DEPARTMENT OF HEALTH & HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION
109 Holton Street
Winchester, Massachusetts

Mr. Dennis Lawyer
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Date: February 22. 2016

Docket No. 03004675
License No. 20-08361-01
Control No. (583771)

Subject: DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR LICENSE AMENDMENT.

Dear Mr. Lawyer::

This Memorandum is in reply to your conversation with myself Ed Baratta, RSO on Monday February 22, 2016.

The closeout of our Denver Facility was previously forwarded to you under separate cover.
I trust this information is satisfactory.

Should you have any questions regarding this Amendment, please contact:

Edmond J. Baratta, Radiation Safety Officer @ 781-756-9742, Cell Phone: 781-799-7838 and/or edmond.baratta@fda.hhs.gov

Sincerely,

2/22/2016

X Edmond J. Baratta

Edmond J. Baratta
Radiation Safety Officed
Signed by: Edmond Baratta -A

Edmond J. Baratta

REC'D IN LAT 2-22-16

589945

NMSS/RGN1 MATERIALS-002

Denver Laboratory Radioactive Contamination Survey 2015

Executive Summary

During the ORA Denver Laboratory Safety Audit held in October 2015, the ORA Assistant Radiation Safety Officer and the ORA Assistant National Safety Officer surveyed the laboratory for contamination of Phophorus-32, Carbon-14, Tritium, and Nickel-63. All survey result contamination levels were below Nuclear Regulatory Commission (NRC) public release limits. Additionally, the assistant RSO returned a total of six Electron Capture Detectors (ECDs) to the instrument manufacturers for disposal or recycling. A representative of Beckman removed and shipped the Cs-137 source associated with the Beckman liquid scintillation counter located in room H1503. The Denver lab currently has two ECDs that remain in use, and all contamination wipe tests are up to date per 10 CFR 31.5, regulations pertaining generally-licensed materials.

History of the use of Radionuclides at the Denver Lab

The FDA ORA Denver Laboratory has a history of using Phosphorus-32 (P-32), Carbon-14 (C-14), Tritium (H-3), and Nickel-63 (Ni-63) for a variety of chemical and biological regulatory analyses.

The laboratory previously used adenosine triphosphate labeled with P-32 to analyze for the presence of bacteria. This procedure has since been abandoned, and since 2009, the laboratory has been decommissioned for P-32; the ORA Nuclear Regulatory Commission (NRC) license no longer authorizes the use of P-32 at the Denver Lab.

During approximately the same time period, the laboratory also used Chloramphenicol labeled with H-3 and C-14 to analyze for the presence Chloramphenicol. At that time, the ORA Radiation Safety Officer did not apply for an amendment to the ORA NRC license authorizing the use of tritium and C-14 at Denver, since Denver acquired the material from Charm Sciences Inc. who hold an exempt distribution license NRC #20-18145-01-E.

The Denver laboratory also holds a number of NRC Generally-Licensed electron capture detectors (ECDs) used for gas chromatographic analysis of pesticides. Possession of generally-licensed material does not require end-users to have a specific NRC materials license because the manufacturer holds an NRC License which allows the distribution of generally-licensed materials to unlicensed end-users. However, the end-users are responsible for complying with regulations specified in 10 CFR 31.5.

Table 1 summarizes radionuclides forms, usage, licensure types, and public release limits pertaining to the Denver lab.

Attachment A shows the floor plan of the Denver Lab that specifies sampling locations with areas surveyed highlighted in yellow and room numbers identified in black font.

Note the Cs-137 source from the Beckman liquid scintillation counter was swipe tested, removed from the counter, and shipped by the manufacturer. See **Attachment B**.

Summary of Survey Conducted

Analysis for removable radioactive contamination was conducted on-site at Denver from 10/20/2015 through 10/22/2015. Wipe samples were analyzed using a Hidex Triathler SN# 2151408. All other samples were analyzed at the Winchester Engineering and Analytical Center using a Perkin Elmer Tricarb 2550 TR/AB.

Areas Surveyed for P-32

Due to the short half-life of P-32, it is extremely unlikely that any P-32 remains in the Denver laboratory. As a precaution, the following areas were surveyed for P-32:

- Lead pigs located in the vault (Room E1744H)
- Areas of P-32 use previously labeled as "Radioactive" (Room H1404)
- The Plexiglas waste container in the vault (Room E1744H)

Results are shown in **Table 2**. All contamination levels were below public release limits

Areas Surveyed for Ni-63

All recent leak tests for sealed Ni-63 sources were not above background levels. Results are shown in Table 3. Since none of the most recent wipe tests showed significant contamination, the ECDs were immediately prepared for shipment and packed in a box that was previously used to store the ECDs inside the vault. The lab where ECDs were used had been renovated, making it impossible to sample for contamination on lab surfaces.

Per Department of Transportation (DOT) regulations, the outside of the box was wipe-tested for the presence of removable contamination. Results were above background levels but below release limits to the general public according to Regulatory Guide 8.23 and according to DOT regulations 49 CFR 173.424(f), 173.424(g). As a precaution, areas and items directly in contact with box were surveyed for Nickel-63 contamination.

- The vault where Ni-63 ECDs boxes were temporarily stored (Room E1744H)
- Gas chromatograph parts stored in boxes connected to the ECD detectors (Room E1744H)
- Tools used to prepare the ECDs for shipment (Room H1503)
- Other work surfaces in which the box came into contact (Room H1503)

Results are shown in Table 5. No sample was found to be above the 220 DPM per 100cm^2 release limit to the general public per NRC Regulatory Guide 8.23.

The ECD's were packed in a new box. No contamination level above background was found on the outside of the new box prior to shipment. On October 22nd, 2015, Denver returned 5 ECDs to Agilent Technologies and one Perkin Elmer ECD to NRD located in Grand Island NY (New York State License #1391-1811).

The original storage box was sent to WEAC for further analysis. Results from WEAC show that contamination on the outside of the box was significantly less than levels found using Hidex Triathler in

Denver. This information coupled with the fact that most recent leak test wipes of the ECDs showed no contamination (see Table 2) indicates that the elevated counts originally found were likely due to natural short-lived radon and thoron breakdown products.

Areas Surveyed for H-3 and C-14

Areas where analyses Chloramphenicol CHARM operations took place were surveyed for removable C-14 and H-3 contamination. A diagram of wipe areas surveyed in Room H1511 is shown in Figure 1.

- The left two hoods in Room H1511
- The waste bin in the cabinet of the third hood from the left in Room H1511
- The benchtop and drawers in Room H1203 where Charm procedure was conducted
- The liquid scintillation counter where samples were potentially analyzed located in room H1503

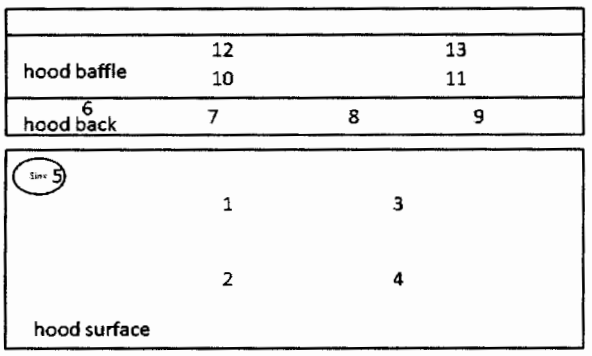
Results of survey are shown in Table 7, Table 8, and Table 9. Some areas in H1511 had detectable levels of contamination above background levels, but no counts were above release limits to the general public. Additionally, contamination levels above background were found in parts of the liquid scintillation counter where evidence of a spill occurred. This area was cleaned and resampled until background levels were achieved. In the past, Denver transferred the liquid scintillation to a university for a significant period of time, and it is unclear whether the residue in the spill was related to CHARM analyses at the Denver Lab.

Conclusion

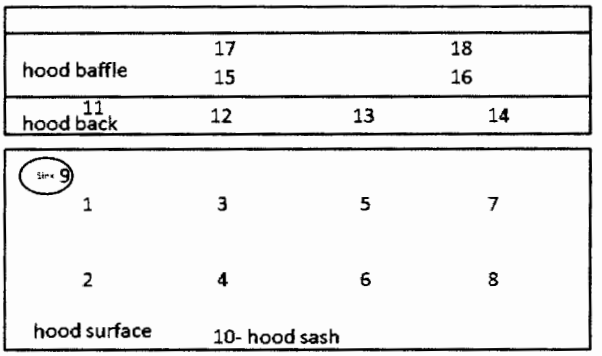
Based on this survey no surfaces showed removable contamination levels above release limits acceptable to the General Public according to *NRC Regulatory Guide 8.23 Radiation Safety at Medical Institutions.* All "Caution Radioactive Material" labeling must be removed from the laboratory in areas previously used P-32 and Charm analyses.

Figures

Figure 1: H-3 and C-14 Survey Areas in Room H1511



Left Hood (See Table 7 for results)



Second to Left Hood (see Table 8 for results)

Tables

Table 1: Summary of Radionuclide Use at the ORA Denver Lab

Radionuclide	Form	Use	Half Life (years)	Last used	Licensure	Removable contamination release limit*
H-3; C-14	Labeled Chloramphenicol	Chloramphenicol Analysis	12.28; 5730	Before 2006	Exempt NRC# 20-18145-01-E (Charm Sciences)	2200 DPM per 100 cm^2
P-32	Adenosine Triphosphate (Decommissioned 2009)	Microbe Identification	0.039	Before 2006	ORA Specific NRC# 20-08361-01 Amendment No. 35	220 DPM per 100 cm^2
Ni-63	Electron Capture Detectors	Pesticide Analysis	100.1	Current	General NRC #07-28762-02G (Agilent) #06-02135-12G (Perkin Elmer)	220 DPM per 100 cm^2
Cs-137	Sealed Source in Liquid Scintillation Counter	Charm Analysis	30	Before 2006	General California# 1313-30GL (Beckman Coulter)	220 DPM per 100 cm^2

*Release limits base on *NRC Regulatory Guide 8.23 Radiation Safety at Medical Institutions*

Table 2: P-32 Survey Results

SWIPE REPORT 10/30/2015

User: Elon Malkin	Instrument: Hidex
Tray ID: NA	Radionuclide: P-32
Vials: 15	Total Activity (uCi): 3.18E-05

Parameter Calculation:	Swipe Area (cm^2): 100
Standard ID: 71-C	Standard (cpm): 117068
Radionuclide: C-14	Background (cpm): 213
Activity at Reference Date (µCi) : 5.84E-02	Activity at run time (dpm): 129515.40
Reference Date: 4/28/2010	Background count time (min): 5
half life (days): 2092883	Sample count time (min): 5
Date of run: 10/20/2015	Backgrond counts: 1065
Activity at run time (µCi): 5.83E-02	Background activity (dpm): 236.08
	Efficiency (cpm/dpm): 90.2%
	Net Critical Level (net cpm): 15.18
	Lower Limit of Detection (net cpm): 33.08
	MDA (dpm): 36.66
Alpha (α) emitter survey: no	MDA (nCi): 1.65E-02

								Warning Level	Action Levels	
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per $100cm^2$ (DPM)	Activity per $100cm^2$ (nCi)	Above MDA	10 DPMα or 100 DPMβ	220 DPMβ per $100cm^2$	22 DPMα per $100cm^2$
1	Pig 1	2	226	13	14.41	6.55E-04	no	no	no	NA
2	Pig 2	3	316	103	114.16	5.19E-03	yes	yes	no	NA
3	Pig 3	4	265	52	57.63	2.62E-03	yes	no	no	NA
4	Pig 4	5	290	77	85.34	3.88E-03	yes	no	no	NA
5	Pig 5	6	288	75	83.13	3.78E-03	yes	no	no	NA
6	Pig 6	7	268	55	60.96	2.77E-03	yes	no	no	NA
7	Pig 7	8	276	63	69.83	3.17E-03	yes	no	no	NA
8	Pig 8	9	276	63	69.83	3.17E-03	yes	no	no	NA
9	Pig 9	10	222	9	9.98	4.53E-04	no	no	no	NA
10	Pig 10	11	253	40	44.33	2.02E-03	yes	no	no	NA
11	Pig 11	13	253	40	44.33	2.02E-03	yes	no	no	NA
12	Pig 12	14	223	10	11.08	5.04E-04	no	no	no	NA
13	Pig 13	15	228	15	16.63	7.56E-04	no	no	no	NA
14	Pig 14	14	229	16	17.73	8.08E-04	no	no	no	NA
15	Pig 15	15	213	0	0.00	0.00E+00	no	no	no	NA

SWIPE REPORT 10/30/2015

User: Elon Malkin	Instrument: Hidex
Tray ID: NA	Radionuclide: P-32
Vials: 1	Total Activity (uCi): 5.57E-07

Parameter Calculation:	Swipe Area (cm^2): 100
Standard ID: 71-C	Standard (cpm): 116451
Radionuclide: C-14	Background (cpm): 245
Activity at Reference Date (µCi) : 5.84E-02	Activity at run time (dpm): 129515.36
Reference Date: 4/28/2010	Background count time (min): 5
half life (days): 2092883	Sample count time (min): 5
Date of run: 10/21/2015	Backgrond counts: 1225
Activity at run time (µCi): 5.83E-02	Background activity (dpm): 273.06
	Efficiency (cpm/dpm): 89.7%
	Net Critical Level (net cpm): 16.28
	Lower Limit of Detection (net cpm): 35.28
	MDA (dpm): 39.32
Alpha (α) emitter survey: no	MDA (nCi): 1.77E-02

								Warning Level	Action Levels	
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per $100cm^2$ (DPM)	Activity per $100cm^2$ (nCi)	Above MDA	10 DPMα or 100 DPMβ	220 DPMβ per $100cm^2$	22 DPMα per $100cm^2$
2S	Pig 2 rerun	3	256	11	12.26	5.57E-04	no	no	no	NA

SWIPE REPORT 10/30/2015

User: Elon Malkin	Instrument: Hidex
Tray ID: NA	Radionuclide: P-32; C-14; H-3; Ni-63
Vials: 6	Total Activity (uCi): -8.45E-07

Parameter Calculation:		Swipe Area (cm^2):	100
Standard ID:	99307	Standard (cpm):	163.75
Radionuclide:	Nickel-63	Background (cpm):	28.5
Activity at Reference Date (µCi) :	8.90E-05	Activity at run time (dpm):	196.54
Reference Date:	1/15/2015	Background count time (min):	4
half life (days):	36562	Sample count time (min):	4
Date of run:	10/23/2015	Backgrond counts:	114
Activity at run time (µCi):	8.85E-05	Background activity (dpm):	41.42
		Efficiency (cpm/dpm):	68.8%
		Net Critical Level (net cpm):	6.21
		Lower Limit of Detection (net cpm):	15.13
		MDA (dpm):	21.99
Alpha (α) emitter survey:	no	MDA (nCi):	9.90E-03

								Warning Level	Action Levels	
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per $100cm^2$ (DPM)	Activity per $100cm^2$ (nCi)	Above MDA	10 DPMα or 100 DPMβ	220 DPMβ per $100cm^2$	22 DPMα per $100cm^2$
1	Rad Waste Plastic Box 1	35	22.95	-5.55	-8.07	-3.67E-04	no	no	no	NA
2	Rad Waste Plastic Box 2	36	29.25	0.75	1.09	4.95E-05	no	no	no	NA
3	Rad Waste Plastic Box 3	37	28.25	-0.25	-0.36	-1.65E-05	no	no	no	NA
4	Rad Waste Plastic Box 4	38	21.5	-7	-10.17	-4.62E-04	no	no	no	NA
5	Rad Waste Plastic Box 5	39	29.75	1.25	1.82	8.26E-05	no	no	no	NA
6	Rad Waste Plastic Box 6	40	26.5	-2	-2.91	-1.32E-04	no	no	no	NA

Table 3: Ni-63 Leak Test Results

SN	Swipe Location	SWIPE (CAL.) DATE	DET. MFR.	MODEL	MDA (nCi)	NET CPM CALC.	EFF. CALC.	ACTIVITY (μCi)	ACTIVITY (nCi)	Pass Contamination Test (<100dpm)
F6684	inlet	7/17/2015	HP	G1223A	0.01	2.26	0.726	1.40E-06	0.0014	yes
F6684	outlet	7/17/2015	HP	G1223A	0.01	1.60	0.726	9.92E-07	0.0010	yes
F6684	housing	7/17/2015	HP	G1223A	0.01	1.20	0.726	7.44E-07	0.0007	yes
U2826	inlet	7/17/2015	HP	G2397A	0.01	1.00	0.726	6.20E-07	0.0006	yes
U2826	outlet	7/17/2015	HP	G2397A	0.01	0.73	0.726	4.53E-07	0.0005	yes
U2826	housing	7/17/2015	HP	G2397A	0.01	3.06	0.726	1.90E-06	0.0019	yes
F2674	inlet	7/17/2015	HP	G1223A	0.01	15.20	0.726	9.43E-06	0.0094	yes
F2674	outlet	7/17/2015	HP	G1223A	0.01	0.86	0.726	5.33E-07	0.0005	yes
F2674	housing	7/17/2015	HP	G1223A	0.01	2.33	0.726	1.45E-06	0.0014	yes
U4769	inlet	7/17/2015	HP	G2397A	0.01	1.60	0.726	9.92E-07	0.0010	yes
U4769	outlet	7/17/2015	HP	G2397A	0.01	1.80	0.726	1.12E-06	0.0011	yes
U4769	housing	7/17/2015	HP	G2397A	0.01	0.26	0.726	1.61E-07	0.0002	yes
U4763	inlet	7/17/2015	HP	G2397A	0.01	1.20	0.726	7.44E-07	0.0007	yes
U4763	outlet	7/17/2015	HP	G2397A	0.01	2.66	0.726	1.65E-06	0.0016	yes
U4763	housing	7/17/2015	HP	G2397A	0.01	4.66	0.726	2.89E-06	0.0029	yes
F4519	inlet	7/17/2015	HP	G1223A	0.01	9.53	0.726	5.91E-06	0.0059	yes
F4519	outlet	7/17/2015	HP	G1223A	0.01	4.73	0.726	2.93E-06	0.0029	yes
F4519	housing	7/17/2015	HP	G1223A	0.01	14.13	0.726	8.76E-06	0.0088	yes
0764	inlet	7/17/2015	PE	N610-0133	0.01	1.86	0.726	1.15E-06	0.0012	yes
0764	outlet	7/17/2015	PE	N610-0133	0.01	1.80	0.726	1.12E-06	0.0011	yes
0764	housing	7/17/2015	PE	N610-0133	0.01	2.00	0.726	1.24E-06	0.0012	yes
U4763	inlet	10/1/2015	HP	G2397A	0.01	-1.50	0.751	-8.99E-07	-0.0009	yes
U4763	outlet	10/1/2015	HP	G2397A	0.01	-1.47	0.751	-8.81E-07	-0.0009	yes
U4763	housing	10/1/2015	HP	G2397A	0.01	-3.75	0.751	-2.25E-06	-0.0022	yes
U4763	GC	10/1/2015	HP	G2397A	0.01	2.09	0.751	1.25E-06	0.0013	yes
AD6359	inlet	10/1/2015	Thermo	Trace 1310	0.01	-4.75	0.751	-2.85E-06	-0.0028	yes
AD6359	outlet	10/1/2015	Thermo	Trace 1310	0.01	1.60	0.751	9.59E-07	0.0010	yes
AD6359	housing	10/1/2015	Thermo	Trace 1310	0.01	0.75	0.751	4.50E-07	0.0004	yes

Table 4: Ni-63 Survey Result of Exterior of Box used to Store ECDs

SWIPE REPORT 11/4/2015

User: Elon Malkin	Instrument: Hidex Triathler
Tray ID: NA	Radionuclide: Nickel 63
Vials: 1	

Parameter Calculation:		Swipe Area (cm^2):	300
Standard ID:	71-H	Standard (cpm):	79172
Radionuclide:	H-3	Background (cpm):	245
Activity at Reference Date (µCi) :	1.21E-01	Activity at run time (dpm):	198564
Reference Date:	4/28/2010	Background count time (minutes):	5
half life (days):	4493	Sample count time (minutes):	1.47
Date of run:	10/21/2015	Backgrond counts:	1225
Activity at run time (µCi):	8.94E-02	Background activity (dpm):	616.37
		Efficiency (cpm/dpm):	39.7%
		Net Critical Level (net cpm):	24.16
		Lower Limit of Detection (net cpm):	51.03
		MDA (dpm):	128.37
Alpha (α) emitter survey:	no	MDA (nCi):	0.0578

							Action Levels (DOT/IATA)	
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per cm^2 (dpm)	Above MDA	22 DPMβ per cm^2	2.2 DPMα per cm^2
1	Agilent Box	1	409	164	1.38	yes	no	NA

Table 5: Ni-63 Survey Results of materials in contact with ECD Storage Box

SWIPE REPORT 10/30/2015

User: Elon Malkin	Instrument: Hidex
Tray ID: NA	Radionuclide: N-63
Vials: 4	Total Activity (uCi): 1.96E-05

Parameter Calculation:	Swipe Area (cm^2): 100
Standard ID: 71-H	Standard (cpm): 79402
Radionuclide: H-3	Background (cpm): 235
Activity at Reference Date (µCi) : 1.21E-01	Activity at run time (dpm): 198533.17
Reference Date: 4/28/2010	Background count time (min): 5
half life (days): 4493	Sample count time (min): 5
Date of run: 10/22/2015	Backgrond counts: 1175
Activity at run time (µCi): 8.94E-02	Background activity (dpm): 589.33
	Efficiency (cpm/dpm): 39.9%
	Net Critical Level (net cpm): 15.95
	Lower Limit of Detection (net cpm): 34.61
	MDA (dpm): 86.79
Alpha (α) emitter survey: no	MDA (nCi): 3.91E-02

								Warning Level	Action Levels	
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per 100cm^2 (DPM)	Activity per 100cm^2 (nCi)	Above MDA	10 DPMα or 100 DPMβ	220 DPMβ per 100cm^2	22 DPMα per 100cm^2
top_shelf_left	vault top left shelf	8	291	56	140.44	6.38E-03	yes	yes	no	NA
top_shelf_right	vault to right shelf	9	278	43	107.83	4.90E-03	yes	yes	no	NA
shelf1-5	vault shelf 1-5	10	282	47	117.87	5.36E-03	yes	yes	no	NA
shelf1-6	vault shelf 1-6	11	261	26	65.20	2.96E-03	no	no	no	NA

SWIPE REPORT 10/30/2015

User: Elon Malkin	Instrument: Hidex
Tray ID: NA	Radionuclide: Ni-63
Vials: 10	Total Activity (uCi): 1.75E-05

Parameter Calculation:	Swipe Area (cm^2): 100
Standard ID: 71-H	Standard (cpm): 79172
Radionuclide: H-3	Background (cpm): 245
Activity at Reference Date (µCi) : 1.21E-01	Activity at run time (dpm): 198563.79
Reference Date: 4/28/2010	Background count time (min): 5
half life (days): 4493	Sample count time (min): 5
Date of run: 10/21/2015	Backgrond counts: 1225
Activity at run time (µCi): 8.94E-02	Background activity (dpm): 616.37
	Efficiency (cpm/dpm): 39.7%
	Net Critical Level (net cpm): 16.28
	Lower Limit of Detection (net cpm): 35.28
	MDA (dpm): 88.76
Alpha (α) emitter survey: no	MDA (nCi): 4.00E-02

								Warning Level	Action Levels	
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per 100cm^2 (DPM)	Activity per 100cm^2 (nCi)	Above MDA	10 DPMα or 100 DPMβ	220 DPMβ per 100cm^2	22 DPMα per 100cm^2
tool1	tool head	1	269	24	60.38	2.74E-03	no	no	no	NA
tool2	tool handle	2	271	26	65.41	2.97E-03	no	no	no	NA
tape	tape	3	264	19	47.80	2.17E-03	no	no	no	NA
r1	agilent parts 1	4	269	24	60.38	2.74E-03	no	no	no	NA
r2	agilent parts 2	5	297	52	130.82	5.95E-03	yes	yes	no	NA
r3	agilent parts 3	6	222	-23	-57.86	-2.63E-03	no	no	no	NA
bb1	ECD blue box 1	8	225	-20	-50.32	-2.29E-03	no	no	no	NA
bb2	ECD blue box 2	9	252	7	17.61	8.00E-04	no	no	no	NA
sc	scissors	10	258	13	32.71	1.49E-03	no	no	no	NA
lsc	liquid scintillation counter top	11	265	20	50.32	2.29E-03	no	no	no	NA
cart	top of cart	12	256	11	27.67	1.26E-03	no	no	no	NA

Table 6: Ni-63 Follow-up Analysis of Original Box used to Store ECDs

SWIPE REPORT 11/3/2015

User: Elon Malkin	Instrument: Perkin Elmer Tri-Carb 2550 TR/AB
Tray ID: NA	Radionuclide: Ni-63
Vials: 5	Total Activity (uCi): 8.43E-06

Parameter Calculation:		Swipe Area (cm^2):	100
Standard ID:	99907	Standard (cpm):	171.75
Radionuclide:	Nickel-63	Background (cpm):	25.5
Activity at Reference Date (µCi) :	8.90E-05	Activity at run time (dpm):	196.51
Reference Date:	1/15/2015	Background count time (min):	4
half life (days):	36562	Sample count time (min):	4
Date of run:	11/2/2015	Background counts:	102
Activity at run time (µCi):	8.85E-05	Background activity (dpm):	34.26
		Efficiency (cpm/dpm):	74.4%
		Net Critical Level (net cpm):	5.87
		Lower Limit of Detection (net cpm):	14.46
		MDA (dpm):	19.43
Alpha (α) emitter survey:	no	MDA (nCi):	8.75E-03

								Warning Level	Action Levels	
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per 100cm^2 (DPM)	Activity per 100cm^2 (nCi)	Above MDA	10 DPMα or 100 DPMβ	220 DPMβ per 100cm^2	22 DPMα per 100cm^2
1	Agilent Box 1	1	86.75	61.25	82.30	3.74E-03	yes	no	no	NA
2	Agilent Box 2	2	59.25	33.75	45.35	2.06E-03	yes	no	no	NA
3	Agilent Box 3	3	30.25	4.75	6.38	2.90E-04	no	no	no	NA
4	Agilent Box 4	4	27.5	2	2.69	1.22E-04	no	no	no	NA
5	Agilent Box 5	5	61.75	36.25	48.71	2.21E-03	yes	no	no	NA

Table 7: H-3 and C-14 Survey Results for Left Most Hood in Room H1511

SWIPE REPORT 10/30/2015

User:	Elon Malkin	**Instrument:**	Perkin Elmer Tri-Carb 2550TR/AB
Tray ID:	NA	**Radionuclide:**	H-3 , C-14
Vials:	13	**Total Activity (uCi):**	-4.76E-07

Parameter Calculation:		**Swipe Area (cm^2):**	100
Standard ID:	99307	**Standard (cpm):**	183.75
Radionuclide:	Ni-63	**Background (cpm):**	28.5
Activity at Reference Date (µCi) :	8.90E-05	**Activity at run time (dpm):**	196.54
Reference Date:	1/15/2015	**Background count time (min):**	4
half life (days):	36562	**Sample count time (min):**	4
Date of run:	10/23/2015	**Backgrond counts:**	114
Activity at run time (µCi):	8.85E-05	**Background activity (dpm):**	41.42
		Efficiency (cpm/dpm):	68.8%
		Net Critical Level (net cpm):	6.21
		Lower Limit of Detection (net cpm):	15.13
		MDA (dpm):	21.99
Alpha (α) emitter survey:	no	**MDA (nCi):**	9.90E-03

								Warning Level	Action Levels
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per $100cm^2$ (DPM)	Activity per $100cm^2$ (nCi)	Above MDA	1000 DPMβ per 100 cm^2	2200 DPMβ per $100cm^2$
1	1	1	41	12.5	18.18	8.26E-04	no	no	no
2	2	2	25.5	-3	-4.36	-1.98E-04	no	no	no
3	3	3	27.75	-0.75	-1.09	-4.95E-05	no	no	no
4	4	4	27.28	-1.22	-1.77	-8.06E-05	no	no	no
5	5	5	25.25	-3.25	-4.72	-2.15E-04	no	no	no
6	6	6	29.5	1	1.45	6.61E-05	no	no	no
7	7	7	30.75	2.25	3.27	1.49E-04	no	no	no
8	8	8	27.05	-1.45	-2.11	-9.58E-05	no	no	no
9	9	9	23	-5.5	-7.99	-3.63E-04	no	no	no
10	10	10	29.5	1	1.45	6.61E-05	no	no	no
11	11	11	25	-3.5	-5.09	-2.31E-04	no	no	no
12	12	12	26.71	-1.79	-2.60	-1.18E-04	no	no	no
13	13	13	25	-3.5	-5.09	-2.31E-04	no	no	no

Table 8: H-3 and C-14 Survey Results for Second to Left Most Hood in Room H1511

SWIPE REPORT

User: Elon Malkin	Instrument: Hidex
Tray ID: NA	Radionuclide: H-3 , C-14
Vials: 26	Total Activity (uCi): 1.72E-04

Parameter Calculation:	Swipe Area (cm^2): 100
Standard ID: 71-H	Standard (cpm): 79402
Radionuclide: H-3	Background (cpm): 236
Activity at Reference Date (µCi) : 1.21E-01	Activity at run time (dpm): 198533.17
Reference Date: 4/28/2010	Background count time (min): 5
half life (days): 4493	Sample count time (min): 5
Date of run: 10/22/2015	Backgrond counts: 1175
Activity at run time (µCi): 8.94E-02	Background activity (dpm): 589.33
	Efficiency (cpm/dpm): 39.9%
	Net Critical Level (net cpm): 15.95
	Lower Limit of Detection (net cpm): 34.61
	MDA (dpm): 86.79
Alpha (α) emitter survey: no	MDA (nCi): 3.91E-02

								Warning Level	Action Levels
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per 100cm^2 (DPM)	Activity per 100cm^2 (nCi)	Above MDA	1000 DPMβ per 100cm2	2200 DPMβ per 100cm^2
LSC1	Liquid Scintilation tray spill 1	4	323	88	220.68	1.00E-02	yes	no	no
LSC2	Liquid Scintilation tray area 2	5	225	-10	-25.08	-1.14E-03	no	no	no
LSC3	Liquid Scintilation tray area 3	6	250	15	37.62	1.71E-03	no	no	no
LSC_post	Liquid Scintilation tray spill 1 post	7	281	46	115.36	5.24E-03	yes	no	no
LSC4	Liquid Scintilation tray area 4	8	209	-26	-65.20	-2.96E-03	no	no	no
waste	Liquid Scintillation waste	9	247	12	30.09	1.37E-03	no	no	no
lab 1	H1511 hood sample 1	10	310	75	188.08	8.55E-03	yes	no	no
lab 2	H1511 hood sample 2	11	359	124	310.96	1.41E-02	yes	no	no
lab 3	H1511 hood sample 3	12	311	76	190.59	8.66E-03	yes	no	no
lab 4	H1511 hood sample 4	13	268	33	82.76	3.76E-03	no	no	no
lab 5	H1511 hood sample 5	14	272	37	92.79	4.22E-03	yes	no	no
lab 6	H1511 hood sample 6	1	352	117	293.41	1.33E-02	yes	no	no
lab 7	H1511 hood sample 7	2	267	32	80.25	3.65E-03	no	no	no
lab 8	H1511 hood sample 8	3	266	31	77.74	3.53E-03	no	no	no
lab 9	H1511 hood sample 9	4	277	42	105.33	4.79E-03	yes	no	no
lab 10	H1511 hood sample 10	5	310	75	188.08	8.55E-03	yes	no	no
lab 11	H1511 hood sample 11	6	254	19	47.65	2.17E-03	no	no	no
lab 12	H1511 hood sample 12	7	280	45	112.85	5.13E-03	yes	no	no
lab 13	H1511 hood sample 13	1	244	9	22.57	1.03E-03	no	no	no
lab 14	H1511 hood sample 14	2	262	27	67.71	3.08E-03	no	no	no
lab 15	H1511 hood sample 15	3	286	51	127.90	5.81E-03	yes	no	no
lab 16	H1511 hood sample 16	4	345	110	275.86	1.25E-02	yes	no	no
lab 17	H1511 hood sample 17	5	267	32	80.25	3.65E-03	no	no	no
lab 18	H1511 hood sample 18	6	281	46	115.36	5.24E-03	yes	no	no
charm_bin	H1511 hood charm bin	7	551	316	792.46	3.60E-02	yes	no	no
charm_bin_post	H1511 hood charm bin	13	323	88	220.68	1.00E-02	yes	no	no

Table 9: H-3 and C-14 Survey Results for Room H1203 Chloramphenicol Operation Surfaces

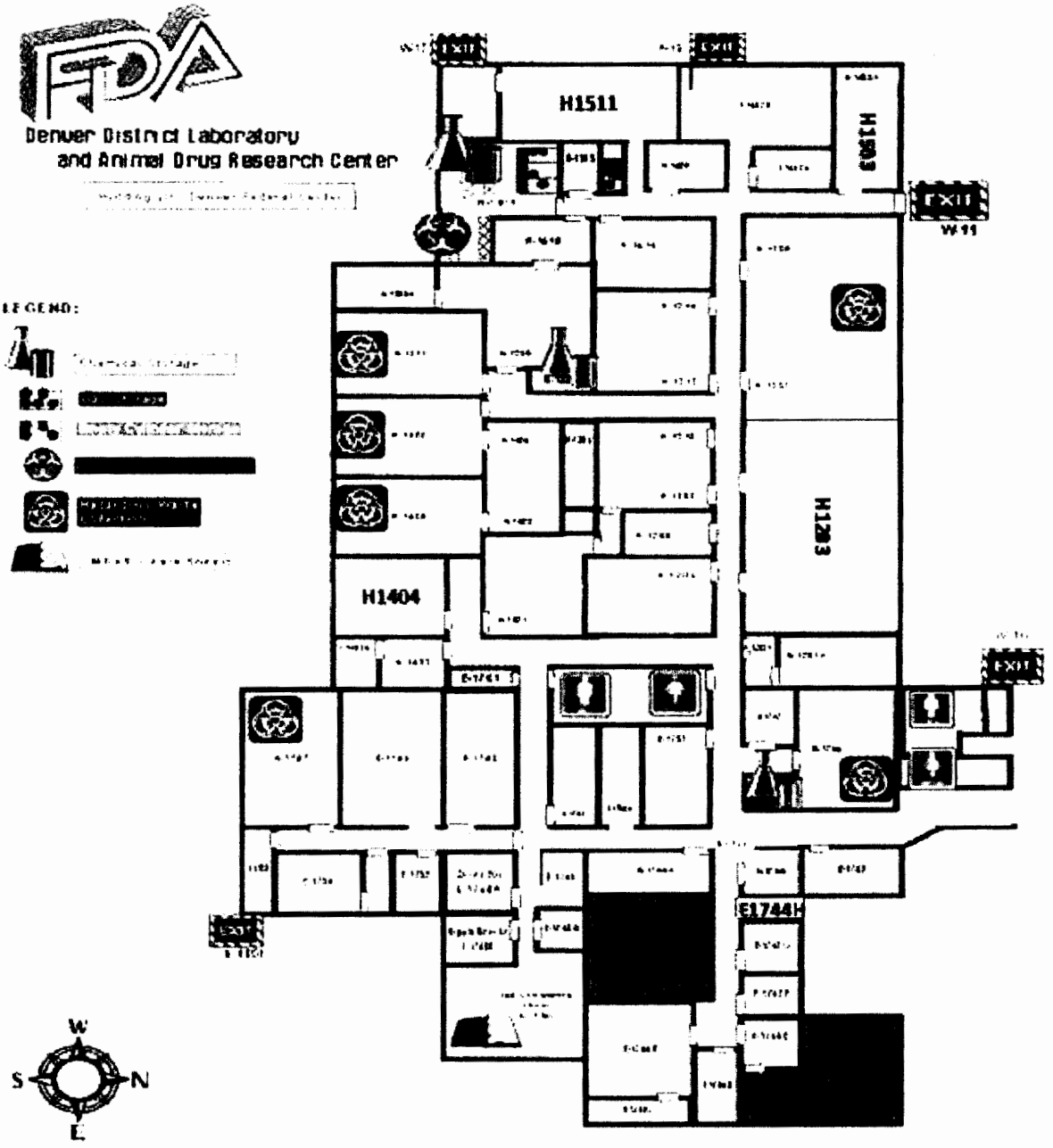
SWIPE REPORT 10/30/2015

User: Elon Malkin	Instrument: Hidex
Tray ID: NA	Radionuclide: H-3 / C-14
Vials: 19	Total Activity (uCi): -2.11E-06

Parameter Calculation:		Swipe Area (cm^2):	100
Standard ID:	99307	Standard (cpm):	163.75
Radionuclide:	Nickel-63	Background (cpm):	28.5
Activity at Reference Date (µCi) :	8.90E-05	Activity at run time (dpm):	196.54
Reference Date:	1/15/2015	Background count time (min):	4
half life (days):	36562	Sample count time (min):	4
Date of run:	10/23/2015	Backgrond counts:	114
Activity at run time (µCi):	8.85E-05	Background activity (dpm):	41.42
		Efficiency (cpm/dpm):	68.8%
		Net Critical Level (net cpm):	6.21
		Lower Limit of Detection (net cpm):	15.13
		MDA (dpm):	21.99
Alpha (α) emitter survey:	no	MDA (nCi):	9.90E-03

								Warning Level	Action Levels
ID	Description	Vial Number	Count rate (cpm)	Net count rate (cpm)	Activity per 100cm^2 (DPM)	Activity per 100cm^2 (nCi)	Above MDA	1000 DPMβ per 100 cm^2	2200 DPMβ per 100cm^2
1	H1203 Surface 1	15	26.75	0.25	0.36	1.65E-05	no	no	no
2	H1203 Surface 2	16	23.5	-5	-7.27	-3.30E-04	no	no	no
3	H1203 Surface 3	17	26.25	-2.25	-3.27	-1.49E-04	no	no	no
4	H1203 Surface 4	18	28.62	0.12	0.17	7.93E-06	no	no	no
5	H1203 Surface 5	19	28.24	-0.26	-0.38	-1.72E-05	no	no	no
6	H1203 Surface 6	20	26.5	-2	-2.91	-1.32E-04	no	no	no
7	H1203 Surface 7	21	29.75	1.25	1.82	8.26E-05	no	no	no
8	H1203 Surface 8	22	26.5	-2	-2.91	-1.32E-04	no	no	no
9	H1203 Surface 9	23	27	-1.5	-2.18	-9.91E-05	no	no	no
10	H1203 Surface 10	24	24	-4.5	-6.54	-2.97E-04	no	no	no
11	H1203 Surface 11	25	21.5	-7	-10.17	-4.62E-04	no	no	no
12	H1203 Surface 12	26	24.75	-3.75	-5.45	-2.48E-04	no	no	no
13	H1203 Surface 13	27	28.75	0.25	0.36	1.65E-05	no	no	no
14	H1203 Surface 14	28	27.5	-1	-1.45	-6.61E-05	no	no	no
15	H1203 Surface 15	29	28	-0.5	-0.73	-3.30E-05	no	no	no
16	H1203 Surface 16	30	29.5	1	1.45	6.61E-05	no	no	no
17	H1203 Surface 17	31	27.25	-1.25	-1.82	-8.26E-05	no	no	no
18	H1203 Surface 18	32	27.25	-1.25	-1.82	-8.26E-05	no	no	no
19	H1203 Surface 19	33	26	-2.5	-3.63	-1.65E-04	no	no	no

Attachment A: Denver District Laboratory Layout and Survey Locations



Areas Surveyed Highlighted in Yellow with room numbers in bold black font

Attachment B: Cs-137 Source Removal

RETURN PACKING LIST **B**

From: U.S. FDA
16th Ave & Kipling St. Bldg. 20-DFC
Denver, CO 80225
Contact Name: Lou Novak
Telephone: 303-236-9866 Fax
E-mail:

Send to:
Eckert & Ziegler Analytics
1380 Seaboard Ind. Blvd.
Atlanta, GA 30318 US
Tel: 404-352-8677
Fax: 404-352-2837
Email: analytics@ezag.com

PO# - 1597547 - 249

RETURN #RA – UWE 280c15B

STOP: This packing list must be affixed to the outside and a copy placed inside of the package. Each returned source to EZA must be on a one-to-one exchange basis only. For additional returns, please contact EZA customer service for more information.

Nuclide	Nominal Activity	Product Code	Capsule Description
Cs-137	30 microCi	CDRB	Plastic Capsule in EZN Packaging

If source is damaged, broken, or leaking, describe under this section and submit a copy of last leak test. Keep a copy of this for your records. It may be requested by your regulatory agency.

Describe leakage if applicable: None

I acknowledge that the above information is true to the best of my knowledge.

Contact Signature: Lou Novak

For EZA Use only.

EZA has received the radioactive source(s) listed above, except as noted below:

Receivers Name_____ Receipt Date:_____

Sources not received:_____ ☐ n/a

Survey Results performed in Calendar Year 2011

STDS (μCi) AT CAL. DATE	
STD B	STD 0.1
6.50E-03	1.40E-03
DATE:	01/07/99

NDA = 2 X BACKGROUND - No action needed
NDA = > 3 - 5X BACKGROUND
NDA = greater than 5X BACKGROUND = observe and monitor
NEGATIVE ACTIVITY ENTERED AS ZERO

DISTRICT	S/N / LOC.	SWIPE (CAL.) DATE	DET. MFR.	MODEL	VIAL	COUNT DATE	Length of Count (min.)	GROSS CPM	BLANK CPM	NET CPM CALC.	NET CPM	GROSS STD(B+0.1) CPM	NET CPM STD(B+0.1)	EFF. CALC.	EFF.	ACTIVITY CALC. (nCi/swipe)	2-sigma ACTIVITY UNCERTAINTY (nCi/swipe))

Survey Results performed in Calendar Year 2011

STDS (µCi) AT CAL. DATE	
STD B	STD 0.1
6.50E-03	1.40E-03
DATE:	01/07/99

DISTRICT	S/N / LOC.	SWIPE (CAL.) DATE	DET. MFR.	MODEL	MDA (nCi/swipe)	NDA Test	Comments

Survey Results performed in Calendar Year 2011

STDS (µCi) AT CAL. DATE	
STD B	STD 0.1
6.50E-03	1.40E-03
DATE:	01/07/99

NDA = 2 X BACKGROUND - No action needed
NDA = > 3 - 5X BACKGROUND
NDA = greater than 5X BACKGROUND = observe and monitor
NEGATIVE ACTIVITY ENTERED AS ZERO

DISTRICT	S/N / LOC.	SWIPE (CAL.) DATE	DET. MFR.	MODEL	VIAL	COUNT DATE	Length of Count (min.)	GROSS CPM	BLANK CPM	NET CPM CALC.	NET CPM	GROSS STD(B+0.1) CPM	NET CPM STD(B+0.1)	EFF. CALC.	EFF.	ACTIVITY CALC. (nCi/swipe)	2-sigma ACTIVITY UNCERTAINTY (nCi/swipe))

Survey Results performed in Calendar Year 2011

STDS (μCi) AT CAL. DATE	
STD B	STD 0.1
6.50E-03	1.40E-03
DATE:	01/07/99

NDA = 2 X BACKGROUND - No action needed
NDA = > 3 - 5X BACKGROUND
NDA = greater than 5X BACKGROUND = observe and monitor
NEGATIVE ACTIVITY ENTERED AS ZERO

DISTRICT	S/N / LOC.	SWIPE (CAL.) DATE	DET. MFR.	MODEL	VIAL	COUNT DATE	Length of Count (min.)	GROSS CPM	BLANK CPM	NET CPM CALC.	NET CPM	GROSS STD(B+0.1) CPM	NET CPM STD(B+0.1)	EFF. CALC.	EFF.	ACTIVITY CALC. (nCi/swipe)	2-sigma ACTIVITY UNCERTAINTY (nCi/swipe))

Survey Results performed in Calendar Year 2011

STDS (μCi) AT CAL. DATE	
STD B	STD 0.1
6.50E-03	1.40E-03
DATE:	01/07/99

DISTRICT	S/N / LOC.	SWIPE (CAL.) DATE	DET. MFR.	MODEL	MDA (nCi/swipe)	NDA Test	Comments