MEDAREX

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1 December 2008

Br. 2

Licensing Assistance Team
Division of Nuclear Materials Safety
US Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Subject: **Request for License Termination; License 29-30119-01** 03033421

Dear Sir:

Medarex, Inc. hereby requests termination of its specific byproduct material license number 29-30119-01.

As of 6 October 2008 our Radiation Safety Officer has left the company. Mr. Kevin Krause, Director, Health Safety & Environment, has taken over the RSO duties on a temporary basis. He is assisted by Wesley R. Van Pelt, PhD, CIH, CHP who has been consulting for Medarex in radiation safety since 2002.

No licensed radioactive materials have been received or used since March 2006. Medarex has determined that it will no longer have the need for licensed radioactive material. Medarex commits to not receiving quantities of licensable radioactive materials until NRC takes final action on this termination request.

All radioactive materials have been removed from the site by radioactive decay (for Cr-51) and by transfer to our radioactive waste contractor Veolia Environmental Services (formerly Onyx). A single bottle of tritiated water containing 11.5 microcuries of H-3 is retained as an exempt quantity not requiring a specific or general license.

Radioactive material storage and use has always been restricted to either Lab 115A or Lab 145A. We have decontaminated and decommissioned both of these lab rooms. Attached are the reports of decommissioning and the final status survey for each room.

If you have any questions or need further documentation please feel free to contact Mr. Kevin Krause, Director, Environment, Health & Safety at (908) 479-2471.

Very truly yours,
Medarex, Inc.

Joseph Chiarappa
Vice President
Technical Operations

Attachments:
Laboratory 115A Decommissioning Report
Laboratory 145A (Cr-51) Decommissioning Report

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MEDAREX

Laboratory 115A Decommissioning Report

Medarex, Inc.
519 Route 173 West
Bloomsbury, New Jersey

NRC License 29-30119-01

Report Date: November 2008

Prepared by:

Jill M. Gordon
Manager, Environmental Health and Safety
Radiation Safety Officer
Medarex, Inc.

Wesley R. Van Pelt, Ph.D., CHP, CIH
President
Wesley R. Van Pelt Associates, Inc.

Introduction

Medarex, Inc., founded in 1987, is a biopharmaceutical company focused on the discovery, development, and potential commercialization of fully human antibody-based therapeutics to treat life-threatening and debilitating diseases, including cancer, inflammation, autoimmune and infectious diseases.

Medarex, Inc. holds Nuclear Regulatory Commission license Number 29-30119-01, currently at Amendment No. 11, which expires 31 March 2014. The Company utilizes radioactive compounds for standard laboratory biochemistry and molecular biology experiments that support product discovery, product development and activity assays. The current license allows the possession and use of radionuclides for research and development in maximum quantities and forms as shown in the table below. Use of these radionuclides is limited to laboratories identified as 115A and 145A.

Element & Mass Number	Chemical or Physical Form	Maximum Amount Possessed at Any One Time	Half-Life
Hydrogen-3	Pre-labeled compounds	185 MBq (5 mCi)	12.28 years
Chromium-51	any	370 MBq (10 mCi)	27.8 days
Iodine-125	Pre-labeled compounds	74 MBq (2 mCi) (For storage of waste material only)	60.2 days

This report documents the June 2006 decontamination and decommissioning of Lab 115A and its release for unrestricted use.

History

Lab 115A is a small lab, approximately 10 x 20 foot, originally designed for use of radioactive material. It has a fume hood, a biosafety cabinet and standard lab benches and shelves.

As of March 2006, all use of radioactive materials ceased in Laboratory 115A. The only radionuclides used in this lab were H-3 and Cr-51. I-125 had been used years before and the last small quantity of I-125 waste was removed on 18 October 2004 by Onyx Environmental and sent to Perma-Fix of Florida, Inc.

Purpose

A request to utilize laboratory 115A for purposes other than radionuclide use was made to the Radiation Safety Officer, Jill Gordon. Ms. Gordon and Dr. Wesley R. Van Pelt, Ph.D., CHP, CIH

of Wesley R. Van Pelt Associates, Inc. prepared and executed a lab decommissioning plan on June 20-22, 2006.

Data Quality Objectives

The purpose of this decommissioning process was to remove all radioactive materials, contaminated objects and residual contamination so that the lab could be released for unrestricted use. NRC regulation 10 CFR 20.1402, states that "A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA)."

The residual radioactivity surface concentration for a uniform surface contamination to give 25 mrem/year was calculated using the default parameters of the NRC code DandD version 2.1.0. The resulting surface contaminations are:

	dpm/100cm2
H-3	113,636,364
Cr-51	5,208,333

Thus, an average uniform contamination in the lab of either 113,000,000 dpm/100 cm^2 of H-3 or 5,000,000 dpm/100 cm^2 of Cr-51 would produce 25 mrem per year. Selecting an *a priori* safety factor of 100 for ALARA, the *a priori* target average surface contamination limits are:

1,130,000 dpm/100 cm^2 of H-3
50,000 dpm/100 cm^2 of Cr-51.

Decommissioning Activities

The decommissioning plan consisted predominantly of collecting and analyzing a sufficient number of wipe samples throughout the lab to determine if contamination was present. Swipe locations included insides of drawers, shelves, drains, floor, hood, benches, equipment, supplies, etc. See Appendix A "Decommissioning Sample Locations" for locations of all swipes. Swipes were done with a cotton swab and covered at least 100 cm^2 of area. A total of 130 swipes were taken, of which three were background swipes (Numbers 128, 129 and 130).

Additional plan activities included decontamination of several small areas when dpm swipe results were above background and disposal of RAM waste.

Swipe samples were analyzed for both beta and gamma emissions with results attached to this report. For beta emitters (H-3), contamination survey swipes were counted in a Perkin Elmer Jet Model 1450 Microbeta liquid scintillation and luminescence counter. For gamma emitters (Cr-51),

contamination survey swipes were counted in a Perkin Elmer Model 1470 Wizard automatic gamma counter. Each swipe was counted on both the automatic gamma counter and then on the liquid scintillation counter.

The remaining stock bottle of H-3 reagent and any suspected contaminated items were placed in a radioactive waste disposal container for removal by Veolia Environmental Services.

Results

Of the 130 swipes collected during the decommissioning activities, liquid scintillation counter analysis indicated slightly elevated activity for 9 locations with a maximum of 137 dpm (Swipe sample number 16). The results of the liquid scintillation counting of all swipes are shown in Appendix C.

The areas/items associated with these 9 samples were decontaminated with Rad-Con Surface Cleaner and new swipes were collected. These 9 locations were then re-surveyed and re-analyzed with the liquid scintillation counter, resulting in activities at or below background levels. (Appendix B, "Lab 115A Decommissioning Additional Beta Samples"). The counting efficiency of the liquid scintillation counter was determined at the time of the decommissioning to be 10.3% when counting Q-tip samples.

The final survey (after decontaminating 9 locations) for H-3 with the liquid scintillation counter showed a maximum result of 11.46 net cpm (see Appendix C). Using a counting efficiency of 10.3% this results in a maximum H-3 contamination of 111 dpm. This is well below the *a priori* ALARA target average surface contamination limit for H-3 of 1,130,000 dpm/100 cm^2.

Gamma counter analysis for Cr-51 indicated no unusual activity for any of the samples. See Appendix D, "Lab 115A Decommissioning Cr-51 Gamma Samples". Of the 140 samples, the highest swipe was 72 cpm (gross) while the background (blank) was 54 cpm. Thus, all gamma swipes are within the variation of background and are considered negligible. The counting efficiency of the Wallac gamma counter has been determined to be 3.18% for Cr-51. The gamma counting efficiency is defined as cpm/dpm and is lower than typical gamma emitters since the gamma abundance (gammas rays per decay) for Cr-51 is only 9%.

The final survey for Cr-51 with the Wallac gamma counter showed a maximum result of 72 - 54 = 18 net cpm (see Appendix D). Using a counting efficiency of 3.18% this results in a maximum Cr-51 contamination of 566 dpm. This is well below the *a priori* ALARA target average surface contamination limit for 50,000 dpm/100 cm^2 of Cr-51.

Disposition of Remaining and Residual Radioactivity

All remaining radioactivity in this room was packaged for disposal as radioactive waste. A single bottle containing tritiated water (11.5 microcuries H-3) for use in lsc instrument calibration was

retained and moved to Room 145A for storage. This is an exempt quantity of H-3 and is exempt from the requirement for a NRC license.

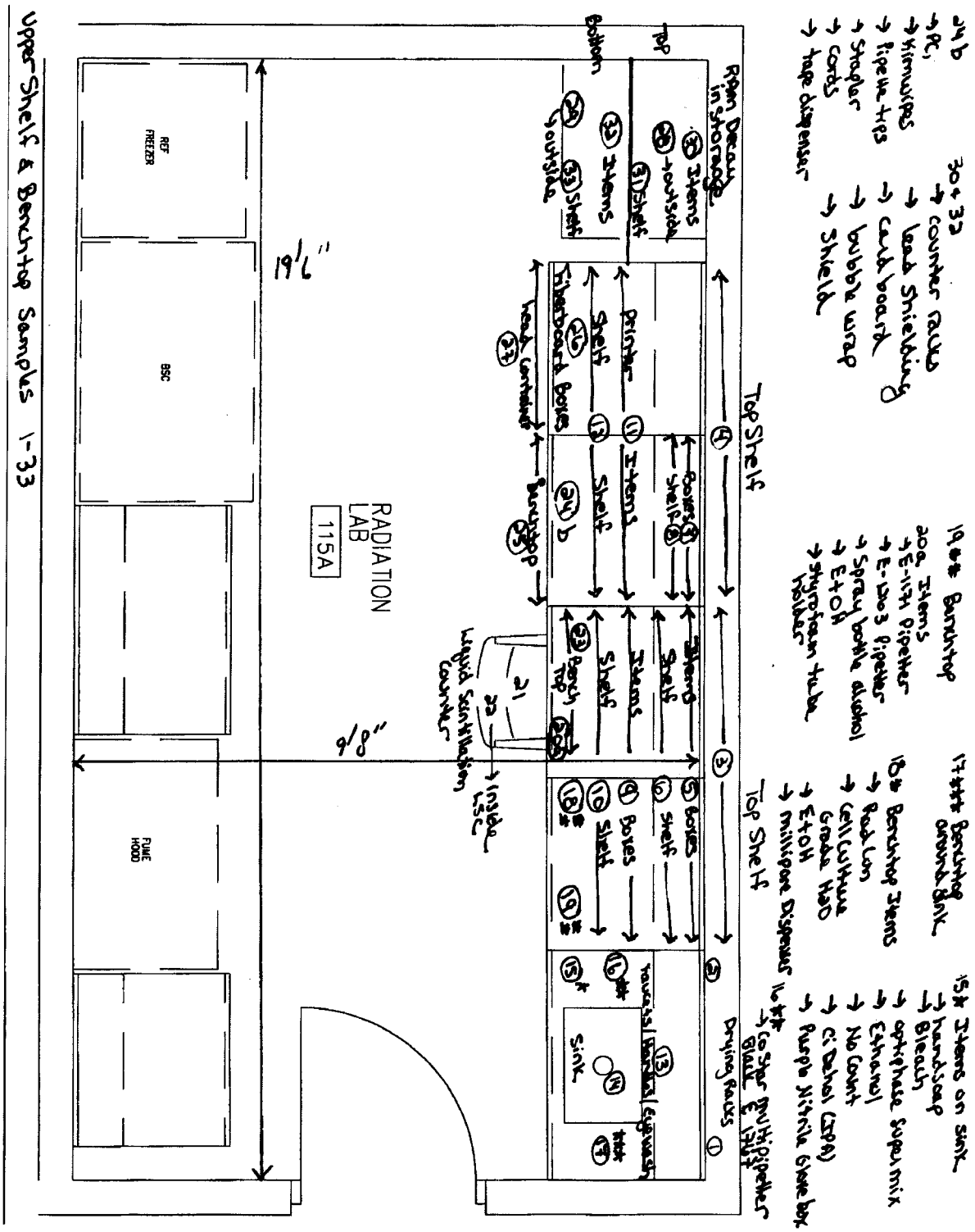
Radioactive waste generated during the decommissioning and previous lab activities was disposed of by Veolia Environmental Services on August 9, 2006.

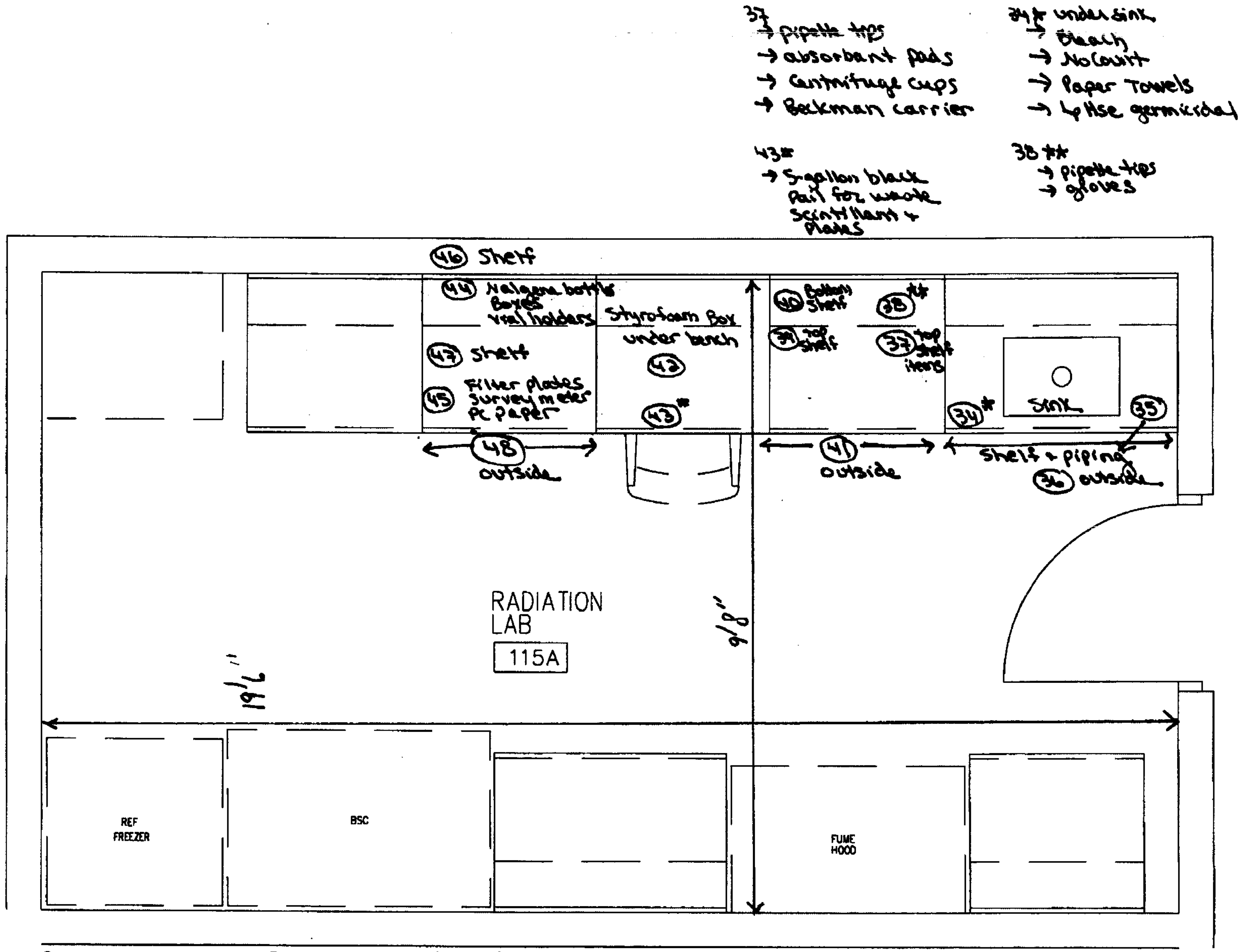
Conclusion

Lab 115A was decontaminated and surveyed showing that the room is well below the NRC contamination levels for release for unrestricted use and has been cleaned to ALARA levels.

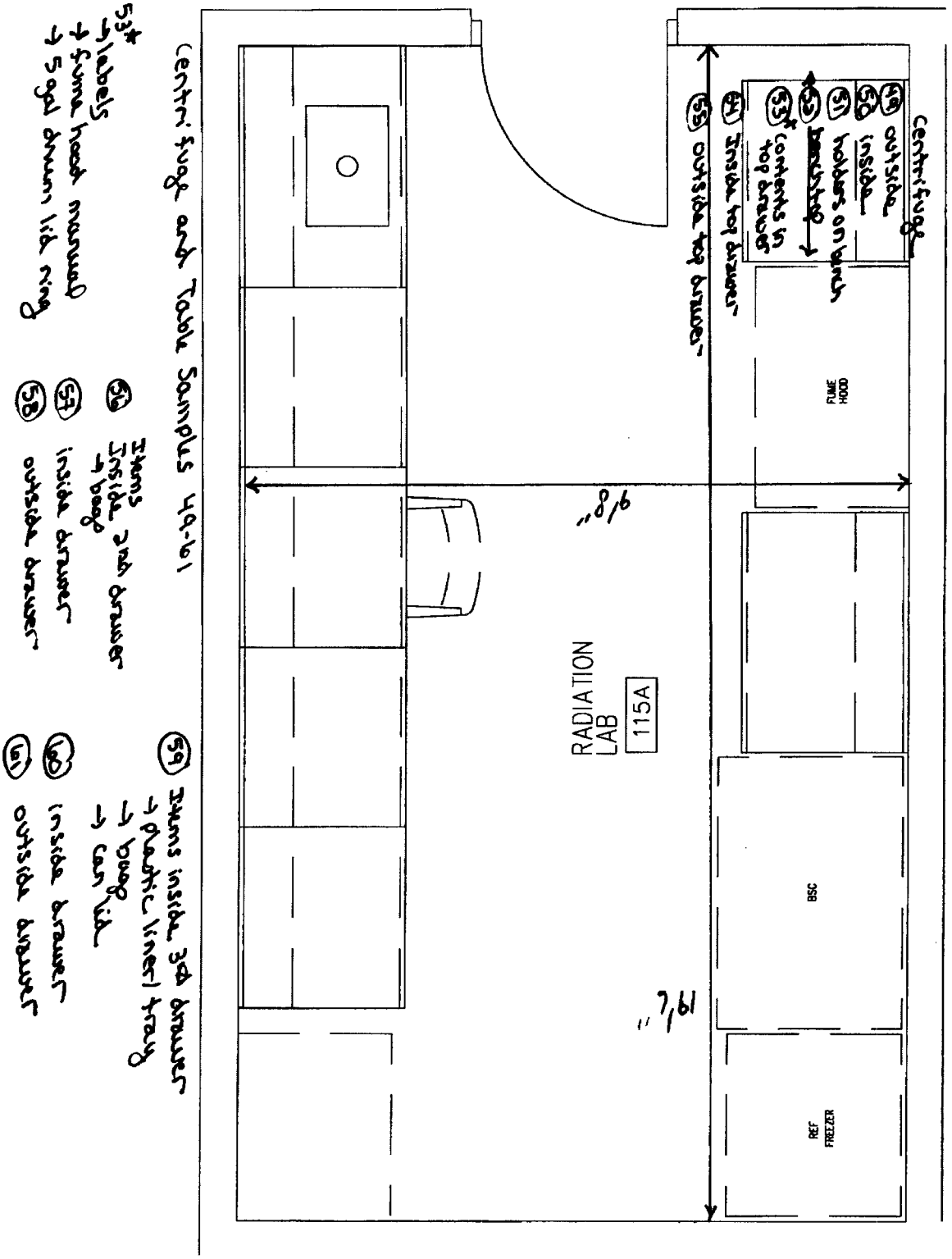
Lab 115A was subsequently released for other than radionuclide use in the 4th quarter of 2006.

Appendix A
Decommissioning Sample Locations

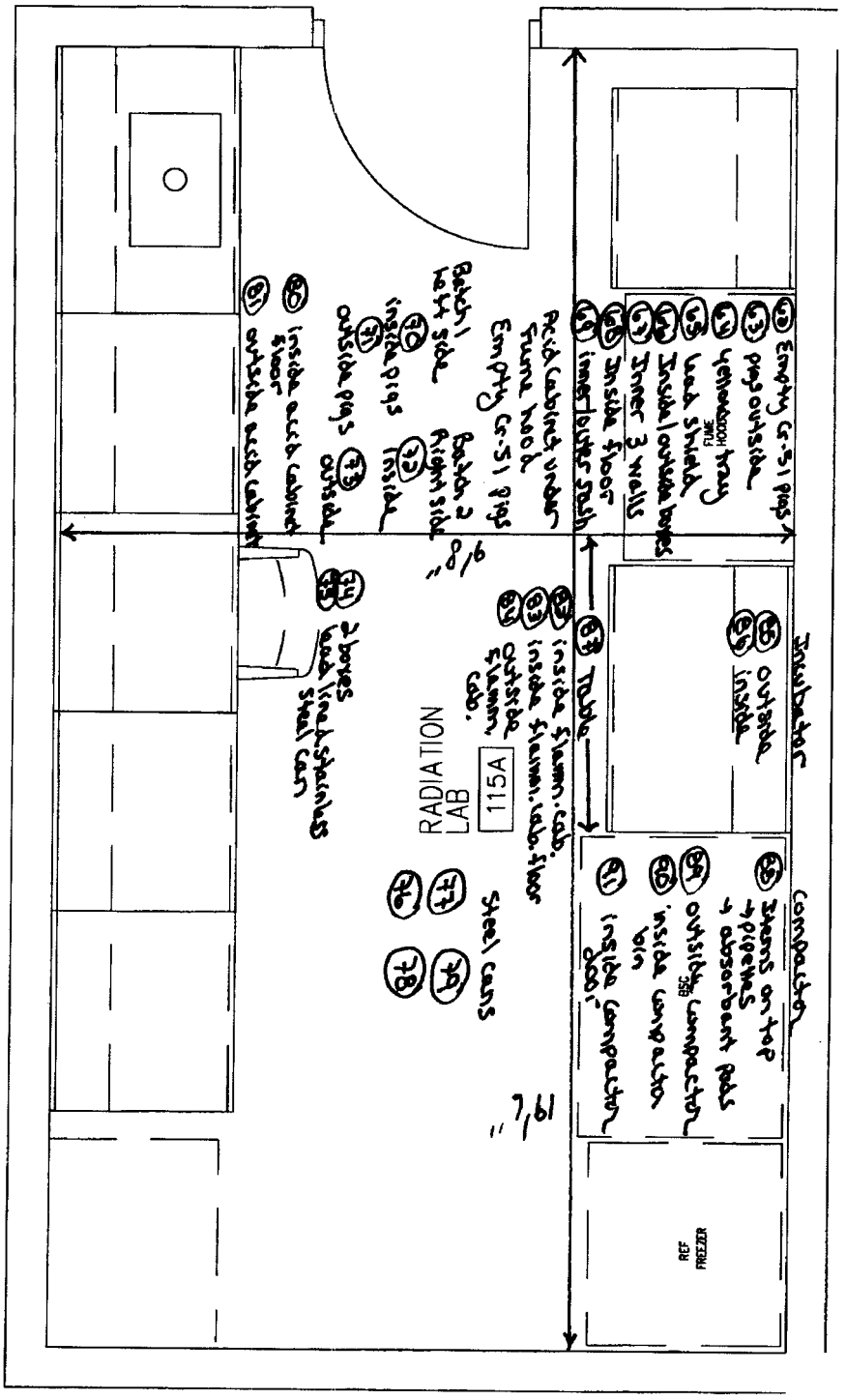


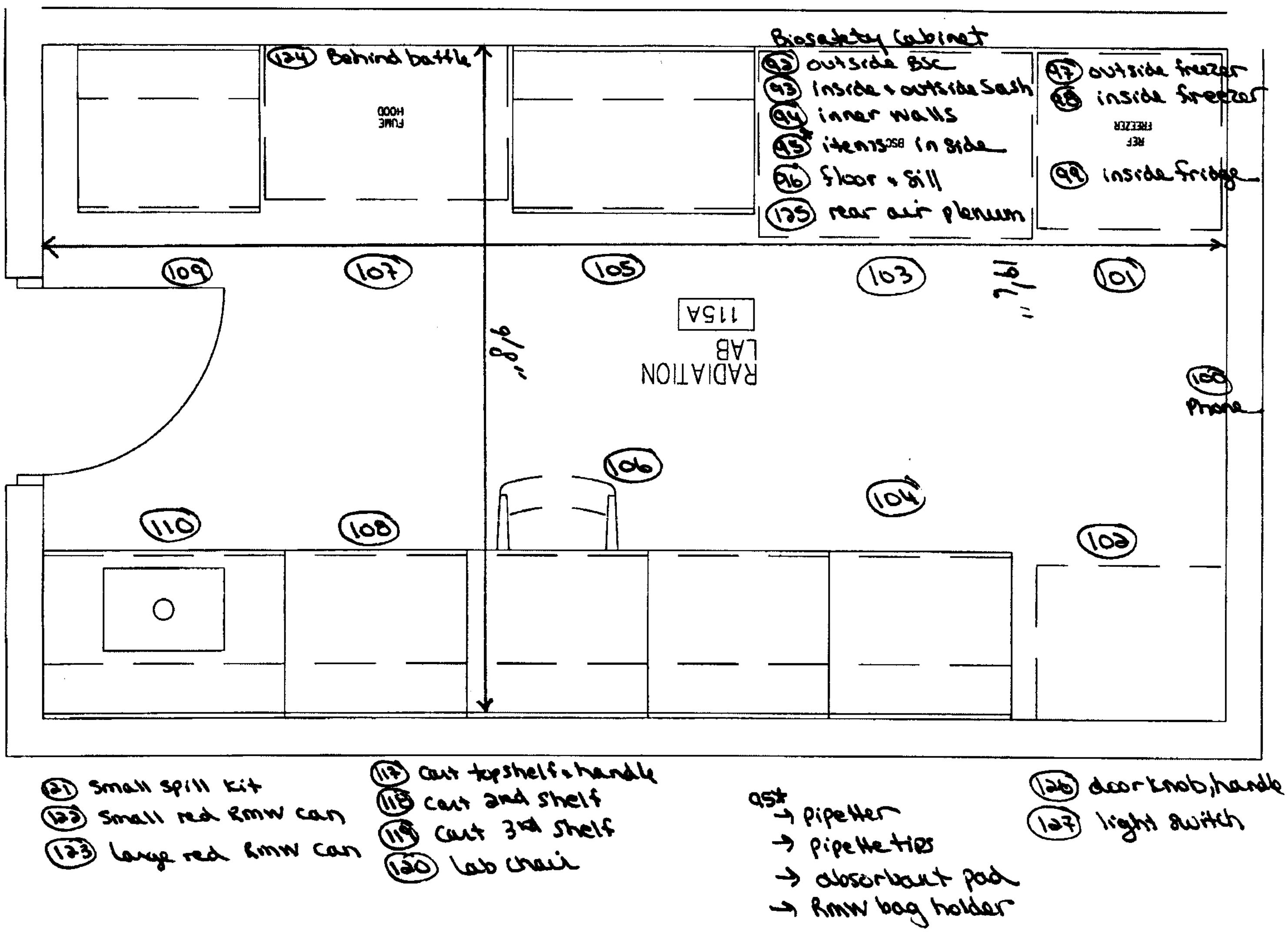


Bottom Cabinet Samples 34-48

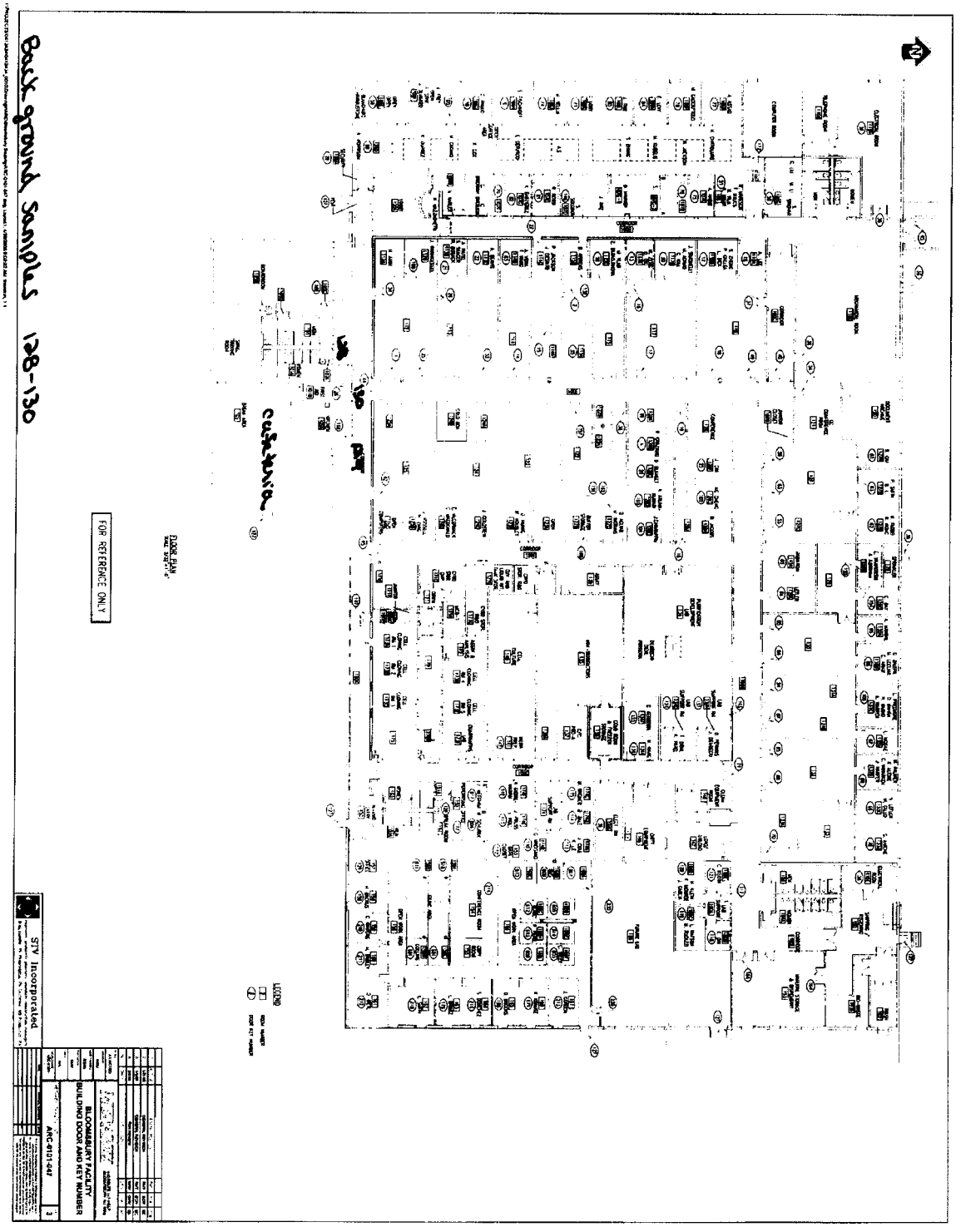

RADIATION LAB
115A
FUME HOOD
BSC
REF FREEZER

Fume hood, incubator, compactor + associated chemical cabinets, miscellaneous samples 03-91





Biosafety Cabinet, refrigerator/freezer, lab floor samples 92-110, 121-123, 117-120, 126-127


Background Samples 128-130
FOR REFERENCE ONLY
STV Incorporated
BLOOMSBURY FACILITY
BUILDING DOOR AND KEY NUMBER

Appendix B
Lab 115A Decommissioning Additional Beta Samples
(Liquid Scintillation Counter)
(After Decon of Selected Locations)

Swipe Sample #	H-3 Net CPM	LOCATION
5	4.46	Boxes on top shelf-next to sink
16	-1.54	Pipetter on left side of sink counter-rear
20	-0.54	Pipetters on benchtop below 2nd wall cabinet from sink
43	1.46	5-gal pail on floor under counter below liquid scintillation counter
51	-2.54	Centrifuge holders
64	-1.54	Yellow tray in fume hood
66	1.46	Cardboard boxes in hood
96	1.46	Biosafety cabinet floor and sill
109	9.46	Floor in front of centrifuge

Appendix C
Lab 115A Decommissioning Beta Emitter Samples
(Liquid Scintillation Counter)

Swipe Sample #	H-3 Net CPM	LOCATION
1	-2.83	Drying racks above sink -right
2	1.17	Drying racks above sink -left
3	-0.83	Top of wall cabinets - right
4	-3.83	Top of wall cabinets - left
5	16.17	Boxes on top shelf-next to sink
6	-0.83	Top shelf surface-next to drying rack
7	3.17	Boxes on top shelf-third cabinet from sink
8	-2.83	Top shelf surface-third cabinet from sink
9	5.17	Boxes on second shelf-next to sink
10	-1.83	2nd shelf surface-next to sink
11	1.17	Printer on 2nd shelf-4th cabinet from sink
12	-0.83	2nd shelf surface-4th cabinet from sink
13	1.17	Faucet/handles, eyewash at sink
14	4.17	Inside sink
15	-1.83	Items on left side of sink counter-front
16	137.17	Items on left side of sink counter-rear
17	-1.83	Items on right side of sink counter
18	0.17	Benchtop items below wall cabinet next to sink-left
19	2.17	Benchtop items below wall cabinet next to sink-right
20	18.17	Benchtop items below 2nd cabinet from sink
21	-3.83	Top of liquid scintillation counter
22	1.17	Inside liquid scintillation counter
23	0.17	Benchtop behind liquid scintillation counter
24	-3.83	PC/assorted items to left of liquid scintillaton counter
25	-4.83	Benchtop to left of liquid scintillation counter
26	0.17	Fiberboard boxes on 4th wall cabinet from sink
27	5.17	Lead container on floor under bench
28	1.17	Outside upper door of RAM decay in storage cabinet
29	-0.83	Outside lower door of RAM decay in storage cabinet
30	-0.83	Items inside top RAM decay in storage cabinet
31	1.17	Shelf surface inside top RAM decay in storage cabinet
32	-3.83	Items inside bottom RAM decay in storage cabinet
33	-1.83	Shelf surface inside bottom RAM decay in storage cabinet
34	-0.83	Items under sink cabine
35	-3.83	Shelf, piping under sink cabinet
36	-0.83	Outside door under sink cabinet
37	-0.83	Items on top shelf of floor cabinet next to sink-right side
38	-2.83	Items on bottom shelf of floor cabinet next to sink-right side
39	-1.83	Items on top shelf of floor cabinet next to sink-left side
40	0.17	Items on bottom shelf of floor cabinet next to sink-left side
41	9.17	Outside door of floor cabinet next to sink

42	0.17	Box under counter below liquid scintillation counter
43	12.17	5-gal pail on floor under counter below liquid scintillation counter
44	1.17	Items on top shelf of 2nd floor cabinet from sink
45	2.17	Items on bottom shelf of 2nd floor cabinet from sink
46	-1.83	Top shelf surface of 2nd floor cabinet from sink
47	-2.83	Bottom shelf surface of 2nd floor cabinet from sink
48	-1.83	Outside door of floor 2nd floor cabinet from sink

Swipe Sample #	H-3 Net CPM	LOCATION
49	0.46	Outside surface of centrifuge
50	7.46	Inside surface of centrifuge
51	16.46	Holders on benchtop
52	1.46	Centrifuge benchtop surface
53	-0.54	Inside top drawer of cabinet below centrifuge
54	4.46	Items inside top drawer of cabinet below centrifuge
55	-1.54	Outside surface of top cabinet drawer below centrifuge
56	-1.54	Items inside 2nd drawer below centrifuge
57	-3.54	2nd drawer below centrifuge inner surface
58	-3.54	2nd drawer below centrifuge outer surface
59	1.46	Items inside 3rd drawer below centrifuge
60	2.46	3rd drawer below centrifuge inner surface
61	11.46	3rd drawer below centrifuge outer surface
62	8.46	Empty Cr-51 pigs inside fume hood
63	2.46	Inside surfaces of Cr-51 pigs in fume hood
64	18.46	Yellow tray holding Cr- 51 pigs in fume hood
65	1.46	Lead shield in fume hood
66	43.46	Inside and outside boxes in fume hood
67	5.46	Inner side and rear surfaces of fume hood
68	3.46	Inner floor surface of fume hood
69	3.46	Fume hood sash inner and outer surface
70	0.46	Inside empty Cr-51 pigs under fume hood-left side
71	0.46	Outside empty Cr-51 pigs under fume hood-left side
72	0.46	Inside empty Cr-51 pigs under fume hood-right side
73	-0.54	Outside empty Cr-51 pigs under fume hood-right side
74	1.46	Inside/outside 2 boxes on floor in front of fume hood
75	-1.54	Inside/outside lead-lined stainless can on floor
76	1.46	Inner/outer surfaces of steel can-left front
77	4.46	Inner/outer surfaces of steel can-left rear
78	2.46	Inner/outer surfaces of steel can-right front
79	-0.54	Inner/outer surfaces of steel can-right rear
80	7.46	Inside acid cabinet on floor under fume hood
81	0.46	Outside acid cabinet on floor under fume hood
82	2.46	Inside flammable cabinet under fume hood
83	-2.54	Inside flammable cabinet floor under fume hood

84	1.46	Outside flammable cabinet under fume hood
85	3.46	Outside surface of incubator on table next to fume hood
86	5.46	Inside surface of incubator on table next to fume hood
87	-1.54	Incubator table surface
88	2.46	Items on top of compactor next to incubator table
89	-0.54	Outside surface of compactor under biosafety cabinet
90	1.46	Inside surface of compactor under biosafety cabinet
91	-0.54	Inside compactor door
92	-2.54	Outside surface of biosafety cabinet
93	2.46	Inner and outer surface of biosafety cabinet sash
94	1.46	Inner walls of biosafety cabinet
95	7.46	Items inside biosafety cabinet
96	11.46	Biosafety cabinet floor and sill
97	-2.54	Outer freezer door surface on fridge next to biosafety cabinet
98	2.46	Inner freezer door surface of fridge next to biosafety cabinet
99	1.46	Inner surfaces of fridge next to biosafety cabinet
100	-0.54	Phone near lab door
101	0.46	Floor in front of fridge
102	1.46	Floor in front of decay in storage cabinet
103	0.46	Floor in front of biosafety cabinet
104	3.46	Floor in front of lab bench across from biosafety cabinet
105	2.46	Floor in front of incubator table
106	-3.54	Floor in front of liquid scintillation counter bench
107	1.46	Floor in front of fume hood
108	1.46	Floor in front of bench across from fume hood
109	19.46	Floor in front of centrifuge
110	-1.54	Floor in front of sink across from centrifuge
111	-1.54	Corridor floor outside lab 115A to left of door
112	0.46	Corridor floor outside lab 115A to left of door-opposite wall
113	1.46	Corridor floor directly in front of lab 115A
114	3.46	Corridor floor directly in front of lab 122
115	-1.54	Corridor floor outside lab 115A to right of door
116	-0.54	Corridor floor outside lab 115A to right of door in front of freezer
117	-1.54	Lab cart top shelf and handle
118	3.46	Lab cart 2nd shelf
119	0.46	Lab cart 3rd shelf
120	-2.54	Lab chair
121	0.46	Lab spill kit
122	2.46	Small red can for regulated medical waste
123	-2.54	Large red can for regulated medical waste
124	4.46	Behind fume hood baffle
125	4.46	Biosafety cabinet rear air plenum
126	1.46	Lab door knob/handle
127	5.46	Lab light switch
128	2.46	Floor in front of large ladies room - background
129	4.46	Floor in front of cafeteria - background
130	5.46	Floor between ladies room and cafeteria-background

Appendix D
Lab 115A Decommissioning Cr-51 Gamma Samples
(Automatic Gamma Counter)

Page 1

Power Failure

END OF COUNTING

POS	RACK	DET	BATCH	TIME	COUNTS	CPM	ERROR %
1	-	1	1	60	61	0.0	112.72
2	1	1	2	60	63	0.0	101.57
3	1	1	3	60	56	0.0	67.94
4	1	1	4	60	44	0.0	34.82
5	1	1	5	60	43	0.0	33.60
6	1	1	6	60	62	0.0	87.97
7	1	1	7	60	57	0.0	69.85

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10	1	1	10	60	55	0.0	58.15
11	2	1	11	60	64	0.0	104.35
12	2	1	12	60	62	0.0	90.04
13	2	1	13	60	57	0.0	63.83
14	2	1	14	60	60	0.0	77.45
15	2	1	15	60	44	0.0	35.19
16	2	1	16	60	46	0.0	37.93
17	2	1	17	60	43	0.0	33.45
18	2	1	18	60	52	0.0	48.33
19	2	1	19	60	40	0.0	30.65
20	2	1	20	60	70	0.0	240.83
21	3	1	21	60	54	0.0	54.08
22	3	1	22	60	72	0.0	404.16
23	3	1	23	60	56	0.0	60.24
24	3	1	24	60	51	0.0	46.77
25	3	1	25	60	55	0.0	57.01
26	3	1	26	60	51	0.0	46.77
27	3	1	27	60	36	0.0	27.01
28	3	1	28	60	52	0.0	49.06
29	3	1	29	60	55	0.0	57.01
30	3	1	30	60	56	0.0	60.24
31	4	1	31	60	53	0.0	51.43
32	4	1	32	60	52	0.0	48.33
33	4	1	33	60	46	0.0	37.93
34	4	1	34	60	54	0.0	54.08
35	4	1	35	60	53	0.0	51.43
36	4	1	36	60	54	0.0	54.32
37	4	1	37	60	57	0.0	63.74
38	4	1	38	60	61	0.0	85.71
39	4	1	39	60	69	0.0	200.00
40	4	1	40	60	67	0.0	143.57
41	5	1	41	60	46	0.0	37.83
42	5	1	42	60	48	0.0	41.08
43	5	1	43	60	54	0.0	55.15
44	5	1	44	60	53	0.0	51.43
45	5	1	45	60	53	0.0	51.43
46	5	1	46	60	50	0.0	44.72
47	5	1	47	60	52	0.0	49.00
48	5	1	48	60	54	0.0	54.09
49	5	1	49	60	42	0.0	32.87
50	5	1	50	60	46	0.0	37.93
51	6	1	51	60	39	0.0	29.20
52	6	1	52	60	69	0.0	190.54
53	6	1	53	60	55	0.0	57.01
54	6	1	54	60	56	0.0	59.26
55	6	1	55	60	62	0.0	90.04
56	6	1	56	60	50	0.0	44.72
57	6	1	57	60	52	0.0	48.33
58	6	1	58	60	57	0.0	63.88
59	6	1	59	60	55	0.0	57.01
60	6	1	60	60	55	0.0	57.01
61	7	1	61	60	48	0.0	41.06
62	7	1	62	60	67	0.0	150.57
63	7	1	63	60	58	0.0	67.47
64	7	1	64	60	71	0.0	302.08
65	7	1	65	60	58	0.0	67.84
66	7	1	66	60	46	0.0	37.93
67	7	1	67	60	64	0.0	107.15
68	7	1	68	60	64	0.0	104.38
69	7	1	69	60	51	0.0	46.77
70	7	1	70	60	49	0.0	42.85
71	8	1	71	60	60	0.0	79.80
72	8	1	72	60	50	0.0	44.72
73	8	1	73	60	56	0.0	60.24

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75	8	1	75	60	61	0.0	85.71
77	8	1	77	60	45	0.0	37.03
78	8	1	78	60	47	0.0	38.99
79	8	1	79	60	65	0.0	118.32
80	8	1	80	60	55	0.0	81.99
81	9	1	81	60	58	0.0	67.84
82	9	1	82	60	57	0.0	62.39
83	9	1	83	60	41	0.0	31.68
84	9	1	84	60	68	0.0	163.87
85	9	1	85	60	53	0.0	51.43
86	9	1	86	60	52	0.0	49.00
87	9	1	87	60	58	0.0	67.84
88	9	1	88	60	48	0.0	41.08
89	9	1	89	60	41	0.0	31.68
90	9	1	90	60	42	0.0	32.78
91	10	1	91	60	58	0.0	69.47
92	10	1	92	60	44	0.0	35.19
93	10	1	93	60	62	0.0	92.84
94	10	1	94	60	61	0.0	83.30
95	10	1	95	60	47	0.0	39.45
96	10	1	96	60	49	0.0	42.83
97	10	1	97	60	54	0.0	54.09
98	10	1	98	60	62	0.0	87.97
99	10	1	99	60	53	0.0	51.43
100	10	1	100	60	43	0.0	33.95
101	11	1	101	60	55	0.0	56.13
102	11	1	102	60	52	0.0	49.00
103	11	1	103	60	51	0.0	46.77
104	11	1	104	60	44	0.0	35.19
105	11	1	105	60	48	0.0	41.79
106	11	1	106	60	50	0.0	45.47
107	11	1	107	60	57	0.0	63.83
108	11	1	108	60	51	0.0	46.77
109	11	1	109	60	56	0.0	45.56
110	11	1	110	60	84	0.0	197.18
111	12	1	111	60	52	0.0	48.32
112	12	1	112	60	67	0.0	156.49
113	12	1	113	60	50	0.0	44.72
114	12	1	114	60	47	0.0	40.04
115	12	1	115	60	66	0.0	131.94
116	12	1	116	60	72	0.0	367.98
117	12	1	117	60	45	0.0	37.03
118	12	1	118	60	41	0.0	31.68
119	12	1	119	60	65	0.0	123.65
120	12	1	120	60	57	0.0	65.28
121	13	1	121	60	51	0.0	46.77
122	13	1	122	60	47	0.0	39.45
123	13	1	123	60	38	0.0	28.73
124	13	1	124	60	59	0.0	72.35
125	13	1	125	60	55	0.0	57.01
126	13	1	126	60	51	0.0	46.77
127	13	1	127	60	57	0.0	65.44
128	13	1	128	60	53	0.0	50.78
129	13	1	129	60	52	0.0	48.33
130	13	1	130	60	57	0.0	65.44
131	14	1	131	60	45	0.0	36.12
132	14	1	132	60	67	0.0	157.37
133	14	1	133	60	58	0.0	67.84
134	14	1	134	60	55	0.0	56.13
135	14	1	135	60	56	0.0	60.24
136	14	1	136	60	53	0.0	52.39
137	14	1	137	60	49	0.0	42.83
138	14	1	138	60	51	0.0	47.68
139	14	1	139	60	50	0.0	45.56

MEDAREX

Laboratory 145A (Cr-51) Decommissioning Report

Medarex, Inc.
519 Route 173 West
Bloomsbury, New Jersey

NRC License 29-30119-01

Report Date: November 2008
Survey Date: October 2008

Prepared by:

Kevin Krause
Director, Environmental Health and Safety
Medarex, Inc.

Wesley R. Van Pelt, Ph.D., CHP, CIH
President
Wesley R. Van Pelt Associates, Inc.

Introduction

Medarex, Inc., founded in 1987, is a biopharmaceutical company focused on the discovery, development, and potential commercialization of fully human antibody-based therapeutics to treat life-threatening and debilitating diseases, including cancer, inflammation, autoimmune and infectious diseases.

Medarex, Inc. holds Nuclear Regulatory Commission license Number 29-30119-01, currently at Amendment No. 11, which expires 31 March 2014. The Company utilizes radioactive compounds for standard laboratory biochemistry and molecular biology experiments that support product discovery, product development and activity assays. The current license allows the possession and use of radionuclides for research and development in maximum quantities and forms as shown in the table below. Use of these radionuclides has always been limited to laboratories identified as 115A and 145A.

Element & Mass Number	Chemical or Physical Form	Maximum Amount Possessed at Any One Time	Half-Life
Hydrogen-3	Pre-labeled compounds	185 MBq (5 mCi)	12.28 years
Chromium-51	any	370 MBq (10 mCi)	27.8 days
Iodine-125	Pre-labeled compounds	74 MBq (2 mCi) (For storage of waste material only)	60.2 days

This report documents the October 2008 final survey and decommissioning of Lab 145A and its release for unrestricted use.

History

Lab 145A is a small lab, approximately 10 x 20 foot, originally designed for use of radioactive material. It was used exclusively by the Quality Control department for testing biochemical materials using a Cr-51 based assay.

As of March 2006, all use of radioactive materials ceased in Laboratory 145A. The only radionuclide ever used in this lab was Cr-51 (half life 27.8 days).

Purpose

A final radiological survey was made on 16 October 2008 by Mr. Kevin Krause of Medarex and Dr. Wesley R. Van Pelt, Ph.D., CHP, CIH of Wesley R. Van Pelt Associates, Inc.

The purpose of the survey was to demonstrate by calculation and measurement that there is no residual radioactivity in Laboratory 145A.

Data Quality Objectives

The purpose of this decommissioning process was to demonstrate that the lab room could be released for unrestricted use. NRC regulation 10 CFR 20.1402, states that "A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a TEDE to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources of drinking water, and the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA)."

The residual radioactivity surface concentration for a uniform surface contamination to give 25 mrem/year was calculated using the default parameters of the NRC code DandD version 2.1.0. The resulting surface contamination value is:

	dpm/100cm2
Cr-51	5,208,333

Thus, an average uniform contamination in the lab of 5,000,000 dpm/100 cm^2 of Cr-51 would produce 25 mrem per year. Selecting an *a priori* safety factor of 100 for ALARA, the *a priori* ALARA target average surface contamination limit is:

50,000 dpm/100 cm^2 of Cr-51.

Radioactive Decay Calculation

The half life of Cr-51 is 27.8 days. The elapsed time since the last use of Cr-51 (March 2006) and the survey date (16 October 2008) is 945 days. This represents a decay time of more than 33 half lives.

The fraction of radioactivity remaining after 945 days is: 0.00000000012

Even if the maximum permissible amount of Cr-51 of 10 mCi were to have been in the Lab 145A in March 2006, the amount remaining at the time of this survey would be: 10 * 0.00000000012 = 0.0000000012 mCi. Converting this amount of radioactivity into dpm yields 2.7 dpm.

Thus, radioactive decay alone will assure the absence of any residual radioactivity.

Decommissioning Activities

The 16 October 2008 decommissioning consisted of a physical examination of Lab 145A and a careful survey for gamma dose rate with a Ludlum Model 3 survey meter with a Model 44-9 thin window Geiger pancake detector probe. This survey meter carries Medarex Equipment # E-5889 and was calibrated by Fluke Biomedical on 29 July 2008. The background dose rate with the survey meter was 0.015 mR/h.

Results

All potentially contaminated surfaces in the lab were scanned with the probe about 5 cm from the surface. The scan included lab equipment, furniture, countertops, shelves, biosafety cabinet and fume hood. In addition, specific items were scanned that were stored in the fume hood:

- Two pigs containing two vials of Cr -51 Sodium Chromate stock solution
- One 5 gallon pail containing miscellaneous items such as latex gloves, test tubes, plates etc.
- Three conical tubes containing between 30-50 mls of a liquid inside a plastic measuring flask
- Three small empty lead pigs
- Two lead lined stainless steel canisters

All readings were within the variation of background of the survey meter. It is estimated that a gross dose rate of three times background (3 x 0.015 = 0.045 mR/h) could have been detected.

Therefore, the maximum dose rate is reported as not detected and less than 0.03 mR/h above background.

Disposition of Remaining and Residual Radioactivity

There are no remaining radioactive materials and no residual radioactive contamination.

Conclusion

Lab 145A was surveyed showing that the room is well below the NRC contamination levels for release for unrestricted use and meets the requirements for ALARA. Lab 145A is released for other than radionuclide use without restriction.

Medarex
519 Route 173 West
Bloomsbury, NJ 08804

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