



December 1, 2009

Mr. Steven Reynolds  
US Nuclear Regulatory Commission  
Region III  
Division of Nuclear Material Safety  
2443 Warrenville Road, Suite 210  
Lisle, Illinois 60532-4352

Re: Response to an Apparent Violation in Inspection Report No. 030-36973/08-01;  
EA-09-221. License Number 34-29200-01MD; Cardinal Health, Charlottesville,  
VA.

Mr. Reynolds,

This letter is in response to the NRC Office of Investigations' investigation completed on August 20, 2009. The investigation was in response to the inspectors' findings during an inspection performed on October 24, 2007. Cardinal Health Nuclear Pharmacy Services' (hereafter Cardinal Health NPS) response to the investigation findings are below.

The reason for this violation is as the Agency stated in its Factual Summary of Office of Investigations Report 3-2008-003. The individual in question, intentionally and at her own will, removed her extremity dosimeters routinely during the period between January 2007 and May 2007 in order to diagnose which handling tasks were contributing to her elevated extremity exposure.

Since this individual was not wearing her extremity dosimeter at all times, the immediate corrective action was for Cardinal Health NPS to perform a dose reconstruction for the period the dosimeters were not worn. The results of the dose reconstruction were then added to her exposure history. The results and explanation of the dose reconstruction can be review in the enclosed report. This dose reconstruction resulted in the addition of 5110 mrem to her right extremity and 1160 mrem to her left extremity. This individual's final year to date exposure did not exceed the 50,000 mrem limit.

Cardinal Health NPS has identified the root cause of this violation; an employee attempting to determine the source of her high extremity exposures. However the methods employed were not in compliance with company policies. This violation occurred due to the deliberate actions of the individual and was an isolated incident. Additionally, the employee did not request assistance from the local management team or the corporate Health Physics Group; resources readily available to every employee.

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Cardinal Health NPS has implemented the following corrective actions which will affect the whole radiation safety program in response to this violation. Cardinal Health NPS Quality and Regulatory Department is developing two programs which employees can use to investigate sources of extremity exposures. The first program will involve providing employees with the resources to monitoring their day to day radioactive material handling duties with a live-time radiation exposure rate and dose assessment instrument. The tool Cardinal Health NPS has chosen is the Unfors NED meter. This program will allow concerned employees to use the meter to investigate which tasks lead to elevated extremity exposure. There are multiple individuals in the Quality and Regulatory Department and within Operations which are trained in the proper use of this meter. Pharmacies will have the option to request a trained individual to perform the investigation or request the Unfors meter and receive guidance from the corporate health physics group on the use of the meter.

Additionally employees have expressed the interest in distinguishing which radionuclides, specifically F-18 and I-131, contribute to their extremity exposure. The second program to be implemented will allow employees to request additional extremity dosimeters to be worn during different nuclide handling activities. For example, when there is an employee who compounds Tc-99m, F-18, and I-131 unit doses, the employee will have one set of extremity dosimeters: for F-18 related handling activities, I-131 handling activities, and another set of extremity dosimeters for all other nuclides, including Tc-99m. The employee will be able to switch to the appropriate nuclide rings for the corresponding activities. This will allow them the ability to see which nuclides are contributing to there overall exposure without being unmonitored during any period of time.

The first monitoring program with the Unfors NED meter was implemented in 2007. The second monitoring program is currently being developed and will be implemented in February 2010. To prevent future occurrences Cardinal Health NPS has communicated the occurrence of this event, investigation, and corrective actions to all of the locations on our consolidated NRC license (34-29200-01MD). This information will disseminated to our remaining locations once the finalized corrective actions are in place. Cardinal Health NPS will achieve full compliance by February 2010.

Should you have any further questions, please contact Vai Paye at 614.757.2646.

Sincerely,



Willie Regits, Ph.D.  
Corporate Radiation Safety Officer  
Quality and Regulatory Department  
Nuclear Pharmacy Services

/vp

cc: NRC Consolidated License File (3)

Encl: Dose Reconstruction Wright-Jimenez



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January 21, 2008

### Purpose

This document is a dose reconstruction for Kristell Wright-Jimenez, a nuclear pharmacist at the Cardinal Health facility in Charlottesville, VA for activities in 2007 during which she has stated she did not wear her extremity dosimeters.

### Description of Event

On May 17, 2007, during an internal audit at the Charlottesville nuclear pharmacy, Ms. Wright-Jimenez stated to the auditor that she often removed her extremity dosimeters during I-131 compounding. Ms. Wright-Jimenez stated that she began this practice after January 1, 2007. She further elaborated that she only removed her extremity rings for I-131 handling, and wore them at all times when performing other activities, such as eluting Mo-99/Tc-99m generators, compounding radiopharmaceutical kits, drawing radiopharmaceutical doses. Ms. Wright-Jimenez was instructed by the auditor to immediately begin wearing her rings at all times while handling radioactive materials. Below is a timeline of the activities and time periods that were monitored by dosimeters and those activities and time periods that were not:

	1/1/2007		5/17/2007		10/2/2007
	↓		↓		↓
Iodine Handling	Not Monitored		Monitored with regular extremity dosimeters		Monitored with I-131 specific dosimeters
All Other RAM Handling	<i>Continuously Monitored</i>				

## Dose Reconstruction

Ms. Wright-Jimenez admitted to not wearing her rings during I-131 handling for the period of 1/1/2007 to 5/17/2007. Therefore, her extremity dose reported by Landauer does not reflect her true cumulative extremity exposure. In an effort to estimate the extremity dose she received while not wearing her extremity dosimeters, her I-131 handling was monitored with a separate set of extremity dosimeters for the time period of October 2, 2007 to January 6, 2008. For each hand, the total activity of I-131 capsules compounded during each wear period was compared to the extremity dose received, and a ratio was calculated. Results are shown in the following table:

Wear Period	Total I-131 compounded (mCi)	Extremity Dose (mrem) on I-131 rings*		Dose Ratio (mrem/mCi)	
		Left Hand	Right Hand	Left	Right
10/1/07-10/7/07	21	M	30	N/A	1.4
10/8/07-10/14/07	64	M	130	N/A	2.0
10/22/07-10/28/07	222	40	240	0.2	1.1
10/29/07-11/4/07	229	120	500	<b>0.5</b>	<b>2.2</b>
11/5/07-11/11/07	483	230	560	<b>0.5</b>	1.2

\* Minimal (M) indicates a reading below the detection threshold of 30 mrem.

In order to calculate a conservative estimate of the extremity doses received during her unmonitored I-131 handling, the highest observed dose ratio for each hand (from the table above) was selected and multiplied by the total activity of I-131 compounded during the unmonitored time period. These estimates are shown in the following table:

Extremity	Total I-131 Compounded	Highest Observed Dose Ratio	Dose Estimate (mrem)
Left Hand	2322 mCi	0.5 mrem/mCi	1160
Right Hand	2322 mCi	2.2 mrem/mCi	5110

Finally, in order to determine the total extremity dose that will be assigned for calendar year 2007, these results were added to the Landauer results for Ms. Wright-Jimenez:

Data Source	Left Hand	Right Hand
Landauer Rings	18660	36930
I-131 Rings	560	1960
I-131 Estimated Dose	1160	5110
<b>Assigned Dose for 2007</b>	<b>20380</b>	<b>44000</b>

**Conclusion**

Based on the calculations presented above, Ms Wright-Jimenez did not exceed the regulatory limit of 50000 mrem for either hand in 2007.

These calculations were performed by:

Chris Walters  
Senior Health Physicist  
Nuclear Pharmacy Services

/cw

Cc: Craig Hansen, Manager, Loc. 222  
License File 222 (5)

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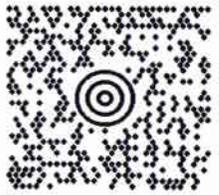
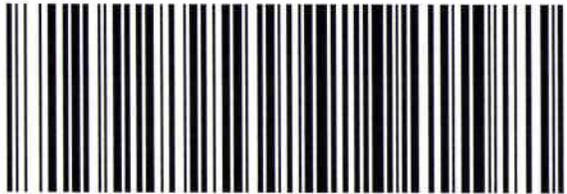
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