Cardinal Health Nuclear Pharmacy Services 7000 Cardinal Place Dublin, OH 43017 614.757.5000 tel

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July 27, 2005

Jim Dwyer NRC Region I 475 Allendale Road King of Prussia, PA 19406

RE: Action Plan for Items of Concern, Inspection Date May 19, 2005, License 45-25339-01MD, Cardinal Health, Charlottesville, VA.

03033893 /2005001

Dear Mr. Dwyer,

This letter is in response to your request for additional data regarding the items of concern resulting from the above inspection. The items of concern are in italics and our findings follow them in plain text.

1. No monitoring of air emissions.

To demonstrate past compliance with exposure limits for the public, Cardinal Health performed the EPA COMPLY analysis for materials released from this facility. It demonstrates that the facility is in compliance with the restraint rule (public exposure less than 10 mrem). A copy of this report is included in Attachment A.

Additionally, an iodine air monitoring system has now been installed at this facility. Air monitoring began at 8:00 AM on Friday, June 10, 2005. On the same day, the pharmacy manager/RSO was trained on the operation of this system to ensure effluents remain below regulatory limits. It may take a few additional weeks to work out any complications and provide training to all personnel. Since installation, this air monitoring system has recorded a year-to-date I-131 effluent concentration of 1.578E-11 uCi/mL, which is 7.9% of the regulatory limit of 2.0E-10 uCi/mL specified in 10CFR20 Appendix B. Complete air monitoring results are provided in Attachment B.

Cardinal Health is now in full compliance with this item.

2. Potential for overexposure (CY 2004) to the extremities of two (2) pharmacists.

Extremity exposure is a very important concern at Cardinal Health. We have been conducting an extensive study to determine the correlation between ring reading and the maximally exposed 10 cm² of skin. As a result of initial findings from this study, Cardinal Health implemented a policy (effective January 1, 2005) to wear extremity badges on the

index finger facing the palm. However, the exposures in questions were received prior to implementation of this policy, and the two individuals in question were found to have worn their rings facing the back of the hand. In order to predict what exposure these individuals may have received to the palm side of their fingers, data from the glove dosimeter study was analyzed. The goal was to calculate a ratio comparing the exposure on the back of the finger to the exposure of the front of that finger. Since both of the individuals in question were found to have worn their rings on their ring finger, the ring finger was chosen as the point of interest.

The results of this analysis demonstrate an average ratio of 1.11 for both the left and right hand at the point of interest (ring finger). Based on these ratios, any individual having worn their rings facing the back of their hands, and having received less than 45,045 mrem in a year would not be expected to receive an overexposure. Neither of the individuals in question exceeded this exposure level in 2004, and therefore neither is believed to have received an extremity overexposure (greater than 50,000 mrem). A description of our data analysis is included in Attachment C.

Additionally, an analysis of hand exposure per radiopharmaceutical dose drawn was performed for both of the individuals in question.

Should you have any further questions, please contact me at 614.757.3147.

Sincerely,

Willie Regits, PhD Manager, Health Physics Compliance

CC: John Miller, Regional Director Craig Barlow, PM, RSO, Loc. 222 File Loc 222 (4)

ATTACHMENT A

COMPLY: V1.6.

5/27/2005 12:58

40 CFR Part 61 National Emission Standards for Hazardous Air Pollutants

REPORT ON COMPLIANCE WITH

THE CLEAN AIR ACT LIMITS FOR RADIONUCLIDE EMISSIONS

FROM THE COMPLY CODE - V1.6.

Prepared by:

Cardinal Health 222 Charlottesville, VA 6464 Canoga Ave, Woodland Hills, CA 91367

Quality & Regulatory 818-737-4000

Prepared for:

U.S. Environmental Protection Agency Office of Radiation and Indoor Air Washington, DC 20460

SCREENING LEVEL 4

DATA ENTERED:

	Release Rate									
Nuclide	(curies/YEAR)									
GA-67	W 1.000E-05									
I-123	D 3.000E-09									
I-131	D 1.000E-06									
IN-111	W 1.000E-05									
MO-99	Y 2.500E-05									
TL-201	D 1.000E-05									
XE-133	4.000E-03									
TC-99M	D 3.750E-02									

Release height 6 meters.

Building height 4 meters.

The source and receptor are on the same building.

Stack diameter 0.20 meters.

Distance from the source to the receptor is 14 meters.

Building width 24 meters.

Default volumetric flow rate from the stack not used. Volumetric flow rate is 64.780 cu m/sec.

Default mean wind speed used (2.0 m/sec).

Distance from the SOURCE to the FARM producing VEGETABLES is 402 meters.

Distance from the SOURCE to the FARM producing MILK is 8045 meters.

Distance from the SOURCE to the FARM producing MEAT is 8045 meters.

NOTES:

Input parameters outside the "normal" range:

Meat farm is unusually FAR. Milk farm is unusually FAR.

Stack diameter is unusually SMALL. Stack flow is unusually HIGH.

RESULTS:

Effective dose equivalent: 3.9E-03 mrem/yr.

Effective dose equivalent: 3.4E-05 mrem/yr due to lodine.

*** Comply at level 4.

This facility is in COMPLIANCE.

It may or may not be EXEMPT from reporting to the EPA.

You may contact your regional EPA office for more information.

*********** END OF COMPLIANCE REPORT *********

ATTACHMENT B

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Cardinal Health Nuclear Pharmacy Services

Activity Released Report

Beginning Date: 1/1/2005 to Ending Date: 12/31/2005

Facility: CHARLOTTESVILLE 713-B HARRIS ST CHARLOTTESVILLE, VA 22903

Test Date/Time	Activity Collected	Activity Al Collected S		Air Flow Avg Sampled Concentration		iume Hood Flow Rate	Avg YTD Concentration	Avg 365 Day Concentration	
Nuclide: I-13	31								
16-Jun-2005 10:17	0.0007734679	uCi	87750000 ml	8.814E-012 uCi	/ ml	193.3 cfm	8.814E-12 uCi / ml	8.814E-12 uCi/m	
	7.735E-004	uCi	8.775E+07 ml						
24-Jun-2005 7:03	0.0040675089	uCi	113280000 ml	1 3.591E-011 uCi	/ ml	193.3 cfm	2.408E-11 uCi / ml	2.408E-11 uCi/m	
	4.068E-003	uCi	1.133E+08 ml						
30-Jun-2005 6:46	0.0004639644	uCi]	86230000 ml	5.381E-012 uCi	/ ml]	193.3 cfm	1.847E-11 uCi / ml	 1.847E-11 uCi/m	
	4.640E-004	uCi	8.623E+07 ml						
07-Jul-2005 10:28	0.0000000000	uCi	103020000 ml	0.000E+000 uCi	/ ml	193.3 cfm	1.359E-11 uCi / ml	 1.359E-11 uCi/m	
	0.000E+000	uCi	1.030E+08 ml						
15-Jul-2005 14:50	0.0026078642	uCi	117820000 ml	2.213E-011 uCi	/ mi	193.3 cfm	1.557E-11 uCi / ml	1.557E-11 uCi/ml	
	2.608E-003	uCi	1.178E+08 ml						
21-Jul-2005 8:19	0.0010328505	uCi	82490000 ml	1.252E-011 uCi	/m.l	193.3 cfm	1.515E-11 uCi / ml	 1.515E-11 uCi / ml	
	1.033E-003	uCi	8.249E+07 ml						
28-Jul-2005 8:32	0.0019883615	uCi	100930000 ml	1.970E-011 uCi	/ ml	183.3 cfm	1.578E-11 uCi / ml	1.578E-11 uCi / m	
	1.988E-003	uCi	1.009E+08 ml						
			<u></u>	l					
(Totals		6	91520000 ml						
		0.3	913E7000 MI						

Average I-131 Concentration (for above date range)	1.578E-011 uCi / ml
Average fume hood flow (for above date range)	191.9 cfm
Total ml of fume hood flow (for above date range)	3.757E+011 ml
Total I-131 released to the environment (for above date range)	5.93 uCi
% effluent limit for I-131 in unrestricted area (for above date range)	7.8910 %

RSO Signature:

Date:

ATTACHMENT C

Analysis of palm side to back of ring finger

This analysis was prepared using data from both the first and second phases of the ongoing OSL glove study. 38 subjects were viewed in total, each having been monitored with the special dosimeter gloves for 4 weeks. Data was analyzed to determine the relationship of exposure on the palmar side of the ring finger versus the exposure to the backside of that finger.

The illustration on the following page details the positioning of the OSL dots on the glove. For the purpose of this analysis, the OSL dots on the palmar side will be called Palm 1 and Palm 2. Palm 1 refers to the ring finger position closest to the palm of the hand while Palm 2 refers to the position at the middle knuckle of the ring finger. Back refers to the OSL dot located at the middle knuckle on the back of the ring finger, or the shaded value on the hand diagram.

The 'Palm Ave' column is the average of Palm 1 and Palm 2 by subject. This average most closely represents a comparison of palmar side to backside and the position where a ring badge was worn.

A ratio of the palm average to the back for each subject was calculated and the combined averages of all ratios for each phase were determined for each hand. Then, the average front-to-back ratios of Phase 1 and Phase 2 were calculated to find an average ratio by hand.



Phase 2	Left Han	d				Right Hand					
	Palm 1	Palm 2	Palm Ave	Back	Ratio	Palm 1	Palm 2	Palm Ave	Back	Ratio	
	(mrem)	(mrem)	(mrem)	(mrem)		(mrem)	(mrem)	(mrem)	(mrem)		
Subject 21	476	623	550	378	1.45	639	877	758	949	0.80	
Subject 22	450	545	498	615	0.81	433	475	454	641	0.71	
Subject 23	1773	1669	1721	1776	0.97	1383	2096	1739.5	1504	1.16	
Subject 24	891	1011	951	1259	0.76	928	1268	1098	1272	0.86	
Subject 25	1775	1868	1822	2921	0.62	1485	2521	2003	2227	0.90	
Subject 26	1007	2333	1670	1367	1.22	1876	2160	2018	2484	0.81	
Subject 27	3797	4754	4276	3124	1.37	2180	4058	3119	2716	1.15	
Subject 28	1210	1442	1326	1337	0.99	1100	1705	1402.5	2033	0.69	
Subject 29	1512	1868	1690	1292	1.31	2009	2368	2188.5	1699	1.29	
Subject 30	1252	1387	1320	1197	1.10	1296	2084	1690	2125	0.80	
Subject 31	1413	2146	1780	1578	1.13	1110	1597	1353.5	2366	0.57	
Subject 32	1547	1902	1725	1228	1.40	2472	3636	3054	1450	2.11	
Subject 33	1077	1093	1085	1242	0.87	815	1176	995.5	1512	0.66	
Subject 34	848	906	877	1263	0.69	488	624	556	634	0.88	
Subject 35	734	945	840	889	0.94	860	1170	1015	1169	0.87	
Subject 36	4804	5644	5224	3994	1.31	3018	4069	3543.5	5327	0.67	
Subject 37	1809	2248	2029	2328	0.87	740	925	832.5	990	0.84	
Subject 38	2089	2069	2079	1263	1.65	1178	1989	1583.5	2290	0.69	
				Average	1.08				Average	0.91	
				Min	0.62				Min	0.57	
				Max	1.65				Max	2.11	

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				IVIAN	1.05				IVIAN	2.11
Phase 1	Left Har	nd				Right Han	d			
	Palm 1	Palm 2	Palm Ave	Back	Ratio	Palm 1	Palm 2	Palm Ave	Back	Ratio
	(mrem)	(mrem)	(mrem)	(mrem)		(mrem)	(mrem)	(mrem)	(mrem)	
Subject 1	454	514	484	339	1.43	297	357	327	272	1.20
Subject 2	1378	1589	1484	1498	0.99	1366	1570	1468	1814	0.81
Subject 3	784	1246	1015	972	1.04	1020	1973	1497	867	1.73
Subject 4	3786	4348	4067	2972	1.37	5093	5539	5316	4787	1.11
Subject 5	3228	3631	3430	5072	0.68	2558	3218	2888	3203	0.90
Subject 6	2082	2522	2302	2304	1.00	5485	6436	5961	4306	1.38
Subject 7	457	609	533	504	1.06	2230	3428	2829	1347	2.10
Subject 8	1614	3094	2354	1202	1.96	1122	1259	1191	736	1.62
Subject 9	764	1083	924	712	1.30	1797	1984	1891	1203	1.57
Subject 10	249	256	253	318	0.79	1283	1782	1533	736	2.08
Subject 11	4823	5064	4944	4786	1.03	3175	3917	3546	3155	1.12
Subject 12	4157	3739	3948	3550	1.11	2520	5654	4087	2587	1.58
Subject 13	1362	1362	1362	911	1.50	1170	1787	1479	1618	0.91
Subject 14	2165	2151	2158	1583	1.36	3432	4384	3908	2866	1.36
Subject 15	6620	4332	5476	4853	1.13	2943	4549	3746	3559	1.05
Subject 16	2363	3728	3046	2832	1.08	1739	3488	2614	3055	0.86
Subject 17	1568	1759	1664	1552	1.07	2264	2955	2610	3533	0.74
Subject 18	1193	1438	1316	1776	0.74	964	1332	1148	2399	0.48
Subject 19	2723	3408	3066	3046	1.01	5038	5396	5217	5078	1.03

Subject 20	1372	2038	1705	1538	1.11	5763	7556	6660	2716	2.45
			Av	erage	1.14			4	Average	1.30
			Mir	ו	0.68			N	<i>M</i> in	0.48
			Ма	x	1.96			Ν	<i>M</i> ax	2.45
Average Ratio	of Phase	1 & Phase	2 - Left Ha	nd		Average Ra	tio of Phase '	1 & Phase 2	2 - Right Ha	hd

Average Ratio		1.11	Average Rat	1.11		
Phase 2	1.14		Phase 2	1.30		
Phase 1	1.08		Phase 1	0.91		
Average Natio 0		a Fliase 2 - Leit Hallu	Average har	IO OF FILASE T	or Fliase 2 - Rig	incriain