



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

August 27, 2009

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

**SUBJECT: NRC INSPECTION REPORT 030-36973/09-13 (FORM 591M PART 1)
CARDINAL HEALTH – SOUTH BEND, INDIANA FACILITY**

Dear Mr. Coffey:

On August 7, 2009, a Nuclear Regulatory Commission (NRC) inspector conducted a routine inspection at your South Bend, Indiana facility, with continued in-office review through August 25, 2009. The in-office review included a review of the pharmacy's gaseous effluent monitoring system and associated effluent calculations. The inspection results were discussed with Mr. Willie Regits of your staff during a final telephonic exit briefing conducted on August 26, 2009.

This inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements, and observation of activities in progress. Within the scope of this inspection no violations of NRC requirements were identified; therefore, no response to this letter or the enclosed NRC Form 591M is required.

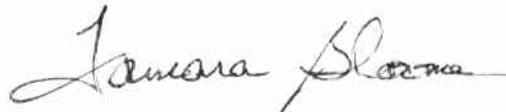
In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading_rm/adams.html.

J. Covey

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Should you have any questions concerning this inspection or enclosed report, please contact Ken Lambert of my staff at (630) 829-9633.

Sincerely,

A handwritten signature in cursive script, reading "Tamara Bloomer".

**Tamara E. Bloomer, Chief
Materials Inspection Branch**

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

Enclosure:
Inspection Report 030-36973/09-13

cc w/encl: State of Indiana

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Cardinal Health South Bend, Indiana		2. NRC/REGIONAL OFFICE U.S. Nuclear Regulatory Commission Region III 2443 Warrenville Road Suite 210 Lisle, Illinois 60532-4351	
REPORT NUMBER(S) 2009-013			

3. DOCKET NUMBER(S) 030-36973	4. LICENSEE NUMBER(S) 34-29200-01MD	5. DATE(S) OF INSPECTION 8/7/09 w/ cont. review to 8/25/09
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LICENSEE:
The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- 1. Based on the inspection findings, no violations were identified.
- 2. Previous violation(s) closed.
- 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Action(s):

- 4. During this inspection certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Licensee's Statement of Corrective Actions for Item 4, above.

I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

Title	Printed Name	Signature	Date
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Michael LaFranzo		8/25/2009

Impact of Glove Box blower in South Bend, IN

The glove box has two (2) arm port holes that are 6 inches tall and 8 inches wide each. The volumetric discharge was determined on April 30, 2009 to be 85.00 CFM with the glove box blower motor running. On August 14, 2009 the volumetric flow rate was calculated based on the a linear flow measurement of 75 lfm per arm port times the total cross sectional area (0.67 sqft) of the arm ports to be 50.25 CFM.

On August 14, 2009 the fume hood performance test was conducted and resulted in a volumetric air discharge of 685.56 CFM. This value is used in the calculation for effluent and includes the 50.25 CFM contribution from the glove box while the motor was off.

The year to date effluent release of I-131 from January 1 to August 14, 2009 has been 301.44 uCi. In terms of effluent concentration calculated with the glove box motor off the effluent was $4.553 \text{ E-11 uCi/ml}$. This is using the average volumetric discharge rate of 693.4 CFM an average of the multiple measurements for the year.

If we are to assume the glove box was turned on the whole time and additional 34.75 CFM ($85 \text{ CFM} - 50.25 \text{ CFM}$) would be added to the average volumetric discharge rate changing it from 693.4 CFM to 728.15 CFM; representing a change of about 4.7% from the actual discharge amount. The effluent concentration would have decreased to from the actual discharge amount $4.339 \text{ E-11 uCi/ml}$.

The gap between the reported effluent ($4.553 \text{ E-11 uCi/ml}$) and the calculated effluent with the glove box motor on ($4.339 \text{ E-11 uCi/ml}$) would only narrow the longer the glove box motor was left on. Additionally, if turning on the glove box decreased the exhaust flow rate of the fume hood this percent change in over estimating the effluent concentration will decrease from 4.7% down to 0%. Cardinal Health has chosen to error on the conservative side and over estimate our effluent concentration due to this variability. We feel this is in the best interest of member of the public and provides a degree of protection should an accidental release occur.