-38222

Enclosure:
Office of Investigations Report Summary

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 you have any questions concerning this matter, please contact Tamara Bloomer of my staff at (630) 829-9627.

Sincerely,

/RA by Patrick L. Louden acting for/

Anne T. Boland, Director
Division of Nuclear Materials Safety

Docket No. 030-38222

Enclosure:
Office of Investigations Report Summary

Distribution:

Andy Campbell	Duane White	Magdalena Gryglak
Nick Hilton	Anne Boland	Sarah Bakhsh
Kerstun Day	Patrick Louden	Patricia Buckley
Mark Satorius	Tamara Bloomer	Tammy Tomczak
Cynthia Pederson	Steven Orth	MIB Inspectors
Cynthia Carpenter	Jared Heck	OEMAIL
James Luehman	Patricia Lougheed	EA-11-146 File
Michele Burgess	Paul Pelke	

*See previous concurrence
DOCUMENT NAME: G:\DNMSIII\Work in progress\LTR- Choice letter-Cardinal Health HQ EICS REV 3.docx
☒ Publicly Available ☐ Non-Publicly Available ☐ Sensitive ☒ Non-Sensitive
To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII DNMS		RIII DNMS		RIII OI		RIII EICS	
NAME	KJLambert: jm		TEBloomer: KJLambert for		SJLangan: MKF for		SKOrth	
DATE	08/11/11		08/11/11		08/ 08/11		08/31/11	
OFFICE	RIII DNMS		RIII		RIII		RIII	
NAME	ATBoland							
DATE	08/31/11							

OFFICIAL RECORD COPY

FACTUAL SUMMARY OF OFFICE OF INVESTIGATIONS REPORT 3-2010-033

On September 7, 2010, the U. S. Nuclear Regulatory Commission's Office of Investigations (OI), Region III Field Office, initiated an investigation to determine whether a Technician II/ local Radiation Safety Officer (RSO) employed by Cardinal Health PET Manufacturing Services in St. Louis, Missouri (Cardinal Health PET), deliberately removed his extremity and whole body dosimeters while handling a chemical (QMA) cartridge containing approximately 4 curies of fluorine-18. The NRC completed its investigation on June 2, 2011.

Title 10 of the Code of Federal Regulations (10 CFR) Section 30.3(c)(3) provide that persons who possess and use accelerator produced radioactive material may continue to use such material provided that the person submits a license application to the NRC within 12 months of September 30, 2008. On December 11, 2009, Cardinal Health PET applied for an NRC license. Furthermore, 10 CFR 30.3(c)(1) mandates that all persons conducting activities under the authority of 10 CFR 30.3(c)(3) must comply with the requirements in 10 CFR Parts 19, 20, 21, 30, and 71. Cardinal Health PET is considered such a person.

As such, Cardinal Health PET must comply with 10 CFR 20.1502(a)(1), which mandates that licensees (in this case, an applicant) monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee at levels sufficient to demonstrate compliance with the occupational dose limits in 10 CFR Part 20. At a minimum, the licensee (applicant) shall supply and require the use of individual monitoring devices by adults likely to receive, in 1 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.

Based on the individual’s job duties and historical monitoring data, the Technician II/local RSO would require extremity monitoring. During the OI Investigation, the individual acknowledged he was aware of the requirement to wear both whole body and ring dosimetry. The individual admitted to making a conscious decision on June 16, 2010, to remove his extremity (ring) dosimetry prior to handling a chemical (QMA) cartridge containing approximately 4 curies of fluorine-18 on two separate occasions. The individual stated that he replaced his extremity dosimetry between the two incidents.

Consequently, the investigation substantiated that the individual deliberately removed his extremity dosimeters while handling a QMA cartridge on two occasions.

Enclosure