

October 26, 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: RESULTS OF THE OFFICE OF INVESTIGATIONS INVESTIGATION
CARDINAL HEALTH – CHARLOTTESVILLE, VIRGINIA FACILITY

Dear Mr. Coffey:

On October 24, 2007, the Nuclear Regulatory Commission (NRC) completed a routine inspection at your corporate office in Dublin, Ohio. During the inspection, the inspectors reviewed internal audits conducted at selected pharmacies and noted that an audit report, dated May 17, 2007, involving the Charlottesville, Virginia facility indicated that an individual was not wearing extremity (ring) dosimetry when compounding iodine-131 doses. On January 23, 2008, a routine inspection was conducted at the Charlottesville, Virginia facility, which confirmed that an individual was not wearing ring dosimetry when compounding iodine-131 doses. 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.

Based on the results of the inspections and the OI investigation, one apparent deliberate 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 failure to wear ring dosimetry while compounding radiopharmaceuticals (iodine-131) in accordance with Section 7.2.1.b of Cardinal Health's Radiation Safety Manual. Section 7.2.1.b of Cardinal Health's Radiation Safety Manual states, 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. The circumstances surrounding the apparent violation, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff at the inspection exit meeting on October 24, 2007. As a result, it may not be necessary to conduct a pre-decisional enforcement conference in order to enable the NRC to make an enforcement decision.

In addition, since you identified the violation, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to (1) respond to the apparent violation addressed above 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, it will be open for public observation and the NRC will issue a press release to announce the time and date of the conference. Please contact Tamara Bloomer at (630) 829-9627 within 7 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 in Inspection Report No. 030-36973/08-01; EA-09-221" and should include for the apparent violation: (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. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. 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: information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned to be taken. 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. The guidance in the enclosed NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

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 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

J. Coffey

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In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report 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 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Website 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. Loudon Acting For/

Steven A. Reynolds, Director
Division of Nuclear Material Safety

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

Enclosures:

1. Office of Investigations Report Summary
2. NRC Information Notice 96-28

J. Coffey

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Letter to Jack Coffey from Steven A. Reynolds dated October 26, 2009

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CARDINAL HEALTH – CHARLOTTESVILLE, VIRGINIA FACILITY

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FACTUAL SUMMARY OF OFFICE OF INVESTIGATIONS REPORT 3-2008-003

On November 14, 2007, the U. S. Nuclear Regulatory Commission's Office of Investigations (OI), Region III Field Office, initiated an investigation to determine whether a radiation safety officer employed by Cardinal Health Nuclear Pharmacy Services, Charlottesville, Virginia, deliberately failed to wear extremity (ring) dosimetry while compounding iodine-131 (radiopharmaceuticals) between January 1 and May 17, 2007.

Cardinal Health's Radiation Safety Manual, Section 7.2.1.b, states, 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.

The individual acknowledged being a dispenser who compounded radiopharmaceuticals on a regular basis. The individual stated during an OI interview that she intentionally removed her ring dosimeters while compounding iodine-131 doses. The individual also voluntarily disclosed this information to an internal auditor and admitted to the auditor that she knew she was not supposed to remove her extremity dosimetry before compounding iodine-131 doses. The individual stated that she was conducting an experiment to try to determine why she was receiving such high radiation dose readings on her extremity dosimetry.