

Aastrom

July 16, 2007

Ms Cassandra F. Frazier
U.S. Nuclear Regulatory Commission
Region III
Materials Licensing Branch
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352
Phone: 630-829-9839
Fax: 630-515-1259

NRC Materials License No. 21-26519-01 (Amendment No.12)
Docket No. 030-33266

Dear Ms Frazier,

An amendment of NRC Materials License No. 21-26519-01 (Amendment No.12) is requested to enable Aastrom Biosciences to vacate and decommission laboratory space located within the licensee's facilities at 24 Frank Lloyd Wright Drive, Domino's Farms, Lobby L while transferring activities to adjacent new laboratory space located across the hallway between Lobby L and Lobby K at the same address.

A Report on the Final Radiological Status of Areas Being Vacated is attached. This survey was performed by Radiation Safety Associates, Inc., Hebron, Connecticut as required for decommissioning of the old laboratory space. We request that the identified areas be released for free use after review by the Nuclear Regulatory Commission.

All activities with licensed material currently have ceased pending approval of the decommissioning process and completion of amendments to enable re-initiation of activities in the new laboratory space in accordance with NRC regulations. A point-by-point list of proposed amendments to the license to enable resumption of activities in the new laboratory space is attached. The basement storage area which is listed as a radioisotope storage area on the current license is retained and will not change.

Please contact me if additional information is required.

Sincerely,



Douglas M. Smith, Ph.D.
Principal Research Scientist
Radiation Safety Officer
Telephone: 734-930-5789
E-Mail: dsmith@aastrom.com

RECEIVED JUL 20 2007

List of proposed changes under the current amendment:

-Line 10 of the Materials License should be changed from Lobby L to Lobby K. The Company address remains the same.

-A blueprint and floor plan of new laboratory space with proposed areas for licensed materials use is attached.

-This entire area consists of a total of 30,000 square feet (sq. ft.) of space (Figure 1). All doors are secure with access only for authorized personnel as shown on the blueprint.

-The Research Laboratory area is approximately 3700 sq. ft. (Figure 2).

-The Radioisotope laboratory (200 sq. ft.) is a secure and locked area within the Research laboratory space with limited access by authorized laboratory personnel (Figure 2). Source material obtained from commercial vendors will be stored in a locked 4°C refrigerator within this radioisotope laboratory as indicated on the floor plan. Nearly all radioisotope work will be carried out in this locked Radioisotope laboratory. This secure room contains a sink, bench space, liquid scintillation counter, 37°C incubators and biological hood space. An additional equipment area with -20°C and -80°C freezers and other equipment is located immediately adjacent to the radioisotope laboratory. Infrequently, additional bench space may be required in the main research lab as shown on the blueprint.

-The Company now employs approximately 65 individuals of whom only 5 are authorized users as indicated on the materials license.

-The office and laboratory space remain located on the second floor (ground level) while waste storage also remains in the secure room located on the first floor (basement). Use of the basement storage room will remain the same and will not change on the current amendment.

-With exception of the proposed new laboratory space, all operations will be conducted exactly as currently described in the Materials License and the Radiation Safety Manual (Attachment D - License application dated September 9, 2003).

-We respectfully request expedited review, if possible, as all research experiments and activities utilizing radioisotopes have been halted pending approval of the proposed amendments.

Figure 1

Aastron Biosciences, Inc.
24 Frank Lloyd Wright Dr.

New Research
Lab

Equipment area

Radioisotope Lab

←
OLD
RESEARCH
LAB
(Refer to
decommissioning
report)

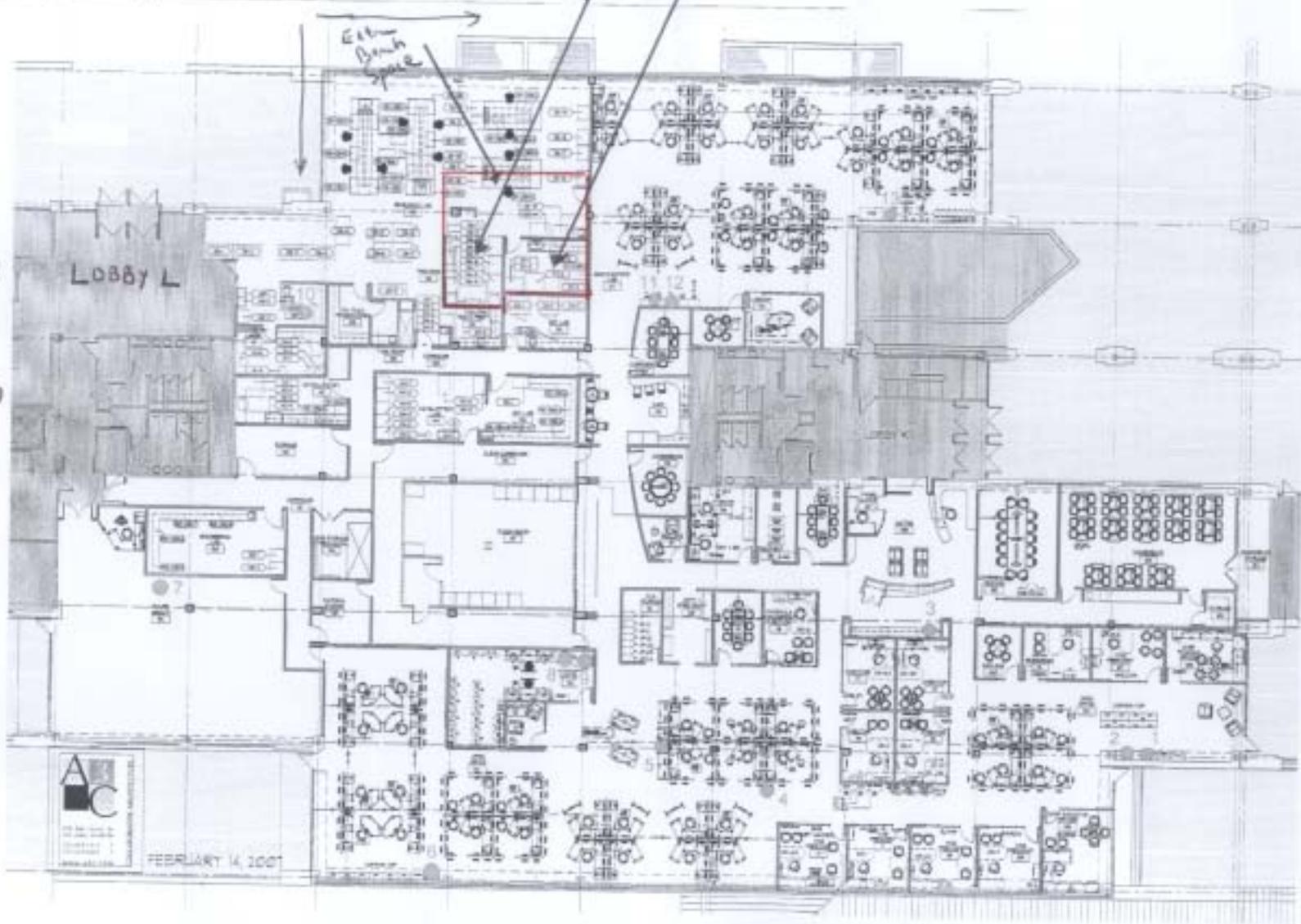
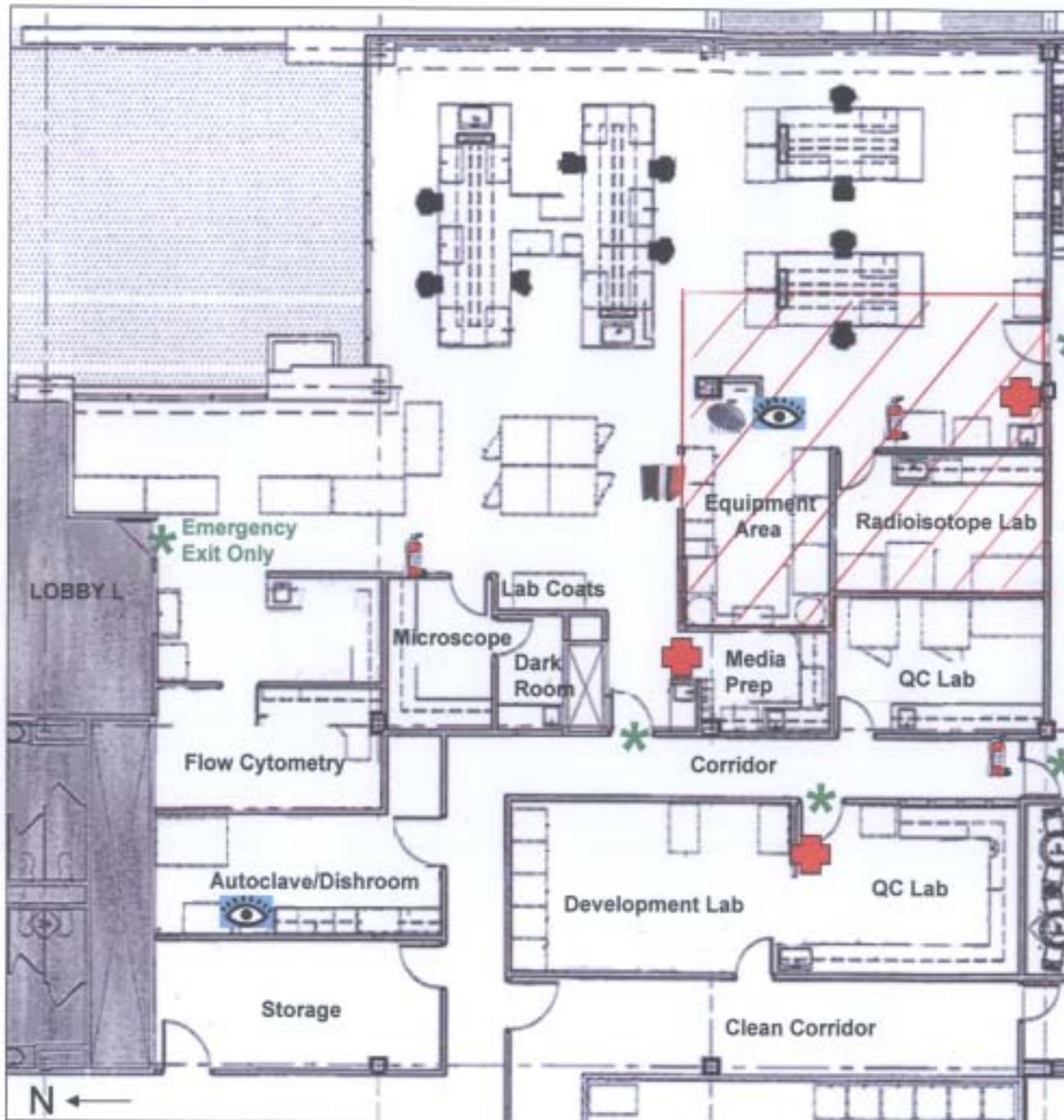


Figure 2

Aastrom
New Research Laboratory



Radioisotope use
area
(Approximately 750 ft²)



- First Aid Supplies
- Eye Wash
- Safety Shower
- Bookshelf: SOPs, MSDS
- Fire Extinguisher
- Entrance/Exit

N ←

**Report on the
Final Radiological Status
Of Areas Being Vacated by
Aastrom Biosciences, Inc.**
24 Frank Lloyd Wright Drive
Domino's Farms Lobby L
Ann Arbor, Michigan

**U.S. Nuclear Regulatory Commission Materials License
21-26519-01 Amendment 12**

Report Date
May 29, 2007

Performed by
Radiation Safety Associates, Inc.
19 Pendleton Drive, PO Box 107
Hebron, Connecticut 06248
(860) 228-0487 Fax (860) 228-4402 www.radpro.com

1.0 BACKGROUND INFORMATION

1.1 General

The subject of this report is Aastrom Biosciences, Inc. (Aastrom), 24 Frank Lloyd Wright Drive, Domino's Farms Lobby L, Ann Arbor, Michigan. Aastrom is licensed by the U.S. Nuclear Regulatory Commission (Materials License 21-26519-01 Amendment 12). It is moving its operation from this space to newer quarters in the same building that better suit its needs.

Prior to this survey, nearly all of the equipment had been moved out of the Gene Therapy Lab (the Restricted Area). The few remaining components were wiped and, if uncontaminated, moved to Aastrom's new laboratory space. Radioactive material, or equipment that might be internally contaminated, was moved to a basement storage area that is currently listed as a use location on the license.

For purposes of this survey the entire space was divided into two (2) survey units. The Gene Therapy Lab and the Darkroom were Restricted Areas and together comprised approximately 414 ft². These combined were considered to be a MARSSIM Class 1 area. The remainder of the Aastrom space was considered a MARSSIM Class 2 area. A drawing of this facility is contained in Attachment A. The surveys were performed on May 16 and 17, 2007.

1.2 Scope of Work

The decommissioning survey of this facility was done according to the guidance in NUREG-1757, Volume 1, Section 8, entitled Group 1 Decommissioning with no decommissioning plan required. This consisted of the following measurements and samples:

- One hundred percent scanning of all surfaces in the Gene Therapy Lab and Darkroom (the Restricted Area), using a gas proportional radiation detector (see Appendix B for information on detection sensitivities);
- Fifty scan survey of all surfaces in the areas outside the Restricted Area;
- Evaluations for total and removable radioactive material at each location exhibiting elevated radiation levels during the scan survey, or at a minimum of one wipe comprising 100 cm² per 300 ft²;
- Wipe samples inside sink drains and traps, ventilation return grilles, and other places that were likely to be contaminated.

2.0 POTENTIAL CONTAMINANTS AND RELEASE CRITERIA

2.1 Potential Contaminants

This license is permitted to possess the following radioisotopes:

- Tritium (³H), t_{1/2} = 12.3y;
- Chromium-51 (⁵¹Cr), t_{1/2} = 27.7 d

- Phosphorus-32 and -33 (^{32}P and ^{33}P), $t_{1/2} = 14.28$ d and 25.3 d respectively; and
- Sulfur-35 (^{35}S), $t_{1/2} = 87.2$ d.

2.2 Release Criteria

The limits used for release of this facility were 2000 dpm/100 cm² total contamination and 200 dpm/100 cm² removable contamination.

3.0 SURVEY INSTRUMENTATION

3.1 Direct Measurements and Scans

Attachment B lists the instruments used in performing the scan and direct surveys. All instruments used had been calibrated within the previous six months using NIST-traceable standards. Calibration certificates and MDA calculations are included in Attachment B. Operational and background checks were performed on these instruments daily. For purposes of calculating detection sensitivity of beta-detecting instruments, the efficiency for ^{35}S was used.

3.2 Wipe Sample Analysis

Wipe samples were counted using Aastrom's liquid scintillation analyzer.

4.0 FINAL STATUS SURVEY PROCEDURES

4.1 Wipe Surveys

4.1.1 Floors, Countertops, Shelves, Drawers and Cabinets

Representative wipe samples of floors, countertops, shelves, drawers, sink interiors and the like were taken using Whatman Number 2 absorbent paper circles, and rubbing them over approximately 100cm² of the surface to be surveyed using moderate pressure.

4.1.2 Sink Drains and Traps

Each sink drain (Restricted Area and Unrestricted Area) were sampled using cotton-tipped wooden applicators and liberally rubbing all accessible interior surfaces.

4.1.3 Floor Drains

There were no floor drains in this facility.

4.1.4 Ventilation Returns

There were five return grills in this facility.

4.2 Surface Scans

Direct scanning of surfaces was performed to identify locations of residual surface and near-surface contamination. Scan surveys were performed on all accessible surfaces in the restricted areas, including floors, countertops, shelves, drawers and walls. Scan surveys were accomplished by maintaining the radiation detector at a distance of approximately 1 cm from the surface being evaluated, and by moving the detector at a velocity that did not exceed one detector-width per second. The audible indicators were used to help identify locations having elevated levels of direct radiation. Scans were performed using the Ludlum Model 43-68 with the Model 2224-1 (sensitive to beta radiation), and the Ludlum 44-17 with the Model 3 (sensitive to low-energy photon radiation).

4.2.1 Background Level Determinations

Background count rates were determined by taking measurements on surfaces similar to those to be assessed but unlikely to be contaminated. Background readings are recorded in Attachment B.

4.2.2 Data Reporting and Interpretation

Values reported were adjusted for contributions from background.

5.0 SURVEY FINDINGS

5.1 Wipe Survey Results

Attachment D to this report contains all the wipe survey locations and the results of the wipe analyses. These locations included sinks and sink drains, air vents, drawers and other fixtures and equipment that may have become contaminated during licensed material use. No removable contamination was detected. Wipe test results are reported in units of dpm/100cm² for comparison with the release criteria.

5.2 Direct Contamination Survey Results

No evidence of residual contamination was found during the direct scan survey. Therefore direct measurements were made in areas considered to be most likely to have been contaminated.

5.3 Direct Gamma Radiation Survey

Since Aastrom is not licensed for any significant photon-emitting radioisotopes, no photon exposure rate measurements were made at a distance of one meter above surfaces.

It was determined that no renovations have occurred during Aastrom's occupancy of these spaces where potentially contaminated areas might have become inaccessible under current conditions.

6.0 FINAL DISPOSITION OF LICENSED MATERIAL

All licensed material was transported to Aastrom's basement storage area awaiting a license amendment to add the new laboratory space to the license. There was no radioactive waste in the laboratory at the time this survey was done, and no radioactive waste was produced during this survey. When this survey concluded there was no licensed radioactive material remaining in the spaces that were abandoned by Aastrom.

7.0 SUMMARY OF FINAL RADIOLOGICAL CONDITIONS

On the date that the final radiological status surveys were completed, there was no detectable residual licensed radioactive material remaining at this facility. Therefore the requirements that radiation from residual licensed radioactive material at this facility must result in a TEDE to an average member of the critical group of less than 10 mrem per year, and that the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA), have been met.

K. Paul Steinmeyer, RRPT
Senior Health Physicist
Radiation Safety Associates, Inc.

Date

LIST OF ATTACHMENTS

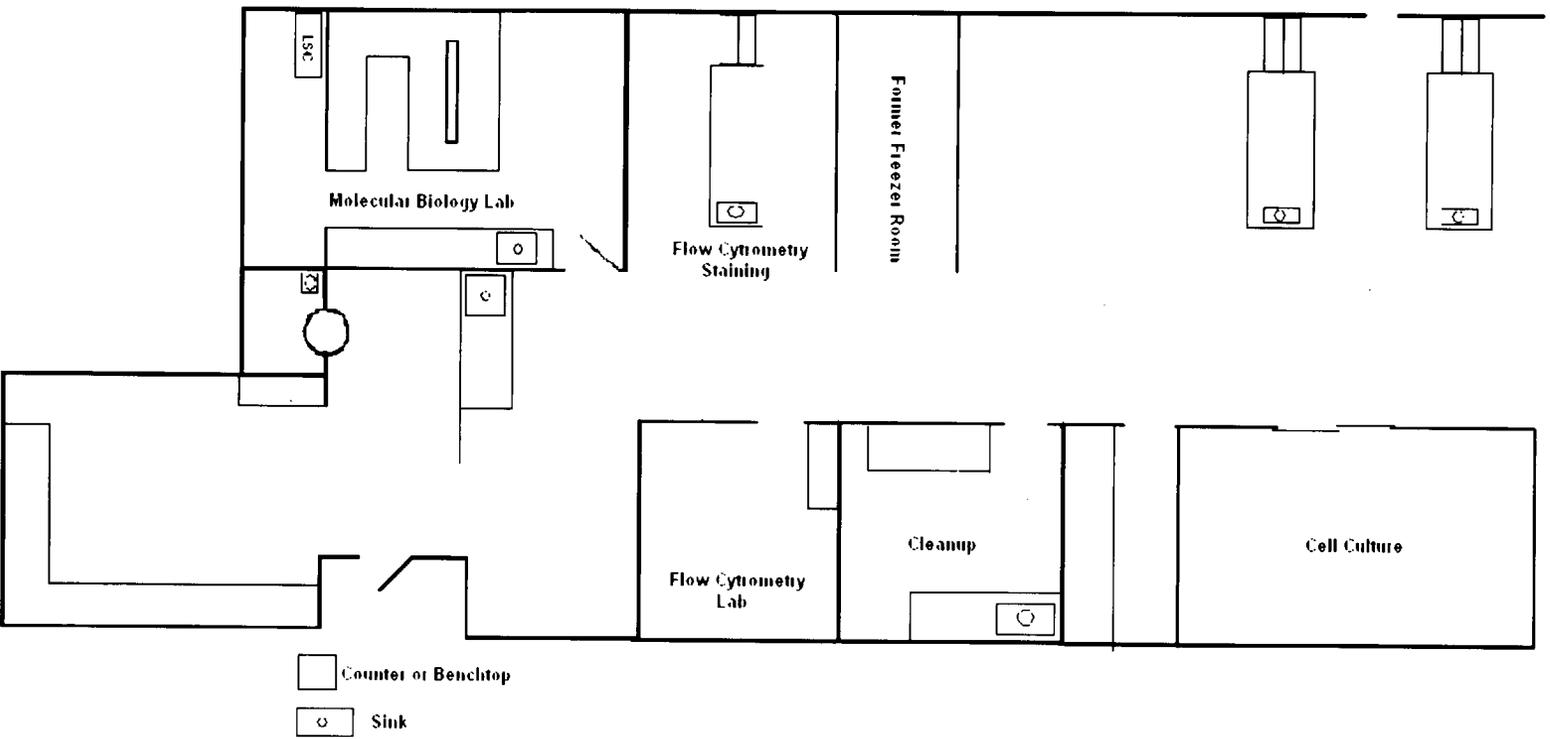
Attachment A: Floor Plan.

Attachment B: Calibration Certificates and MDA Calculations.

Attachment C: Direct Survey Measurement Locations and Results

Attachment D: Wipe Sample Locations and Results

**ATTACHMENT A
Floor Plan of Survey Area**



ATTACHMENT B

Instruments Used Calibration Certificates and MDA Data

Type of Measurement	Instrumentation		Bkgd.*	4π Eff. (%)	L _c and MDA	Photograph
	Detector	Instrument				
Surface scans and direct activity: beta	Gas proportional detector Ludlum Model 43-68	Scaler/Count-rate meter, Ludlum, Model 2224	217 cpm	4.6% (³⁵ S)	L _c = 140 net cpm MDA = 3794 dpm/100 cm ² (Ratemeter) L _c = 20 net cpm MDA = 484 dpm/100 cm ² (Direct Measurement)	
				22.2% (³² P)	L _c = 59 cpm MDA = 601 dpm/100 cm ² (Ratemeter) L _c = 20 cpm MDA = 200 dpm/100 cm ² (Direct Measurement)	
Surface scans: low-energy photons	Thin Crystal Scintillation Ludlum Model 44-17	Ratemeter, Ludlum Model 3	900 cpm	18.2% (¹²⁵ I)	L _c = 193 net cpm MDA = 2173 dpm/detector	
Surface scans	G-M Pancake Ludlum Model 44-9	Ratemeter, Ludlum Model 3	40 cpm	4.6% (³⁵ S)	L _c = 25 net cpm MDA = 1304 dpm/detector	

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ATTACHMENT B
MDA Data
Detector Held Stationary at 1 cm Above the Surface

Meter: Ludlum Model 2224-1, s/n: 129459 Digital Ratemeter/Scaler
Detector: Ludlum Model 43-68, s/n 091223 (126 cm² thin-window gas proportional counter)

All values calculated to 95% CL via MARSSIM methods.

$$MDA_{95\%} = \frac{3 + 3.29 \sqrt{R_b t_s \left(1 + \frac{t_s}{t_b}\right)}}{(t_s) \left(\frac{126}{100}\right) (E)}$$

A. Counting Statistics Based on the Efficiency for Sulfur-35
(Worst Case Detection Limits)

Direct (Static) Measurement of Surface Contamination

INPUT DATA:

Background Count = 214 cpm
Background Counting Time = 5 minutes
Sample Counting Time = 5 minutes
Detector Efficiency = 4.6 %
Detector Area = 126 cm²

RESULTS:

Minimum Detectable Activity (MDA) = 535.5 dpm/100 cm²

B. Counting Statistics Based on the Efficiency for Phosphorus-32
(Best Case Detection Limits)

Direct (Static) Measurement of Surface Contamination

INPUT DATA:

Background Count = 214 cpm
Background Counting Time = 5 minutes
Sample Counting Time = 5 minutes
Detector Efficiency = 22.2 %
Detector Area = 126 cm²

RESULTS:

Minimum Detectable Activity (MDA) = 111 dpm/100 cm²

ATTACHMENT B
MDA Data
Scan (Dynamic) Survey

Each technician performing direct surveys was tested to determine the minimum counting rate he could aurally perceive in excess of the background counting rate for the instrument being used. Using the methodology provided in NUREG/CR-5849, it was shown that the scanning MDA was adequate to detect the ALARA concentration levels.

$$\text{MDA} = \frac{D_i \times R_b}{E \times \frac{A}{100}}$$

Where:

D_i = Audibly discernable increase in instrument counting rate

D_i = $\frac{\text{Discernably different cpm} - \text{Bkgd cpm}}{\text{Bkgd cpm}}$

R_b = Background counting rate (cpm)

E = Instrument counting efficiency (counts per disintegration)

A = Area of the detector sensitive area (cm²)

Ludlum Model 44-17 with Ludlum Model 3

Each technician was able to aurally discern an increased counting rate of 1200 cpm in a 900 cpm background. For a background counting rate of 900 cpm, a $D_i = 0.33$, detector area = 20.4 cm², and an efficiency of 18.2% (for ¹²⁵I).

$$\text{MDA} = \frac{0.33 \times 900}{0.182 \times \frac{20.4}{100}} = 8,080 \text{ dpm} / 100\text{cm}^2.$$

Ludlum Model 43-68 with Ludlum Model 2224-1

Each technician was able to aurally discern an increased counting rate of 350 cpm in a 220 cpm background. For a background counting rate of 220 cpm, a $D_i = 0.59$, detector area = 126 cm², and an efficiency of 4.6% (for ³⁵S).

$$\text{MDA} = \frac{0.59 \times 220}{0.046 \times \frac{126}{100}} = 2243 \text{ dpm} / 100\text{cm}^2.$$

For ³²P (eff. = 22.2%):

$$\text{MDA} = \frac{0.59 \times 220}{0.222 \times \frac{126}{100}} = 464 \text{ dpm} / 100\text{cm}^2$$

Calibration Certificates

CERTIFICATE OF CALIBRATION (COUNT-RATE INSTRUMENT)

RSA Laboratories, Inc.

21 Pendleton Drive, P.O. Box 61
Hebron, Connecticut 06248
(860) 228-0721 Fax (860) 228-4402

Customer and Contact: Radiation Safety Associates, Inc., Attn: K. Paul Steinhilber (860) 228-0487

Customer Address: P.O. Box 107, 19 Pendleton Drive, Hebron, CT 06248

Inst. Mfr. & Model Ludlum Model 2224-1

Inst. Type Scaler/Ratemeter

Inst. s/n 129459

Det. Mfr. & Model Ludlum 43-68

Det. Type Gas Proportional

Det. s/n 091223

Cal. Date 09 May 2007

Due Date 09 May 2008

Cal. Interval 1 year

Environmental conditions: Temperature: 72°F Relative Humidity: 42% Atmospheric Pressure: 29.88 inches Hg

Pre calibration Checks:

Continuity - ok

Battery check

Slow response check

Mechanical check

Audio check

Window operation

Det. zero 1000 Vdc

Meter zero

Reset check

Fluores check

Alarm test - See statements

Geiger probe check

Fast response check

Alarm set

Pulse generator s/n 54926

Oscilloscope s/n 171-09029

Voltmeter s/n 57410002

HV Reader (2 points) Ref. div. 900 V/ 900 V Ref. div. 1700 V/ 1700 V

Comments: Alpha threshold = 120 mV; Beta threshold = 4.0 mV; Beta window = 4.0 mV to 30 mV. Local background = 1 cpm alpha, 270 cpm beta. Th230 efficiency measured on contact.

5% of source used for previous check #6 Isotope Cs-137 Dedicated Source? Yes
Reading #1 28,000 cpm Reading #2 28,000 cpm Reading #3 28,000 cpm Mean 28,000 cpm
Precision: $\pm 1.0\%$ $\pm 10.20\%$ $\pm 0.02\%$ $\pm 0.02\%$

Range Multiplier	Reference Calibration Point	Instrument Indication
x 1000	48,000 cpm	48,000 cpm
x 1000	100,000 cpm	100,000 cpm
x 100	40,000 cpm	40,000 cpm
x 100	10,000 cpm	10,000 cpm
x 10	400 cpm	400 cpm
x 10	100 cpm	100 cpm
x 1	400 cpm	400 cpm
x 1	100 cpm	100 cpm
1.000 count	100,000 cpm	100,000 cpm

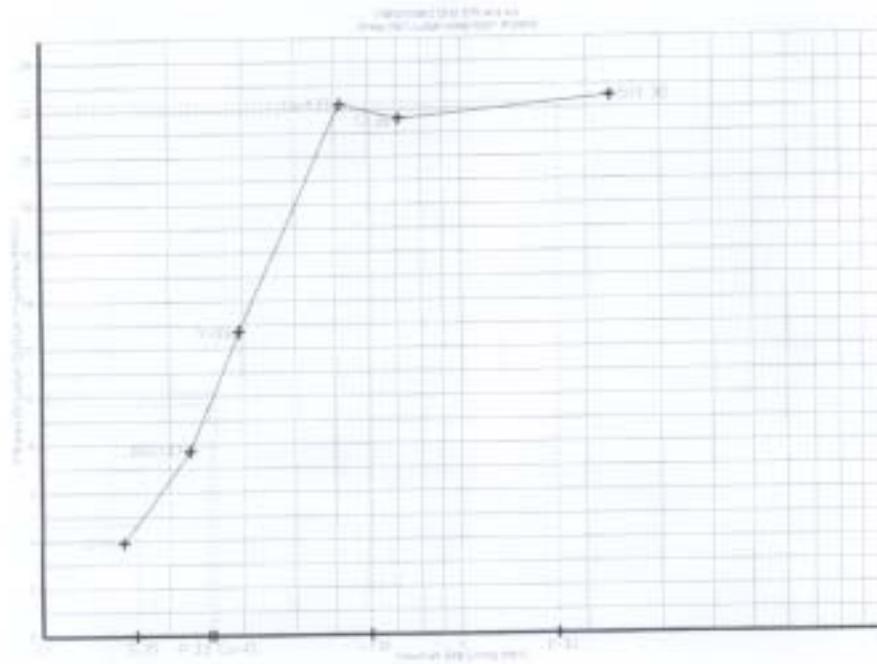
All ranges calibrated individually.

Range Multiplier	Cal. Source Used (range and activity)	Source Activity (dpm)	Reference Reading (cpm)	Cal. Instrument Efficiency (%)
1.000 count	1.34 14476	202,000	2.1 cpm 6,871 dpm	6.0% 3.9%
1.000 count	66.147 4030	4,204	3.4 cpm 497 dpm	6.0% 7.7%
1.000 count	31.99 40701	21,989	4.1 cpm 1,191 dpm	6.0% 12.7%
1.000 count	64.117 4090	14,700	4.1 cpm 4,889 dpm	6.0% 22.2%
1.000 count	13.36 40700	12,299	3.1 cpm 5,605 dpm	6.0% 11.6%
1.000 count	61.5 40 40701	41,700	4.1 cpm 9,672 dpm	6.0% 22.1%
1.000 count	31.24 912 0470001	31,800	4.140 cpm 4,221 dpm	18.6% 3.8%

RSA Laboratories ID# 11287. Instrument indicates within $\pm 10\%$ of calibration points unless otherwise indicated. Source-to-detector geometry window distance for efficiency determinations is 1 cm unless otherwise specified. RSA Laboratories, Inc. certifies that the above instrument has been calibrated with standards traceable to the National Institute of Standards and Technology, or have been derived from accepted values of natural physical constants, or have been derived by the same type of calibration techniques.

Calibrated by: Walt D. Newton

Date: 09 May 2007



RSA Calibration ID# 01207

Calibrated by: Kurt D. Newton

Date: 09 Mar 2007

Page 2 of 2

**CERTIFICATE
 OF CALIBRATION**
 (COUNT-RATE INSTRUMENT)

*** RSA Laboratories, Inc.**
 19 Pendleton Drive, P.O. Box 61
 Hebron, Connecticut 06248
 (203) 228-0721 Fax (203) 228-4402

Customer and Contact: Radiation Safety Associates, Inc., Attn: K. Paul Steinmeyer (860) 228-0487
 Customer Address: P.O. Box 107, 19 Pendleton Drive, Hebron, CT 06248
 Inst. Mfr. & Model Ludlum Model 3 Inst. Type Survey Meter Inst. s/n 94440
 Det. Mfr. & Model Ludlum 44-17 Det. Type Low Energy Gamma Det. s/n 165826
 Cal. Date 09 May 2007 Cal. Date 09 May 2008 Cal. Interval 1 year

Environmental conditions: Temperature: 70°F Relative Humidity: 41% Atmospheric Pressure: 29.88 inches Hg

Pre-calibration Checks:

- | | | | |
|--|---|---|---|
| <input checked="" type="checkbox"/> Contamination survey | <input checked="" type="checkbox"/> Battery check | <input checked="" type="checkbox"/> Slow response check | <input checked="" type="checkbox"/> Det. scale 1000 Vdc |
| <input checked="" type="checkbox"/> Mechanical check | <input checked="" type="checkbox"/> Audio check | <input type="checkbox"/> Window operation | |
| <input checked="" type="checkbox"/> Meter zero | <input checked="" type="checkbox"/> Beam check | <input type="checkbox"/> Hatten check | |
| <input checked="" type="checkbox"/> Geostopion check | <input checked="" type="checkbox"/> Fast response check | <input type="checkbox"/> Alarm set | <input checked="" type="checkbox"/> Det. zero: 36 mV |

HPMv program s/n 94926 Oscilloscope s/n 171-00928 Voltmeter s/n 57410002
 RIV Reader (2 ports) Ref./Int. V V Ref./Int. V V

Comments: Local background = 2,300 cpm.

S/N of source used for precision check 2886 Isotope Co-137 Dedicated Source? (Yes/No)
 Reading #1 3,600 cpm Reading #2 3,600 cpm Reading #3 3,600 cpm Mean 3,600 cpm
 Precision: $\sigma < 10\%$ $\sigma < 10-20\%$ (Out of tolerance)

Range Multiplier	Reference Calibration Point	Instrument Indication
x 100	400,000 cpm	400,000 cpm
x 100	100,000 cpm	100,000 cpm
x 10	40,000 cpm	40,000 cpm
x 10	10,000 cpm	10,000 cpm
x 1	4000 cpm	4000 cpm
x 1	1000 cpm	1000 cpm
x 0.1	400 cpm	400 cpm
x 0.1	100 cpm	100 cpm

All ranges calibrated electronically.

Range Multiplier	Cal. Source Used (Isotope and S/N)	Source Activity (dpm)	Instrument Reading (cpm)	Instrument Efficiency (%)
x 1	Co-137 #2886	16,750	3,600	7.8%
x 10	1-125 (NBS-1945-08169) (stock)	129,870	28,800	18.2%

RSA Laboratories Ltd H206. Instrument indicates within $\pm 10\%$ of calibration points unless otherwise indicated. Source-to-detector entry window distance for efficiency determinations is 1 cm unless otherwise specified. RSA Laboratories, Inc. certifies that the above instrument has been calibrated with standards traceable to the National Institute of Standards and Technology, or have been derived from accepted values of natural physical constants, or have been derived by the same type of calibration techniques.

Calibrated by: Kurt D. Newton



Date: 09 May 2007

**CERTIFICATE
OF CALIBRATION
(COUNT-RATE INSTRUMENT)**



RSA Laboratories, Inc.
21 Pendleton Drive, P.O. Box 61
Hebron, Connecticut 06248
(860) 228-0721 Fax (860) 228-4402

Customer and Contact: Radiation Safety Associates, Inc., Attn: K. Paul Steinmeyer (860) 228-0487
Customer Address: P.O. Box 107, 19 Pendleton Drive, Hebron, CT 06248
Inst. Mfr. & Model Ludlum Model 3 Inst. Type Survey Meter Inst. s/n 115369
Det. Mfr. & Model Ludlum Model 44-9 Type G-M Pancake Det. s/n 116450
Cal. Date 20 November 2006 Due Date 20 November 2007 Cal. Interval 1 year

Environmental conditions: Temperature: 70°F Relative Humidity 35% Atmospheric Pressure 29.84 inches Hg

Pre-calibration Checks:

- Contamination survey
- Battery check
- Slow response check
- Mechanical check
- Audio check
- Window operation
- Det. volts 900 Vdc
- Meter zero
- Reset check
- Plateau check
- Input zero 34 mV
- Geigerium check
- Fast response check
- Alarm set

Pulse generator s/n 94926 Oscilloscope s/n 171-04928 Voltmeter s/n 37410002
OHV Reader (2 points) Ref. Inst. V V Ref. Inst. V V

Comments: Th-230 efficiency measured on contact with probe face.

S/N of source used for precision check #2941 Isotope Co-137 Dedicated Source? Yes No
Reading #1 13,000 cpm Reading #2 13,000 cpm Reading #3 13,000 cpm Mean 13,000 cpm
Precision: $\pm < 10\%$ $\pm 10-20\%$ Out of tolerance

Range Multiplier	Reference Calibration Point	Instrument Indication
x 100	520,000 cpm	530,000 cpm
x 100	120,000 cpm	120,000 cpm
x 10	52,000 cpm	50,000 cpm
x 10	12,000 cpm	12,000 cpm
x 1	5,200 cpm	5,300 cpm
x 1	1,200 cpm	1,200 cpm
x 0.1	520 cpm	520 cpm
x 0.1	120 cpm	120 cpm

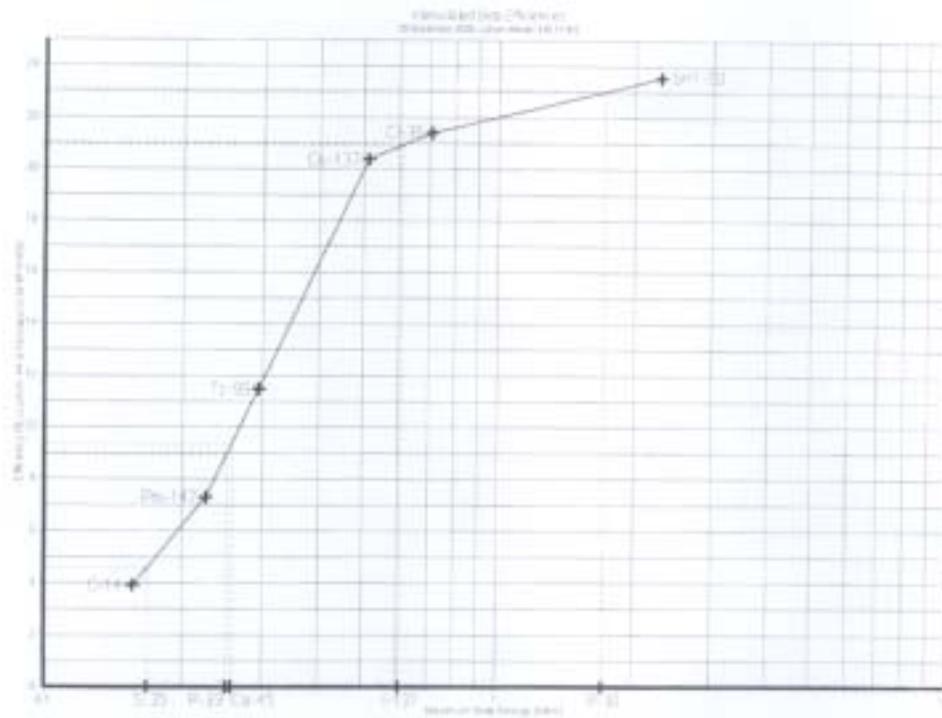
All ranges calibrated electronically.

Local background (cpm) = 50

Range Multiplier	Cal. Source Used (isotope and S/N)	Source Activity (dpm)	Instrument Reading (cpm)	4 σ Instrument Efficiency (%)
x 10	C-14 #4456	202,100	8000	3.93
x 0.1	Pu-147 #3301	4,795	400	7.30
x 1	Tl-99 #0702	23,044	2700	11.49
x 1	Co-137 #2886	16,921	3500	20.39
x 1	Cl-36 #0700	23,598	5100	21.40
x 10	Sr-90 #0711	42,242	10,000	23.55
x 1	Th-230 #91TH2200210	38,900	3500	8.87

RSA Laboratories ID# 10842. Instrument indicates within $\pm 10\%$ of calibration points unless otherwise indicated. Source-to-detector every window distance for efficiency determinations is 1 cm unless otherwise specified. RSA Laboratories, Inc. certifies that the above instrument has been calibrated with standards traceable to the National Institute of Standards and Technology, or have been derived from accepted values of natural physical constants, or have been derived by the ratio-type of calibration techniques.

Calibrated by: Kurt D. Newton Date: 20 November 2006



RSA Laboratory ID# 10042.

Calibrated by: Kurt D. Newton

Date: 20 November 2006

**CERTIFICATE
OF CALIBRATION**
(EXPOSURE RATE INSTRUMENT)

RSA Laboratories, Inc.
21 Pendleton Drive, P.O. Box 61
Hebron, Connecticut 06248
(860) 228-0721 Fax (860) 228-4402

Customer and Contact: RSA Laboratories, Inc., Attn: K Paul Steinmeyer (860) 228-0487
Customer Address: 19 Pendleton Drive, Hebron, CT 06248
Inst. Mfr. & Model Ludlum Model 3 Inst. Type Survey Meter
Det. Mfr. & Model Ludlum 44-9 Type Pancake G-M
Cal. Date 20 November 2006 Exp. Date 20 November 2007

Int. s/n 115369
Det. s/n 116450
Cal. Interval 1 year

Environmental conditions: Temperature: 70°F Relative Humidity 35% Atmospheric Pressure 29.54 inches Hg

Pre-calibration Checks:

- | | | | |
|--|---|---|---|
| <input checked="" type="checkbox"/> Contamination survey | <input checked="" type="checkbox"/> Battery check | <input checked="" type="checkbox"/> Slow response check | <input checked="" type="checkbox"/> Det. volts 900 Vdc |
| <input checked="" type="checkbox"/> Mechanical check | <input checked="" type="checkbox"/> Audio check | <input checked="" type="checkbox"/> Window operation | <input checked="" type="checkbox"/> High sens. 34 μ V |
| <input checked="" type="checkbox"/> Meter zero | <input checked="" type="checkbox"/> Reset check | <input checked="" type="checkbox"/> Plateau check | |
| <input checked="" type="checkbox"/> Geigerpin check | <input checked="" type="checkbox"/> Fast response check | <input checked="" type="checkbox"/> Alarm set | |

- | | | |
|---|--|--|
| <input checked="" type="checkbox"/> Pulse generator s/n 94926 | <input checked="" type="checkbox"/> Oscilloscope s/n 171 04928 | <input checked="" type="checkbox"/> Voltmeter s/n 37410002 |
| <input checked="" type="checkbox"/> HV Readout (2 points) Ref./Int. _____ V | _____ V Ref./Int. _____ V | _____ V |

Comments: Calibration performed with detector facing beam.

S/N of source used for precision check #2941 Isotope Cs-137 Dedicated Source? Yes No
Reading #1 3.5 mR/h Reading #2 3.5 mR/h Reading #3 3.5 mR/h Mean 3.5 mR/h
Precision: \pm < 10% \pm 10-20% Out of tolerance

Range	Reference Calibration Point	Instrument Indication
x 100	130 mR/h	130 mR/h
x 100	40 mR/h	40 mR/h
x 10	15.4 mR/h	15.5 mR/h
x 10	4.9 mR/h	5.0 mR/h
x 1	1.54 mR/h	1.50 mR/h
x 1	0.49 mR/h	0.50 mR/h
x 0.1	0.150 mR/h	0.15 mR/h
x 0.1	0.050 mR/h	0.05 mR/h

No ranges were calibrated electronically.

Sources used: ⁶⁰Cesium 750 mCi s/n KB-6244 and KB-6250, and ¹³⁷Cesium 750 μ Ci s/n 163

RSA Laboratories Log #10842. Calibration points calculated to center of detector volume unless otherwise specified. Instrument indicates within \pm 10% of calibration points unless otherwise indicated. RSA Laboratories, Inc. certifies that the above instrument has been calibrated with standards traceable to the National Institute of Standards and Technology, or have been derived from accepted values of natural physical constants, or have been derived by the ratio-type of calibration techniques.

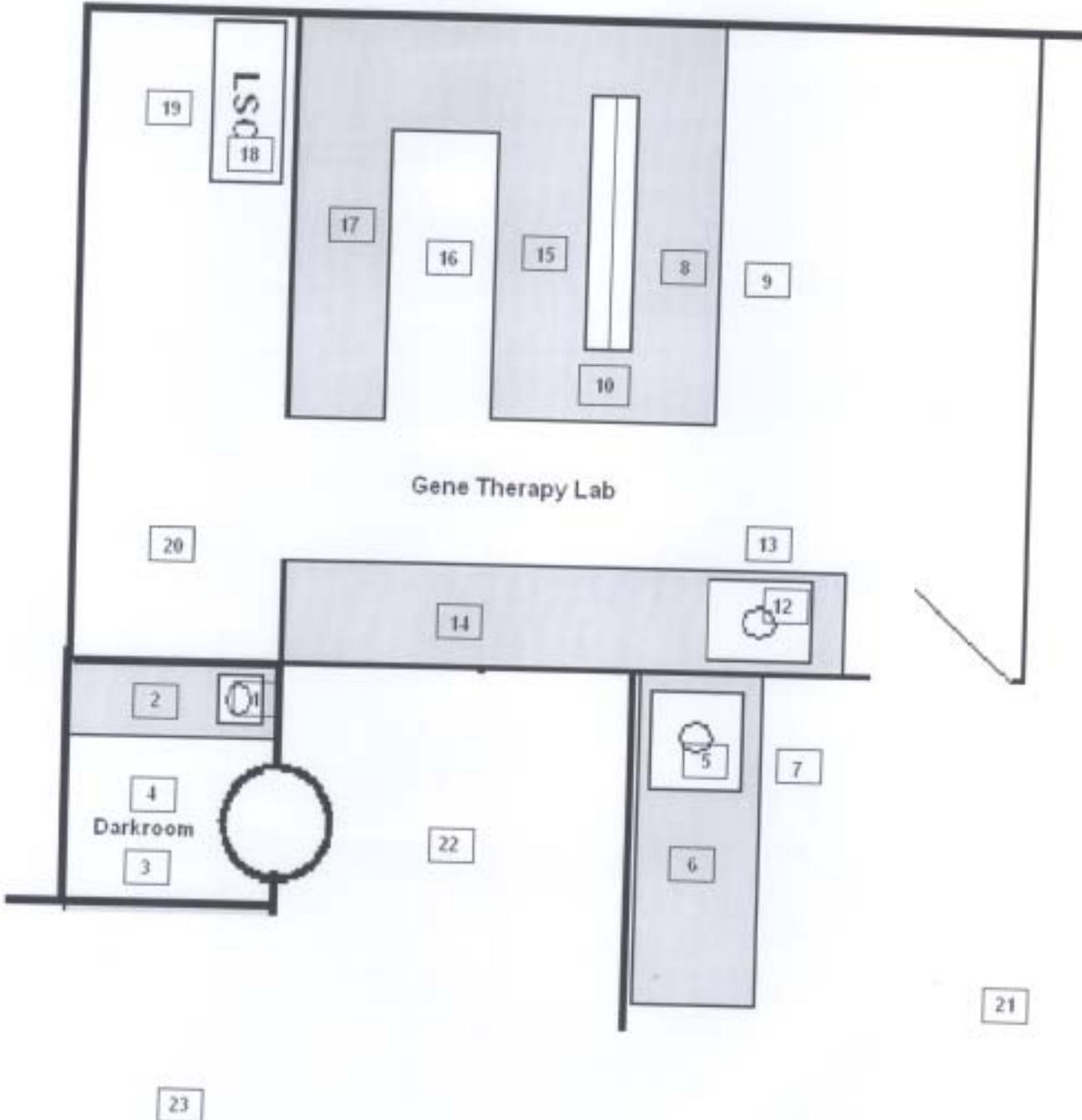
Calibrated by: Karl D. Newton



Date: 20 November 2006

ATTACHMENT C

Direct Measurement Locations
Restricted Area (Gene Therapy Lab and Darkroom)



ATTACHMENT C

Direct Measurement Data Restricted Area (Gene Therapy Lab and Darkroom)

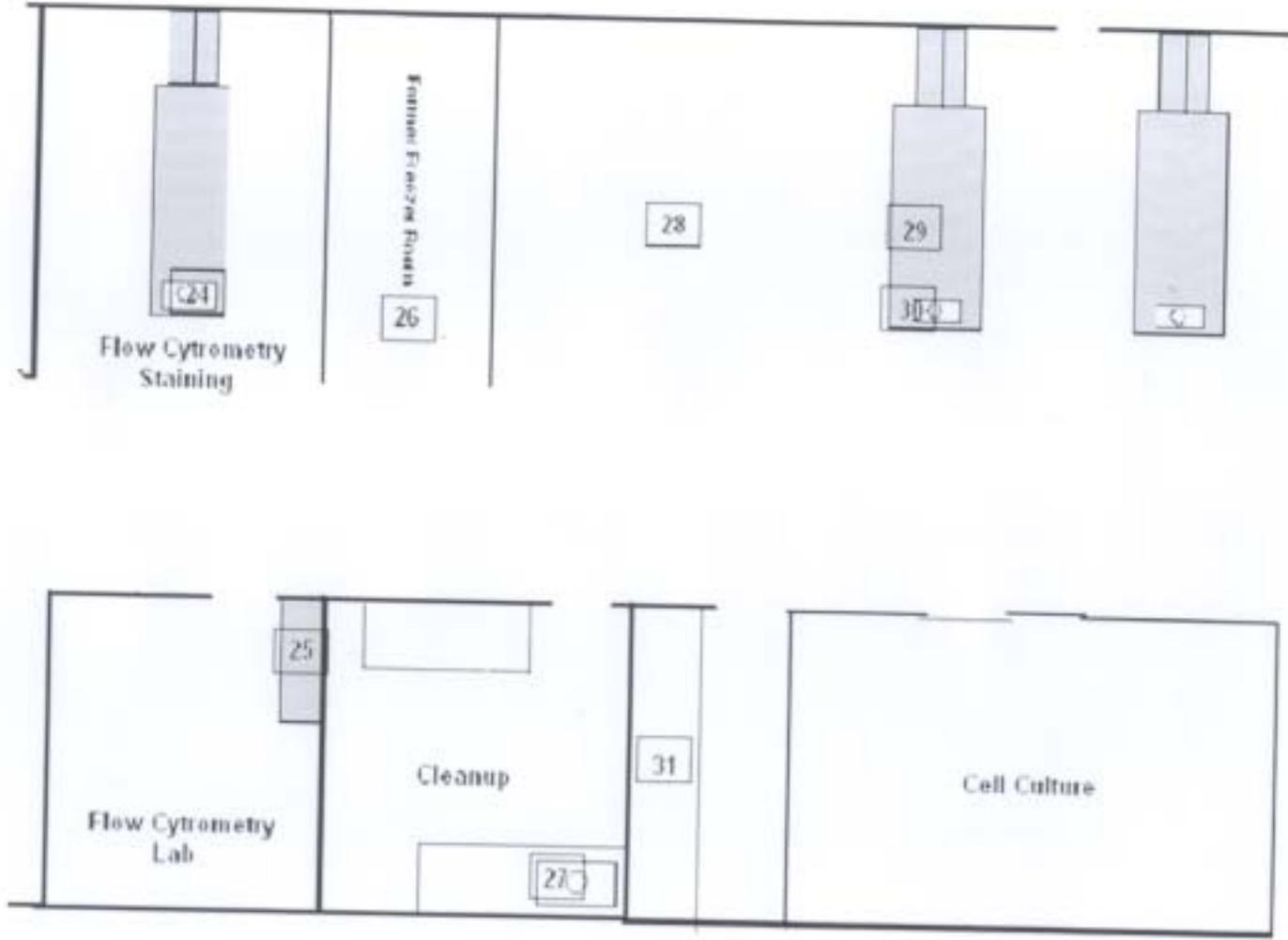
Background = 214 cpm Eff. (S-35) = 0.046 MDA = 535.5 dpm/100 cm²
 Eff. (P-32) = 0.222 MDA = 111 dpm/100 cm²

Release Criterion = 2000 dpm/100 cm² total contamination

	Room	Location	Net cpm	dpm/100 cm ²
1	Darkroom	Sink	5	109
2	"	Counter	0	--
3	"	Counter	-5	--
4	"	Floor	30	652
5	Wash Area	Sink	25	543
6	"	Counter	-18	--
7	"	Floor	44	957
8	Gene Therapy Lab	Counter	-7	--
9	"	Floor	42	913
10	"	Counter	-7	--
11	"	Floor	14	304
12	"	Sink	-8	--
13	"	Floor	2	43
14	"	Counter	-12	--
15	"	Counter	-21	--
16	"	Floor	14	304
17	"	Counter	10	217
18	LSC Room	LSC	5	109
19	"	Floor	30	652
20	"	Floor	12	261
21	Wash Room	Floor	29	630
22	File Room	Floor	35	761
23	Office	floor	-1	--

ATTACHMENT C

Direct Measurement Locations



ATTACHMENT C

Direct Measurement Data

Background = 214 cpm

Eff. (S-35) = 0.046 MDA = 535.5 dpm/100 cm²

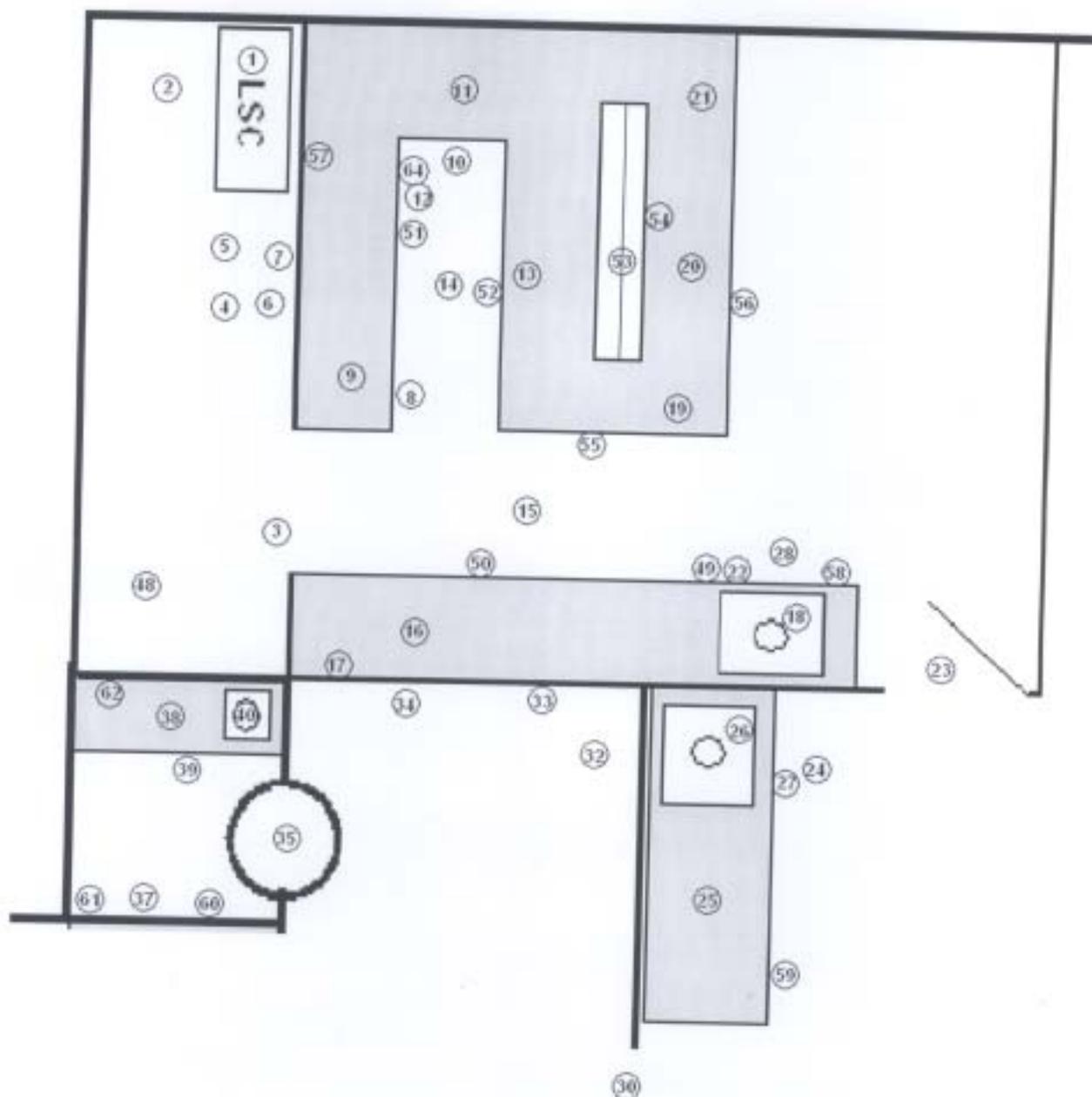
Eff. (P-32) = 0.222 MDA = 111 dpm/100 cm²

Release Criterion = 2000 dpm/100 cm² total contamination

	Room	Location	Net cpm	dpm/100 cm²
24	Flow Cytometry	Sink	8	174
25	Flow Cytometry Lab	Counter	10	217
26	Freezer Corridor	Floor	23	500
27	Cleanup	Sink	6	130
28	General Lab	Floor	41	891
29	"	Counter	-5	--
30	"	Sink	-6	--
31	Incubator Alcove	counter	24	522

ATTACHMENT D

Wipe Sample Locations Restricted Area (Gene Therapy Lab and Darkroom)



ATTACHMENT D
Wipe Sample Results
Restricted Area (Gene Therapy Lab and Darkroom)

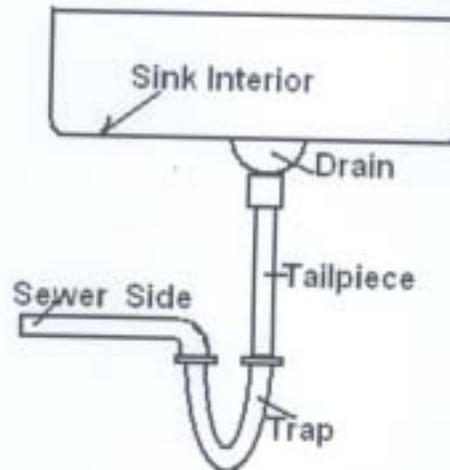
	Room	Location	Net cpm	dpm/100 cm²
1	Gene Therapy Lab	LSC	39	78
2	"	Floor	42	84
3	"	Floor	33	66
4	"	Plexiglas box	43	86
5	"	"	23	46
6	"	Metal can	27	54
7	"	Plexiglas box	36	72
8	"	Floor	31	62
9	"	Counter top	40	80
10	"	Refrigerator	29	58
11	"	Counter top	31	62
12	"	Plexiglas shield	30	60
13	"	Counter top	37	74
14	"	Floor	32	64
15	"	"	35	70
16	"	Counter top	48	96
17	"	Shelf	23	46
18	"	Sink	38	76
19	"	Counter top	34	64
20	"	"	34	64
21	"	Centrifuge	43	86
22	"	Plexiglas shield	33	66
23	"	Floor	31	62
24	Outside Gene Therapy lab	"	24	48
25	"	Counter top	48	96
26	"	Sink	34	38
27	"	Under sink	38	76
28	Gene Therapy lab	Floor	37	74
30	"	Floor	37	74
32	Outside darkroom	File cabinets	36	72
33	"	Shelves	39	78
34	"	Refrigerator	39	78
35	Darkroom	Dark room entry	32	64
37	Darkroom	Under counter	40	80
38	"	Counter top	37	74
39	"	Under counter	45	90
40	"	Sink	37	74
48	Gene Therapy lab	Floor	40	80
49	"	Bottles	40	80
50	"	shelves	34	68
51	"	Refrigerator	31	62

52	"	Shelves	34	68
53	"	Center shelves	21	42
54	"	Drawers	41	82
55	"	Cabinet	72	144
56	"	Shelves	38	76
57	"	Shelves	34	68
58	"	Drawer	33	66
59	Outside Gene Therapy lab	Drawer	32	64
60	Darkroom	"	39	78
61	"	Cabinet	53	106
62	"	Cabinet	38	76
64	Gene Therapy Lab	"	33	66

Wipe Sample Results
Ventilation Returns
Restricted Area (Gene Therapy Lab and Darkroom)

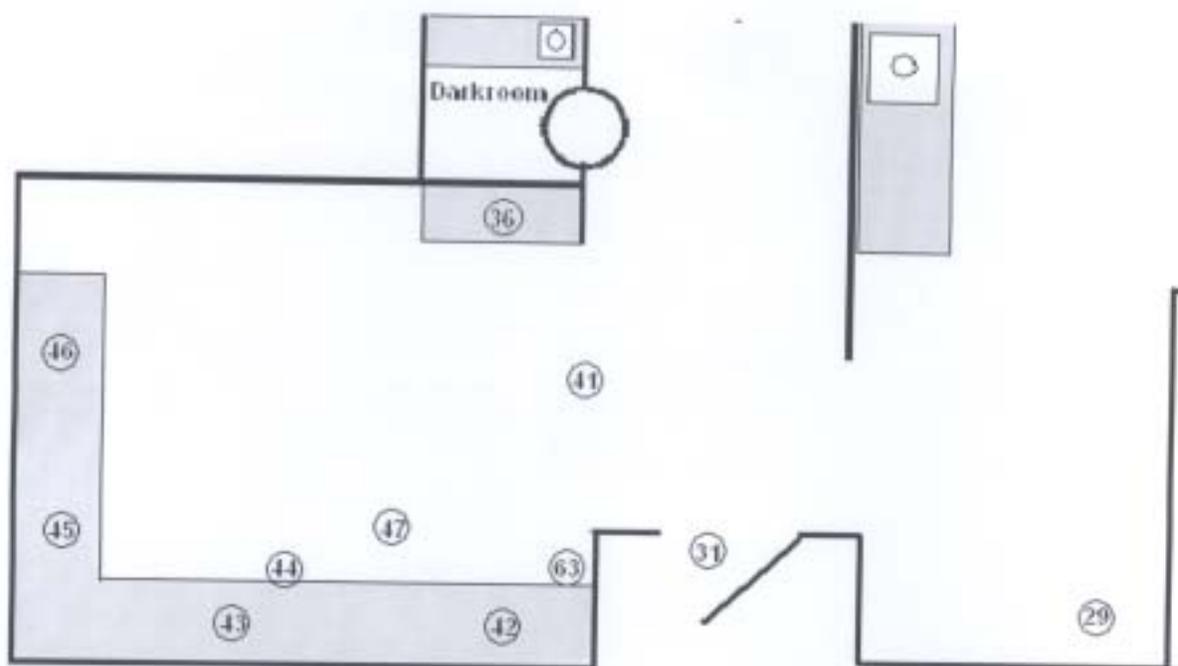
	Room	Location	Net cpm	dpm/100 cm²
1	Gene Therapy Lab	Ceiling	35	70
2	"	LSC area	31	62
3	Darkroom	Vent return	48	96
4	Outside Gene Therapy Lab	Vent return	28	56
5	Next to darkroom	Vent return	37	74

ATTACHMENT D
Wipe Sample Locations
Restricted Area Sinks



	Room	Location	Net cpm	dpm/100 cm²
1	Wash up	Sink interior	23	46
2	"	Trap	20	40
3	"	Tailpiece	13	26
4	"	Sewer side	17	34
5	Darkroom	Sink interior	17	34
6	"	Trap	18	36
7	"	Tailpiece	16	32
8	"	Sewer side	27	54
9	Disposal Sink Gene Therapy	Tailpiece	35	70
10	"	Trap	31	62
11	"	Sewer side	48	96

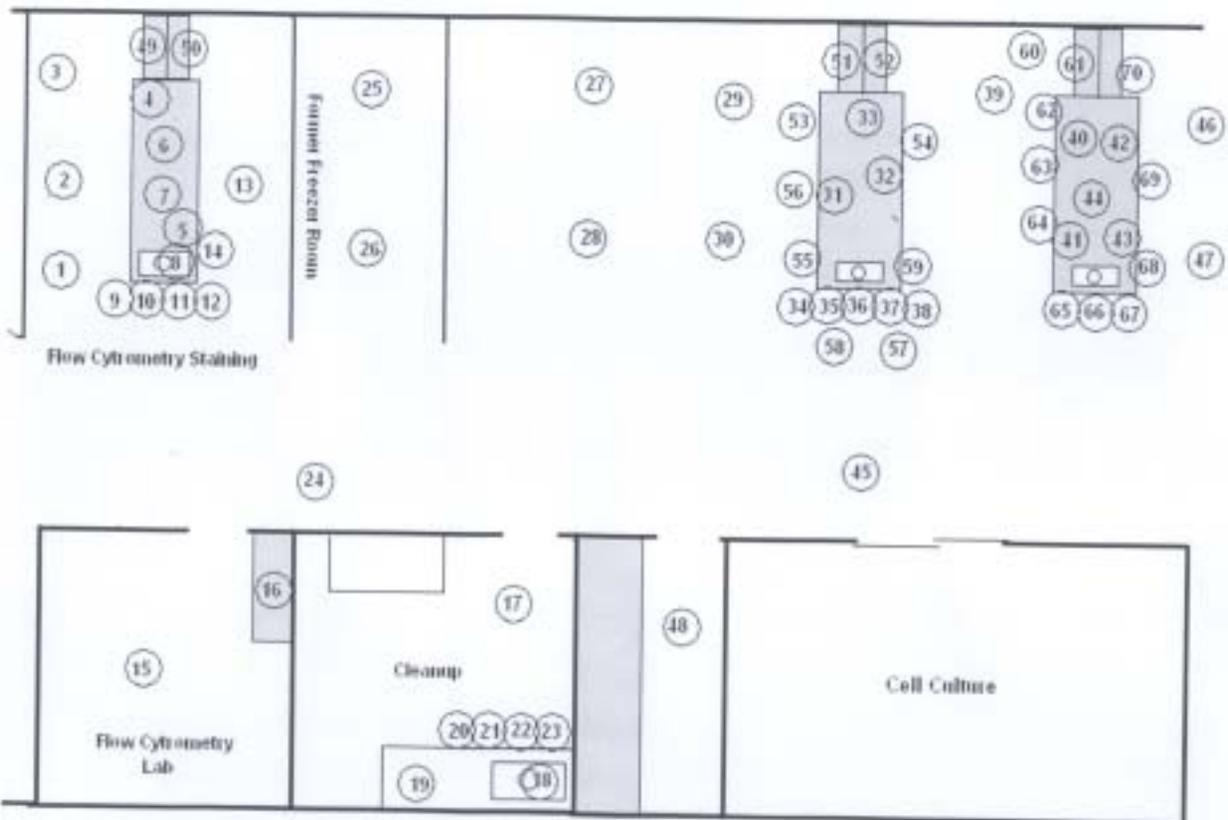
ATTACHMENT D
Wipe Sample Locations
Unrestricted Area (Section 1)



Wipe Sample Results
Unrestricted Area (Section 1)

	Room	Location	Net cpm	dpm/100 cm ²
29	Outside Gene Therapy lab	Refrigerator	39	78
31	Doorway	"	37	74
36	Workroom	Counter top	36	72
41	"	Floor	31	62
42	"	Counter top	41	82
43	"	Shelves	38	76
44	"	Cabinets	36	72
45	"	Counter top	60	120
46	"	Floor	24	48
47	"	Floor	38	76
63	Workroom	Drawer	35	70

ATTACHMENT D
Wipe Sample Locations
Unrestricted Area (Section 2)

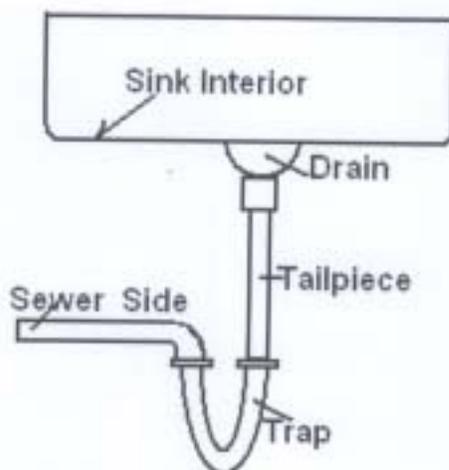


ATTACHMENT D
Wipe Sample Results
Unrestricted Area (Section 2)

	Room	Location	Net cpm	dpm/100 cm²
1	Flow Cytr. Staining	Floor	42	84
2		"	40	80
3		"	54	108
4		Bench	53	106
5		"	43	86
6		Center shelf	34	68
7		"	44	88
8		Sink interior	37	74
9		Under sink	41	82
10		Sink trap	38	76
11		Tail piece	33	66
12		Sewer side of drain	24	48
13		Floor	33	66
14		Shelves under bench	37	74
15	Flow Cytr. Lab	Floor	32	64
16	"	Small bench top	33	66
17	Cleanup room	Floor	46	92
18	"	Sink interior	31	62
19	"	Sink drain board	37	74
20	"	Under sink	35	70
21	"	Sink trap interior	33	66
22	"	Sink drain tailpiece	35	70
23	"	Drain-sewer side	36	72
24	Corridor	Floor	32	64
25	Freezer room	"	54	108
26	"	"	27	54
27	General Lab	"	44	88
28	"	"	27	54
29	"	"	20	40
30	"	"	37	74
31	"	Bench	40	80
32	"	"	33	66
33	"	Shelves above	24	48
34	"	Sink interior	30	60
35	"	Sink trap	31	62
36	"	Drain tailpiece	27	54
37	"	Drain sewer side	33	66
38	"	Under sink	25	50
39	"	Floor	16	32
40	"	Bench	14	28
41	"	"	13	26
42	"	"	23	46
43	"	"	15	30

44	"	Shelves above bench	20	40
45	Corridor	Floor	10	20
46	General Lab	"	19	38
47	"	"	17	34
48	Small room	"	13	26

ATTACHMENT D
 Wipe Sample Locations
 Unrestricted Area Sinks



	Room	Location	Net cpm	dpm/100 cm ²
1	Wash up	Sink interior	23	46
2	"	Trap	20	40
3	"	Tailpiece	13	26
4	"	Sewer side	17	34
5	Darkroom	Sink interior	17	34
6	"	Trap	18	36
7	"	Tailpiece	16	32
8	"	Sewer side	27	54

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