

Purdue Pharma L.P.

6 Cedarbrook Drive Cranbury, New Jersey 08512 609-409-5123 Fax# 609-409-5799

June 30, 2005

Attention: Betsy Ullrich Division of Nuclear Materials Safety U.S. Nuclear Regulatory Commission, Region I

475 Allendale Road

King of Prussia, PA 19406-1415

RE:

Mail Control # 136944 Docket #: 03005882

NRC License # 29-30698-01

Dear Ms. Ullrich:

On 12-21-04 Purdue requested Amendment No. 5 to License #29-30698-01. amendment was approved and an updated license was issued on 1-14-05 in accordance with letters dated 12-21-04 and 1-11-05.

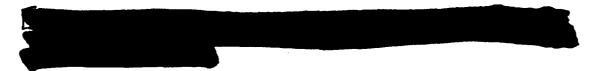
In approving Amendment No. 5, the NRC requested a Decommission Survey for the major "Authorized Use Areas" deleted from the license. The Decommission Survey was completed and the report submitted on 4-21-05. The NRC issued correspondence dated 6-10-05 in response to the 4-21-05 Decommission Report.

This letter and enclosures provide the additional information requested in the NRC correspondence dated 6-10-05 under Mail Control #136944.

la. In Purdue's license application dated November 19, 2001, Biology Labs and Vivarium space were outlined to illustrate potential locations for handling or storing licensed material. Licensed material was not handled in the entire outlined area, only Authorized Use Areas. The use of radioactive material in any area of the building requires prior notification to the RSO. Safety inspections and Radiation Safety Committee Meetings routinely verify that licensed material is only handled in Authorized Use Areas.

The Decommission Survey Report dated 4-21-05 includes data for B-113, B-117, B-119, B-123 and the Liquid Waste Storage Area (No room number assigned).

Survey data for B-104, B-107, B-132, B-141, B-202, B-206, Colony Rm. #2 and Procedure Rm. #4 are provided with this letter as enclosures. These areas were surveyed prior to the 12-21-04 Amendment Request and recorded in the site Decommission File.



Decommission survey data has now been provided for all decommissioned locations where licensed material was previously handled or stored.

- 2. Carbon-14 was used in a one-time experiment on the center bench in B-117. Carbon-14 was inadvertently omitted from Table 1 in the Decommission Survey Report dated 4-21-05. The surveys conducted are adequate for Carbon-14 clearance because: a) the MicroBeta Liquid Scintillation Counter used to analyze wipe samples was adjusted with the windows wide open which is the proper setting to detect Carbon-14, and b) the Carbon-14 release criteria value used in the survey was 5,000 dpm/100 cm2 which is well below the 158,000 dpm/100 cm² value cited in NUREG-1500. Therefore, the survey conducted in B-117 was of sufficient scope and sensitivity to detect Carbon-14 contamination.
- 3. The total square footage occupied in this facility was 110,000 ft². The total area where licensed material was used or stored was 2,327 ft².

Thank you in advance for your time and effort in this matter. Please do not hesitate to contact me at 609-409-5826 if you have any questions or need additional information.

Sincerely,

Mathew L. Swan, CIH, CSP

Director, Environment, Health & Safety

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Enclosures

Memorandum

To: Decommission File

From: Mathew Swan ma

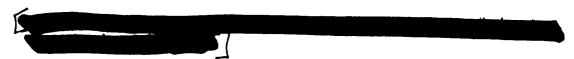
Date: 8/28/2002

Re: Room Decommissioning

(3-141)

Radioactive material was used at the Purdue Cranbury facility starting in April of 2002. At that time, the Storage Room adjacent to the Biology Loading Dock was designated as the Solid Radioactive Waste and Regulated Medical Waste Storage Room. In late August of 2002, this room was re-designated as an Isolation Room for the new Transgenic Vivarium. The room was officially decommissioned. and cleared for general use activities.

The Storage Room was officially cleared for general use based on handheld meter and wipe sampling results. Attached are a Survey Form, Sampling Map and a LSC printout. This memo and attached sampling results officially documents the decommissioning of the Solid Radioactive Waste and Regulated Medical Waste Storage Room adjacent to the Biology Loading Dock.





RADIATION SAFETY MANUAL

SECTION 6 / VERSION 3.0 (APRIL 2002)

LOCATION: Cranbury NJ

APPENDIX E: AREA SURVEY FORM

Page 1 of 2

Lab Name:	Rudioacque Wase Stage	Sample Blank:	#'s 11-24 on prison
Lab Number:	8-141	% Efficiency:	
Survey Date:	8/22/02	Instrument:	Wallac Micro Beper

SAMPLE LOCATION / DESCRIPTION (location map on pg. 2)	СРМ	DPM
1 See Map		1
2	See pr	ntout
3		
4		
5		
6	V	
COMMENTS Room was decommissioned	d to a	aldor
for renovations.		

Performed By:	Suit Penneylem	8/22/02
Reviewed By:	no h	8/02/02

DRAFT FOR REVIEW

Page 9

DRAFT FOR REVIEW

Date Printed: 4/9/2002



RADIATION SAFETY MANUAL

SECTION 6 / VERSION 3.0 (APRIL 2002)

LOCATION: Cranbury NJ

APPENDIX E: AREA SURVEY FORM Page 2 of 2

Lab Name:	Dry Redrocope Wask	Lab Number:
Survey Date:	18/20/02	
	SAMPLE I	LOCATION MAP
l	(4 4
} '		5 5
3 -	3	6 6
	10 10	dowbrob 7 Shelf I Hallmay

Date Printed: 4/9/2002

c:\data\cranbury lab surveys\A13_016.txt

RUN INFORMATION:

========

2: 277.4 CCPM

Counting protocol no: 13
Name: LAB_SURVEYS_H-3_S-35_I-125
DPM standardization protocol no: -

Thu 22-Aug-2002 12:23

======	==								
	SAMPLE	POS	CPM1	DPM1	CPM2	DPM2	СРМЗ	FLAG	Dry Waste Run See map
	Unk_1	A01	4	0	7	0	13		Dry Waste Nu
	Unk 2	A02	1	0	13	0	17		• (
	Unk_3	A03	1	0	4	Ö	12		_
	Unk_4	A04	6	0	25	0	76		(pe man
	Unk 5	A05	3	0	4	Ó	14		30- 1
	Unk 6	A06	19	Ō	15	Ŏ	12	-	
	Unk_7	B01	2	0	9	Ō	7		
	Unk_8	B02	3	0	13	Ō	15		
	Unk_9	B03	0	0	10	Ō	13		
	Unk 10	B04	2	0	12	Δ	19		_
	Onk_11	805	1	0	6	0	6		_ ,
	Unk_12	B 06	4	0	9	0	7	. 1	~~ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
	Unk_13	C01	3	0	7	0	3		Blesol Whees
	Unk_14	C02	5	0	19	0	6	. 1	• •
	Unk_15	C03	2	0	8	0	8		wha
	Unk_16	C04	2	0	13	0	10		4,
	Unk_17	C05	0	0	12	0	15	. ᄉ	
	Unk_18	C06	0	0	12	0	9	V	
	Unk_19	D01	2	0	14	0	14		
	Unk_20	D02	1	0	11	0	12		
	Unk_21	D03	40	0	28	0	9		
	Unk_22	D04	1	0	8	0	14		
	Unk_23	D05	2	0	12	0	13		
	Unk_24	D06	2	0	6	0	9		
Total cou	unt rate 1:	106.2	CCPM						

Wallac Oy 1450 MicroBeta

ONG

Memorandum

To: Decommission File

From: Mathew Swan 🥕 2

Date: 11/21/2002

Re: Room Decommissioning

(B-132)

Radioactive material was used at the Purdue Cranbury facility starting in April of 2002. At that time, a Liquid Radioactive Waste Room was established adjacent to the glass washing room. In early November of 2002, this room was identified as necessary for support of building renovations. The room was officially decommissioned and cleared for general use activities.

The Liquid Radioactive Waste Room was officially cleared based on handheld meter and wipe sampling results. Attached are a Survey Form, Sampling Map and a LSC printout. This memo and attached sampling results officially documents the decommissioning of the Liquid Radioactive Waste Room.

Page 1 of 2

Lab Name:	Liquid waste storage	Sample Blank:	2 to 4 cpm	
Lab Number:	ab Number: N/A B-132		50	
Survey Date:	11/1/02	Instrument:	Wallac MicroBeta	

SAN	IPLE LOCATION / DESCRIPTION (location map on pg. 2)	СРМ	DPM
1	Floor	2	<mda< th=""></mda<>
2	Floor	1	<mda< td=""></mda<>
3	Floor	0	<mda< td=""></mda<>
4	Sink	3	<mda< td=""></mda<>
5	Shelf	2	<mda< td=""></mda<>
6	Shelf	4	<mda< td=""></mda<>
7	Floor	0	<mda< td=""></mda<>

COMMENTS

Decommissioning survey, this room will no longer be used for radioactive waste storage. There were \underline{no} liquid waste discharges via the sink in this room.

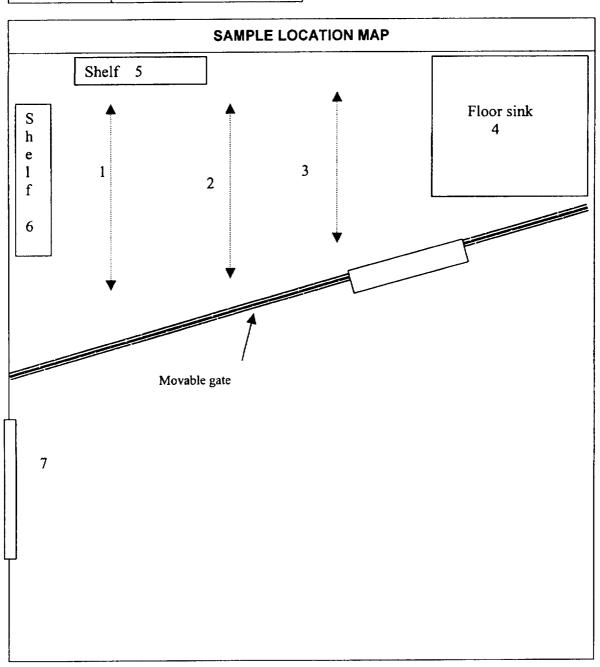
Performed By: Scott Dennerlein, SD&A, LLC

Reviewed By:

2 Swan

Page 2 of 2

Lab Name:	Liquid waste storage	Lab Number:	N/A	B-132
Survey Date:	11/1/02			



DPM standardization protocol no: -

c:\data\cranbury lab surveys\A13_028.txt

RUN INFORMATION:

Counting protocol no: 13 Name: LAB_SURVEYS_H-3_S-35_I-125 Fri 1-Nov-2002 12:40

Liquid Wasse Ru Decom.

COLUMNS:

=======								
	SAMPLE	POS	CPM1	DPM1	CPM2	DPM2	CPM3	FLAG
	Unk_1	A01	2	0	11	0	14	
	Unk_2	A02	1	0	6	0	17	•
	Unk_3	A03	0	0	11	0	11	
	Unk_4	A04	3	0	1 1	0	13	Wipes
	Unk 5	A05	2	0	17	0	28	44.6
	Unk 6	A06	4	0	6	0	18	•
	Unk 7	B01	0	0	6	0	14	
	Unk 8	802	2	0	10	0	5	
	Unk 9	B03	0	0	9	0	9	
	Unk_10	B04	4	0	17	0	13	Buckground
	Unk 11	B05	4	0	12	0	17	Buckground
	Unk 12	B06	0	0	9	0	16	
	Unk_13	C01	2	0	16	0	15_	•
	Uni 14	C02	0	0	10	0 _	14	•
	Unk_15~	C03	0	0	12	0	12	•
	Unk_16	C04	1	0	12	0	11	
	Unk_17	C05	5	0	22	0	16	Emory
	Unk_18	C06	>	0 /	5	0	10	1.7
	Unk_19	D01	2	مسو	12	0	12	welk
	Unk_20	D02	1	8	8	0	10	
	Unk_21	D03 _	45	0	29	D	53	•
	Unk_22	DO	0	0	₹5	0	13	
	Unk_23	D05	4	0	9	0	10	•
	11mk_24	D06	1	0	6	7	10	
Total cou	unt rate 1:	55.1 C	CPM				_	
	2: 28	1.3 CCPM						

Memorandum

To: Decommission File

From: Mathew Swan 2n-2.

Date: December 2003

Re: Room Decommissioning – Lab B-107

Radioactive material was used at the Purdue Cranbury facility starting in April of 2002. Radioactive material was used in B-107 starting in July 2002. By December 2003, no further use of radioactive material was scheduled for this laboratory.

Lab B-107 was officially cleared for general use based on handheld meter and wipe sampling results. Attached are a Survey Form, Sampling Map and a LSC printout. This memo and attached sampling results officially documents the decommissioning of Lab B-107.

Page 1 of 2

Lab Name / #:	B-107	Sample Blank:	×- 2	27
Performed By:	5 Dennerlein	% Efficiency:		50%
Survey Date:		Instrument:		
Radioactive Mate	erial Containers Labeled?	Removed	Yes	No
Waste Inventory	is Logged and Maintained?	N/A	Yes	No
Radiation Meters	Available and Operational	? <i>N/</i> A	Yes	No

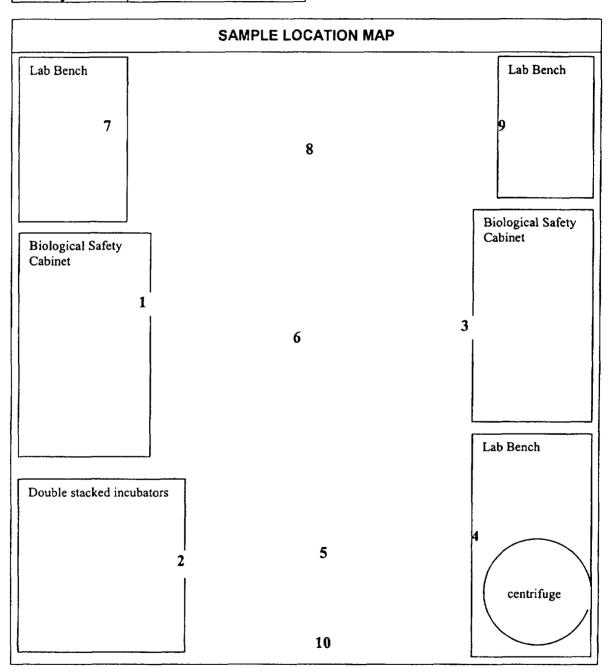
SAMPLE LOCATION / DESCRIPTION (location map on pg. 2)	СРМ	Net CPM	DPM
1 See Mup	23	-4	2 MDA
2	27	Ó	
3	26	-1	
4	26	-1	
5	10	-17	
6	21	 	
7	20		
8	24	-7	
9	31	3	
10	25	- 2	
11\	47	- 0	
12		-	
13	+		
14	-		
15			
16			
17			
18			\
19			
20 /			
rad material removed	survey -	All was	ie and
rud material removed	from art	o poice 1	D SULVEY.

Net CPM = CPM - Average Sample Blank DPM = Net CPM divided by 0.5 <u>Note:</u> 1)

2)

Page 2 of 2

Lab Name:	Isolation Lab	Lab Number:	B-107	
Survey Date:	12/11/03			



c:\data\3h-swipes\A17_004.txt

RUN INFORMATION:

Counting protocol no: 17 Name: PACKAGE_AREA_SURVEYS

CPM normalization protocol no: -

Thu 11-Dec-2003 13:50

*** DETECTORS NOT NORMALIZED

COLUMNS	,
======	

SAMPLE	POS	CCPM1
Unk_1	AG1	23
Unk_2	A02	27
Unk_3	A03	26
Unk 4	A04	26
Unk_5	A05	10
Unk_6	A06	21
Unk_7	B01	20
Unk_8	802	24
Unk_9	B03	21
Unk_10_	B04	25
Unk_11	B05	49 \
Unk_12	B06	25 \
Unk_13	C01	25 \
Unk_14	C02	20 \
Unk_15	C03	29 \
Unk_16	C04	22
Unk_17	C05	24
Unk_18	C06	23 /
Unk_19	D01	26 /
Unk_20	D02	29 /
Unk_21	D03	23 /
Unk_22	D04	26 /
Unk [23	D05	22 '
Unk_24	D06	18
Total count rate:	584.6 CCI	РМ

X = 27 $L_C = 2.33\sqrt{27} - 2.33(52) = 12$

584.6 CCPM

Critical level

27+12 = 39

Memorandum

To:

Decommission File

From:

Mathew Swan M.

Date:

August 2004

Re:

Decommission File - Program Update

Radioactive material was used at the Purdue Cranbury facility starting in April of 2002. To date, there have been four memos pertaining to site decommission activities. This fifth memo dated 8/30/04, is intended to document site changes and to update site authorized use areas.

Decommission Activities Review

Previous site decommission activities include the following:

1.	August 2002	Solid Radioactive Waste Storage Room
2.	September 2002	Vivarium Procedure Room #4
3.	November 2002	Liquid Radioactive Waste Storage Room
4.	Quarter 4, 2003	B-107 Tissue Culture Room

Current Decommission Activities

The site business climate changed significantly in the summer of 2004. The site business changes dictated changes in the use of radioactive material on site. The site changes are summarized below:

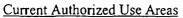
- 1. The Immunotherapeutics Department was discontinued which affected a major portion of the radioactive material use on site.
- 2. Without the Immunotherapeutics Department, radioactive material was no longer used in the Vivarium.
- 3. The Molecular Biology Department moved from the second floor to the first floor lab space vacated by the Immunotherapeutics Department. Radioactive material was no longer used on the second floor.

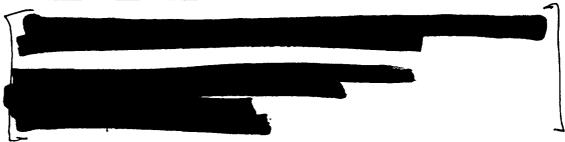
Site decommission activities associated with the site changes in the summer of 2004 described above include the following:

1. Decommission second floor authorized use areas (B-202, B-206)

- 2. Decommission Vivarium use areas (Colony Rm. #2, Procedure Rm. #4)
- 3. Decommission B-104 use area

Enclosed with this memo are copies of the lab diagrams, sample locations and analysis results print out. Areas B-202, B-206, Vivarium Colony Rm. 2, Vivarium Procedure Rm. 4 and B-104 were cleared for general use activities.





Beta Plate Counter Wipe Identification Log

Location: Vivarium Colony Rm 2

Loaded By: S. Dennerlein

Count Date <u>7/22/04</u>

Sample Type:

Wipes

Liquids____

Sample Location #	Analysis Results
(See Map)	(See Micro Beta Printout)
1-8	Floor (1-8)
9	Sink (9)
10-12	Refrigerator (inside and out) (10-12)
13 - 20	Cage rack (13-20)
21 - 26	Biosafety cabinet (21-26)
27 - 32	Biosafety cabinet (27-32)
	Background wipes (33-48)
,,,,,,	
· · · · · · · · · · · · · · · · · · ·	

Comments

Decommissioning survey, dry paper wipes of 100 cm² surface area. The average background is 44 cpm. The Critical Level is 59 cpm. There were no wipes above the critical level. This counter log identifies the wipes on the attached Package/Area Survey printout.

APPENDIX E: AREA SURVEY FORM Page 2 of 2

Lab Name:	Vivarium Colony Rm. 2	Lab Number:	SAME	
Survey Date:	7/22/04			
	SAMPLE LO	OCATION MAP		
Bio safety cabinet 21 - 26	8	7		Bio safety cabinet
13- 20	Cage rack	·	5	
	4		3	·
Refrig 10 - 12	3			
	Sink		1	••••••

9

Beta Plate Counter Wipe Identification Log

Location:	vivarium Procedure Km. 4	

Loaded By: S. Dennerlein

Count Date <u>7/22/04</u>

Sample Type:

Wipes

Liquids____

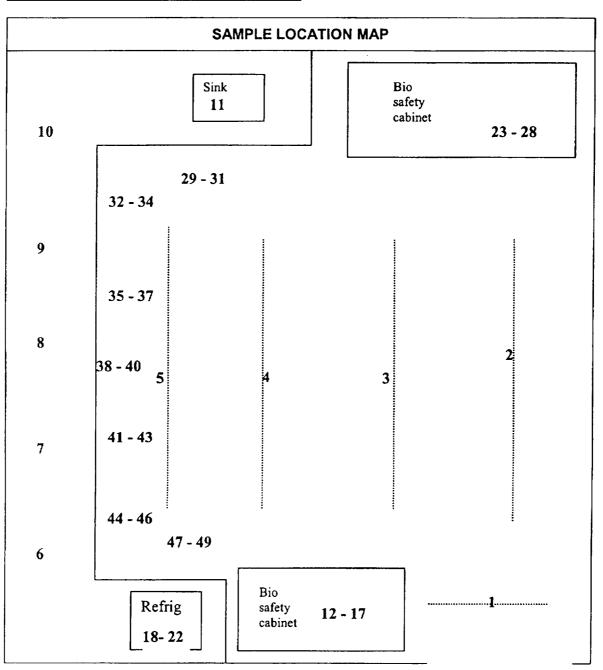
Sample Location #	Analysis Results
(See Map)	(See Micro Beta Printout)
1-5	Floor (49 – 53)
6 - 10	Benchtop (54 – 58)
11	Sink (59)
12 - 17	Biosafety cabinet (60 – 65)
18-22	Refrigerator (inside and out) (66 - 70)
23 - 28	Biosafety cabinet (71 – 76)
29 - 49	Drawers (77 – 97)
	Background wipes (33 – 48)

Comments

Decommissioning survey, dry paper wipes of 100 cm² surface area. The average background is 44 cpm. The Critical Level is 59 cpm. There were no wipes above the critical level. This counter log identifies the wipes on the attached Package/Area Survey printout.

Page 2 of 2

Lab Name:	Vivarium Procedure Rm. 4	Lab Number:	SAME
Survey Date:	7/22/04		



Beta Plate Counter Wipe Identification Log

|--|

Loaded By: S. Dennerlein

Count Date 7/22/04

Sample Type:

Wipes

Liquids

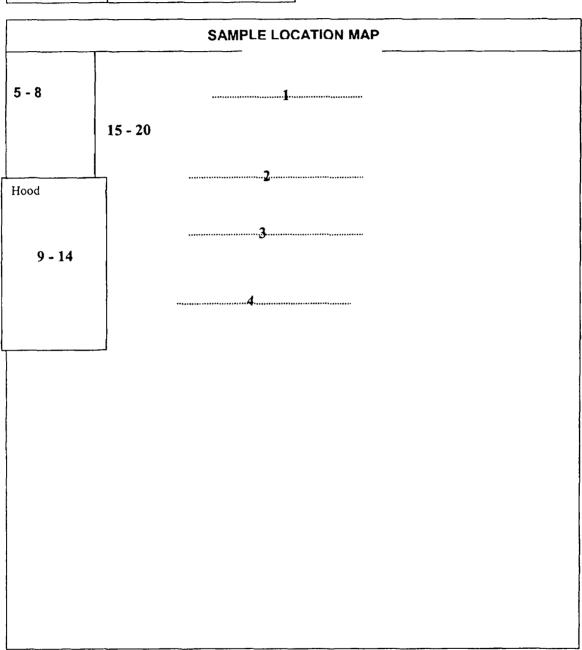
Sample Location #	Analysis Results
(See Map)	(See Micro Beta Printout)
1-4	Floor (111-114)
5 - 8	Bench top (115-118)
9-14	Hood (119-124)
15 - 20	Drawers (125-130)
	Background wipes (33-48)
	

Comments

Decommissioning survey, dry paper wipes of 100 cm² surface area. The average background is 44 cpm. The Critical Level is 59 cpm. There were no wipes above the critical level. This counter log identifies the wipes on the attached Package/Area Survey printout.

Page 2 of 2

Lab Name:	Immuno Lab	Lab Number:	B-104
Survey	7/22/04		
Date:			



c:\data\3h-swipes\A17_080 txt

RUN INFORMATION

Counting protocol no: 17

Name: PACKAGE_AREA_SURVEYS CPM normalization protocol no: -

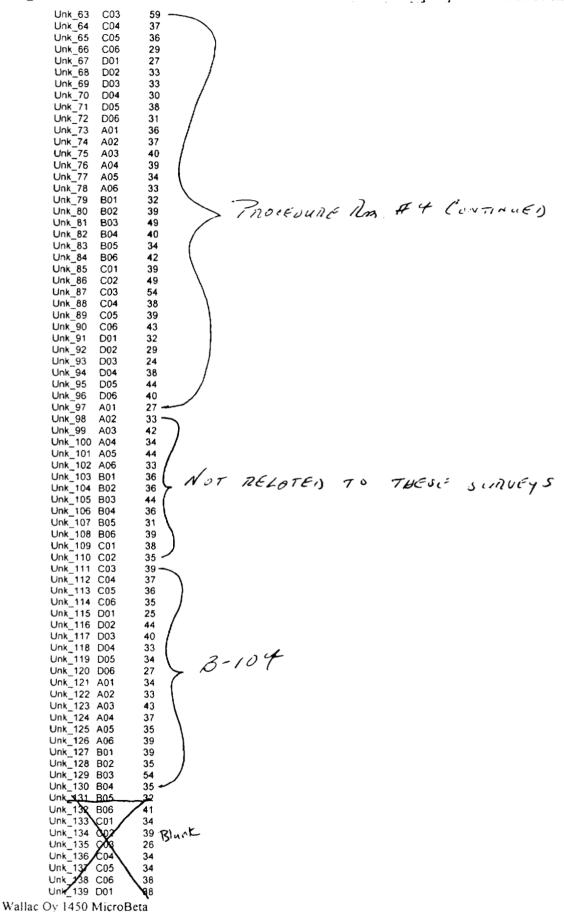
Thu 22-Jul-2004 11:07

*** DETECTORS NOT NORMALIZED

COLUMNS:

=======

```
SAMPLE POS
                          CCPM1
        Unk_1
                 A01
                          50
        Unk_2
                 A02
                          28
        Unk 3
                 A03
        Unk_4
                          57
                 A04
                          37
        Unk_5
                 A05
        Unk_6
                 A06
                          31
        Unk_7
                 B01
                          35
        Unk_8
                 802
                          36
        Unk_9
                 B03
                          37
        Unk_10
                          32
                 B04
        Unk_11
                 805
                          29
        Unk_12
Unk_13
                 B06
                          47
                          33
                 C01
                          31
        Unk_14
                 C02
        Unk_15
                 C03
                          49
        Unk_16
                 C04
                          36
                                   COLONY Rm. #2
        Unk_17
                          27
                 C05
        Unk_18
                 C06
                          34
        Unk_19
                 D01
                          46
        Unk_20
Unk_21
                          41
                 D02
                 D03
                          34
        Unk_22
                          39
                 D04
        Unk_23
                 D05
                          46
        Unk_24
                 D06
        Unk_25
Unk_26
                 A01
                          33
                 A02
                          44
        Unk_27
                 A03
                          35
        Unk_28
Unk_29
                 A04
                          47
                 A05
                          39
        Unk_30
                 A06
                          50
        Unk_31
                 B01
                          39
        Unk_32
                 B02
                          28
        Unk_33
Unk_34
Unk_35
Unk_36
                 B03
                          47
                 B04
                          34
                 B05
                          33
                 B06
                          30
        Unk_37
Unk_38
Unk_39
                 C01
                          41
                 C02
                          39
                          42
                 C03
                                    GEHERRL BRCKGROUND
        Unk_40
Unk_41
                          33
                 C04
                 C05
                          37
        Unk_42
                 C06
                          29
        Unk_43
                 D01
                          38
        Unk_44
                          34
                 D02
        Unk_45
                          34
                 D03
                          27
        Unk_46
                 D04
        Unk_47
                          32
                 D05
        Unk_48
Unk_49
                 D06
                          38
                 A01
                          25
        Unk_50
                 A02
                          49
        Unk_51
Unk_52
                          34
                 A03
                          32
                 A04
        Unk_53
                 A05
                          42
        Unk_54
                 A06
                          27
                                  PROVESURE RM #4
        Unk_55
                 B01
                          38
        Unk_56
Unk_57
Unk_58
                 B02
                          44
                          41
                 B03
                 B04
                          51
        Unk_59
                 B05
                          40
        Unk_60
                          41
                 B06
                 C01
                          42
        Unk_61
        Unk_62
                 C02
                          52
Wallac Oy 1450 MicroBeta
```



Beta Plate Counter Wipe Identification Log

Location: **B202, B206**

Loaded By: S. Dennerlein

Count Date 8/19/04

Sample Type:

Wipes_

Liquids____

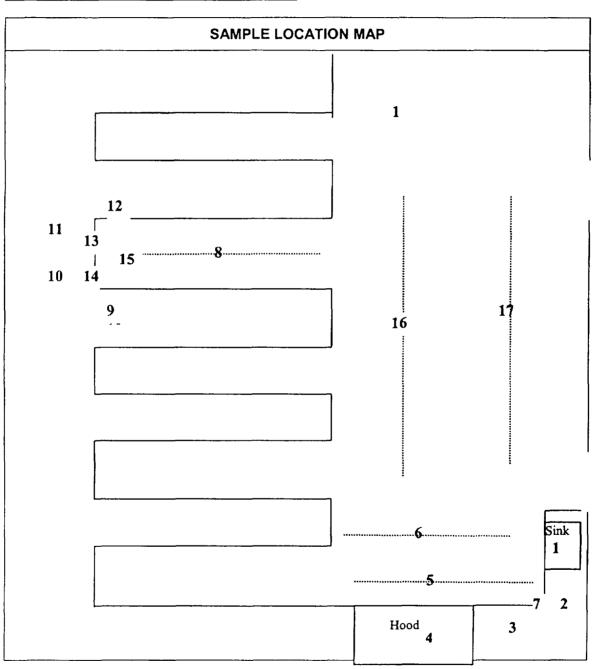
Sample Location #	Analysis Results
(See Map)	(See Micro Beta Printout)
1-17	B-202, Sink, bench, hood, floor (1-17)
18-19	Background wipes (18-19)
1-5	B-206, Bench top, floor (20-24)
i	
i	

Comments

Decommissioning survey, dry paper wipes of 100 cm² surface area. The average background is 43 cpm. The Critical Level is 50 cpm. There were no wipes above the critical level. This counter log identifies the wipes on the attached Package/Area Survey printout.

APPENDIX E: AREA SURVEY FORM Page 2 of 2

Lab Name:	Molec Bio, Center and End Bay, 2 nd Floor	Lab Number:	B-202
Survey Date	8/19/04		



Page 2 of 2

Lab Name:	Molec Bio, Instrument Lab, 2 nd Floor	Lab Number:	B-206	
Survey Date	8/19/04			
SAMPLE LOCATION MAP				
1 LSC 3				
	5			

Package/Area Surveys (17)

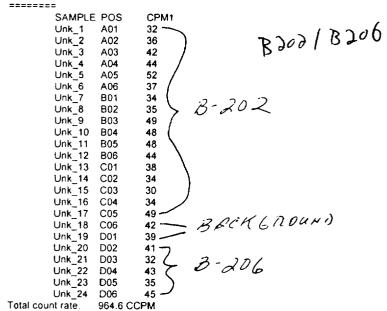
c:\data\3h-swipes\A17_088.txt

RUN INFORMATION

Counting protocol no: 17 Name: PACKAGE_AREA_SURVEYS CPM normalization protocol no: - Thu 19-Aug-2004 12:23

*** DETECTORS NOT NORMALIZED

COLUMNS:



Beta Plate Counter Wipe Identification Log

Location: B112

Loaded By: S. Dennerlein

Count Date <u>6/28/05</u>

Sample Type:

Wipes _

Liquids____

Sample #	Description		
1-8	floor		
9 - 10	shelves		
11-16	walls		
17 - 24	Background wipes		

Comments

Decommissioning survey, dry paper wipes of 100 cm² surface area. The average background is 39 cpm. The Critical Level is 56 cpm. There were no area wipes above the critical level. This counter log identifies the wipes on the attached Package/Area Survey printout. Dose rate measurements were at background level. All direct readings with pancake probe at background level

c:\data\3h-swipes\A17_002.txt

RUN INFORMATION:

--------Counting protocol no: 17

Name: PACKAGE_AREA_SURVEYS

CPM normalization protocol no: -

Tue 28-Jun-2005 10:51

Room 2-112

*** DETECTORS NOT NORMALIZED

COLUMNS:

======= SAMPLE POS CPM1 Unk_1 A01 39 -Unk_2 A02 33 Unk_3 A03 Unk_4 Unk_5 Unk_6 A04 39 A05 39 A06 37 Unk_6 Unk_7 Unk_8 Unk_9 Unk_10 Unk_11 Unk_12 Unk_13 Unk_14 Unk_15 Unk_16 B01 46 B02 43 B03 54 **B**04 36 B05 50 B06 40 C01 36 C02 43 C03 33 C04 28 -Unk_17 Unk_18 Unk_19 Unk_20 Unk_21 Unk_21 C05 36 C06 40 D01 61 BECKEROUND 30 40 D02 D03 37 D04 Unk_23 D05 30 Unk_24 D06 36 Total count rate: 940.1 CCPM 30 36 =