



Purdue Pharma L.P.

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April 21, 2005

Licensing Assistance Section
Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Re: *NRC License # 29-30698-01* 03035882
Purdue Pharma LP
Cranbury, New Jersey Facility

05 APR 26 17:15

RECEIVED
REGION 1

Dear Sir/Madam:

On 12/21/04 Purdue requested a License Amendment to reflect significant facility changes. Several locations were being decommissioned and several researchers were being deleted from the Radiation Safety Program. As part of the amendment process, the NRC requested a Decommissioning Survey to release the major areas for "Unrestricted Use".

There was no evidence of contamination on any surfaces surveyed. All areas meet the criteria for release for unrestricted use. No further radiological controls need to be applied to these areas.

Please review the enclosed report and contact me at 609-409-5826 if you need any additional information. Your time and assistance in this matter is appreciated.

Mathew L. Swan, CIH, CSP
Director, Environment, Health & Safety

Decommissioning Survey Report

For

Purdue Pharma LP

NRC License # 29-30698-01

Dated 4/21/05

Conducted By: Scott Dennerlein & Associates LLC

Introduction

During the month of February 2005 Scott Dennerlein & Associates, LLC, conducted a decommissioning survey for Purdue Pharma LP at the 6 CedarBrook Drive facility in Cranbury, New Jersey. The intent of the survey was to release the following areas for unrestricted use due to a significant reduction in the overall Radiation Safety Program: B-113, B-117, B-119, B-123 and Liquid Waste Storage Area. This survey was planned and conducted according to the methods presented in the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM). MARSSIM provides guidance on determining the number of data points required in each survey unit, the interpretation of survey results, choice of instrumentation, and data reduction. Values for radioactivity-to-dose conversions are obtained from the "Regulatory Guide on Release Criteria for Decommissioning" (NUREG-1500). Much of the Quality Assurance plan is developed based on an EPA document, "Guidance for the Data Quality Objectives Process". (EPA /600/R-96)

Site Description and History

This research facility is a two story brick building situated in a pharmaceutical/biotech research park. The areas surveyed were all on the first floor in the West Wing of the building.

Radionuclides of Concern

The NRC license for this site is 29-30698-01. The licensed material used was ^{90}Y , ^{125}I , ^3H , ^{35}S , ^{51}Cr and ^{14}C . Radioactive material was not used in the areas surveyed for approximately 3 months prior to this decommissioning survey.

Release Criteria

A Total Effective Dose Equivalent (TEDE) of 25 millirem per year has been set in Subpart E - Radiological Criteria for License Termination, Title 10 of the Code of Federal Regulations, Part 20.1402. However, that regulation also invokes the ALARA principle. That is "...the NRC will consider that the licensee has complied with the ALARA requirement if the

licensee can demonstrate that the TEDE to the average member of the critical group does not exceed 3 millirem per year”.

This site will be decontaminated such that, at a maximum, the highest TEDE received by an individual occupying the site after release would be 3 millirem. For comparison, the typical range of TEDE in the United States is 200 – 400 millirem per year. This hypothetical dose is based on the building occupancy scenario/model of NUREG/CR5512, which in turn is used to calculate the surface contamination limits presented in Table B-1 of NUREG 1500. Those values for the relevant, long-lived radio-nuclides are presented in Table 1, below.

**Table 1. Surface contamination values which deliver 3 mrem/y
under the building occupancy scenario.**

Radionuclide	Surface Contamination (dpm/100cm ²)
³ H	5,290,000
³⁵ S	1,340,000

Residual Radioactivity Limits

Residual radioactivity limits are called Derived Concentration Guideline levels (DCGL) in MARSSIM. Since the detection of surface contamination with current field instrumentation is essentially a “gross beta” measurement which cannot distinguish specific radionuclides, the most restrictive value of the listed radionuclides would normally be selected as the DCGL for this project. However, the footnote to Table B-1 states “For most radionuclides, based on the ALARA principle and best industry practice, it is not necessary to leave contamination in excess of 5,000 dpm/100cm² “. Therefore the DCGL for this project will be 5,000 dpm/100cm², with the knowledge that this value would deliver a TEDE far below 3 mrem/y.

Survey Units

The laboratories were surveyed as Class 1 survey units according to the MARSSIM classification scheme. Class 1 areas are rooms where unsealed forms of radioactive

materials were used until the close of research activities, and/or material used in the past with half-lives greater than 65 days, and/or material with half-lives less than 65 days were used within two years of this decommissioning. Laboratories B-113, and B-119 were surveyed as one unit due to their small size, while B-117, B-123 and the Liquid Waste Storage Area were each treated as separate survey units. A map is enclosed in Appendix A that illustrates the building west wing and specific rooms designated for decommissioning.

Survey Design

The number of data points necessary for a given survey unit in this survey plan is based on using the one sample Sign test for analysis of the data. This statistical test is appropriate when the contaminant is not present in background, or is present at such a small fraction of the DCGL as to be insignificant. The only long lived isotopes authorized on this license are ^3H and ^{35}S , which fall into this category of radionuclides. In terms of data reduction, this means the survey units are not compared to a reference (i.e. non-impacted) area, but are compared directly to the DCGL. Equation 5-2 is then used to determine the number of data points in each survey unit as follows;

$$N = \frac{(Z_{1-\alpha} + Z_{1-\beta})^2}{4(\text{sign } p - 0.5)^2}$$

We define each “data point” as a measurement location for both an integrated surface activity count (beta/gamma) and wipe sample. These are in addition to the scanning surveys conducted in each survey unit. The contamination limits for this decommissioning project are less than 5,000 dpm/100 cm² for total (fixed and removable) radioactivity.

The first step in determining the number of samples is to define the gray region. The gray region is the range of values where the consequences of making a decision error are minor. Typically the lower boundary of the gray region (LBGR) is one half of the DCGL, therefore the shift or delta (Δ) is equal to DCGL-LBGR. For this project;

$$\Delta = 5,000 \text{ dpm/100cm}^2 - 2,500 \text{ dpm/100cm}^2$$

The next step is to estimate the standard deviation of the measurements of the contaminants. If results from characterization surveys are not available, it is reasonable to assume a relative standard deviation of 30%.

The DCGL and LBGR are then expressed in counts per minute (i.e. the “raw” data) based on 4% efficiency for the detection of C-14 and a 169 cm² probe. This would make the gray region from 225 cpm to 113 cpm. Thirty percent of the DCGL would give a standard deviation of 68. The relative shift would then be;

$$\Delta/\sigma = (225-113)/68 = 1.6$$

The value of Sign p as obtained from Table 5.4 in the MARSSIM manual for a relative shift of 1.6 is 0.945201.

The acceptable error rates for this project are 0.10 for a Type I error and 0.05 for a Type II error. That is, there is a 5% chance of releasing a survey unit that, in reality does not meet the release criteria (Type I). Conversely, there is a 90% chance of not releasing a survey unit that truly does meet the release criteria. The percentiles, $Z_{1-\alpha}$ and $Z_{1-\beta}$ represented by these decision errors are 1.645 and 2.326.

Substituting all the values determined above into Equation 5.2 in MARSSIM gives the number of data points as;

$$N = \frac{(1.645 + 2.326)^2}{4 (0.945201 - 0.5)^2} = 20$$

The number of data points is increased by 20% to account for missing or unusable data, making

$$N = 20 \times 1.2 = 24$$

As a check on this calculation, the number of data points necessary based on the error rates and relative shift was also determined using Table 5.5 in MARSSIM. That value is 24 data points. Therefore, we obtained at least 24 data points in each survey unit. Not included in that number are biased measurements, obtained in areas where professional judgment would suggest contamination could be encountered such as sinks and behind fume hood baffles.

In the typical laboratory setting, any contamination encountered is most likely isolated spots. MARSSIM, in Section 5.5.2.4 states that the preceding statistical tests are appropriate for uniformly distributed contamination, and operational procedures must be employed to address “hotspots”. Specifically, “systematic measurements and sampling, in conjunction with surface scanning, are used to obtain an adequate assurance level that small areas of elevated radioactivity will satisfy the release criterion.” The method employed for this survey includes enough randomly located data points to satisfy the statistical test, as well as 100% survey coverage of bench tops, hood interiors, sinks, and floors in front of bench tops to detect small areas of elevated activity.

Equipment and Techniques

The type of detector used for both the scanning and fixed location measurements was a “pancake” G-M probe connected to a scaler / ratemeter. To scan areas the probe was moved at a speed of one probe width per second at a height of approximately ¼ inch, utilizing the audio output to locate hotspots. Class 1 survey units require 100% coverage of all horizontal surfaces, inside drawers, hoods, and the walls up to two meters in height. Fixed location measurements were obtained with the same probe and a one minute integrated count. Any removable contamination was sampled by wiping a ¼” inch dry filter paper over one hundred square centimeters in the same location as the fixed measurement. Table 2 on the next page lists the field detector, laboratory equipment and their associated parameters.

Table 2. Detection Sensitivities for Survey Instrumentation

Detector*	Probe area (cm ²)	Background (cpm)	Efficiency (cpm/dpm) 4π	Approximate Sensitivity		
				L _c counts	L _D counts	MDC dpm/100 cm ²
Ludlum model 3 #109793	15	60	0.07 (¹⁴ C)	18	39	3,714
Wallac microbeta 156-2000 keV	N/A	30	0.51 (³ H)	13	29	57

Where ;

$$L_c = 2.33 \sqrt{B}$$

$$L_D = 3 + 4.65 \sqrt{B}$$

$$MDC = \frac{3 + 4.65 \sqrt{B}}{T \epsilon_T A}$$

*where T = integrated count time

ε_T = total efficiency

A = area of probe / 100 cm²

B = background countrate

The calibration procedures and daily operational and source checks are discussed in the quality assurance section.

Statistical Test of Measurement Results

The summary data listed below in Table 3 would represent the total beta/gamma, both fixed and removable, if present. Wipe samples were taken in these same locations to independently verify the absence of removable contamination. According to the ALARA philosophy, removable contamination should be cleaned, regardless of the level.

Table 3: Summary of Statistical Tests

Location	Survey Type	N	S+	Critical Value	Meets Release Criteria?
Lab B-113/B-119	Total β/γ	30	30	17	YES
Lab B-117	Total β/γ	40	40	25	YES
Lab B-123	Total β/γ	30	29	17	YES
Liquid Waste Area	Total β/γ	10	10	8	YES

The statistical test is simply, how many data points exceed the release criteria (represented by a value of -1) versus the number that are below the release criteria (represented by a value of 1). The "ceiling value" for hot spots is three times the release criteria, that is, no single spot regardless of size can exceed 15,000 dpm/100 cm².

The individual measurements are presented on the spreadsheets provided on pages 8-12. Specific sampling locations are illustrated in Appendix A.

Decommission Survey Conclusion

There was no evidence of contamination on any surfaces surveyed. All areas meet the criteria for release for unrestricted use. No further radiological controls need to be applied to these areas.

Laboratories B-113/B-119
Total Beta/Gamma Results (Pancake Probe Measurements)

Location	Gross Counts	Net cpm	dpm/100 cm2	DCGL-data	Sign	
1	50	-10	-952	4048	1	
2	52	-8	-762	4238	1	
3	61	1	95	4905	1	
4	48	-12	0	5000	1	
5	54	-6	-571	4429	1	
6	53	-7	-667	4333	1	
7	64	4	381	4619	1	
8	68	8	762	4238	1	Background (cpm) 60
9	50	-10	-952	4048	1	Efficiency 0.07
10	53	-7	-667	4333	1	Probe Area/100 cm2 0.15
11	61	1	95	4905	1	Count time 1
12	46	-14	-1333	3667	1	
13	49	-11	-1048	3952	1	
14	51	-9	-857	4143	1	
15	54	-6	-571	4429	1	
16	61	1	95	4905	1	
17	63	3	286	4714	1	
18	46	-14	-1333	3667	1	
19	43	-17	-1619	3381	1	
20	51	-9	-857	4143	1	
21	52	-8	-762	4238	1	
22	56	-4	-381	4619	1	
23	56	-4	-381	4619	1	
24	48	-12	-1143	3857	1	
25	42	-18	-1714	3286	1	
26	58	-2	-190	4810	1	
27	59	-1	-95	4905	1	
28	61	1	95	4905	1	
29	60	0	0	5000	1	
30	53	-7	-667	4333	1	

Number of Positive Differences

30

The number of positive values exceeds the critical value of 17, (obtained from Table I.3 in MARSSIM) so the null hypothesis ("The residual radioactivity in the survey unit exceeds the release criterion") is rejected and it is concluded that the survey unit meets the release criterion.

Laboratory B-117
Total Beta/Gamma Results (Pancake Probe Measurements)

Location	Gross Counts	Net cpm	dpm/100 cm2	DCGL-data	Sign	
1	45	-15	-1429	3571	1	
2	48	-12	-1143	3857	1	
3	51	-9	-857	4143	1	
4	54	-6	0	5000	1	
5	42	-18	-1714	3286	1	
6	56	-4	-381	4619	1	
7	48	-12	-1143	3857	1	
8	53	-7	-667	4333	1	Background (cpm) 60
9	56	-4	-381	4619	1	Efficiency 0.07
10	50	-10	-952	4048	1	Probe Area/100 cm2 0.15
11	48	-12	-1143	3857	1	Count time 1
12	49	-11	-1048	3952	1	
13	50	-10	-952	4048	1	
14	52	-8	-762	4238	1	
15	48	-12	-1143	3857	1	
16	51	-9	-857	4143	1	
17	46	-14	-1333	3667	1	
18	55	-5	-476	4524	1	
19	54	-6	-571	4429	1	
20	61	1	95	4905	1	
21	51	-9	-857	4143	1	
22	52	-8	-762	4238	1	
23	58	-2	-190	4810	1	
24	53	-7	-667	4333	1	
25	53	-7	-667	4333	1	
26	54	-6	-571	4429	1	
27	61	1	95	4905	1	
28	60	0	0	5000	1	
29	48	-12	-1143	3857	1	
30	53	-7	-667	4333	1	

The number of positive values exceeds the critical value of 17, (obtained from Table I.3 in MARSSIM) so the null hypothesis ("The residual radioactivity in the survey unit exceeds the release criterion") is rejected and it is concluded that the survey unit meets the release criterion.

Laboratory B-117 (continued)

Total Beta/Gamma Results (Pancake Probe Measurements)

[illegible]

40

The number of positive values exceeds the critical value of 25, (obtained from Table I.3 in MARSSIM) so the null hypothesis ("The residual radioactivity in the survey unit exceeds the release criterion") is rejected and it is concluded that the survey unit meets the release criterion.

Laboratory B-123
Total Beta/Gamma Results (Pancake Probe Measurements)

Location	Gross Counts	Net cpm	dpm/100 cm2	DCGL-data	Sign	
1	41	-19	-1810	3190	1	
2	48	-12	-1143	3857	1	
3	51	-9	-857	4143	1	
4	52	-8	-762	4238	1	
5	54	-6	-571	4429	1	
6	49	-11	-1048	3952	1	
7	51	-9	-857	4143	1	
8	48	-12	-1143	3857	1	Background (cpm) 60
9	47	-13	-1238	3762	1	Efficiency 0.07
10	53	-7	-667	4333	1	Probe Area/100 cm2 0.15
11	57	-3	-286	4714	1	Count time 1
12	48	-12	-1143	3857	1	
13	51	-9	-857	4143	1	
14	51	-9	-857	4143	1	
15	47	-13	-1238	3762	1	
16	1	-59	-5619	-619	-1	
17	53	-7	-667	4333	1	
18	48	-12	-1143	3857	1	
19	51	-9	-857	4143	1	
20	54	-6	-571	4429	1	
21	59	-1	-95	4905	1	
22	61	1	95	4905	1	
23	48	-12	-1143	3857	1	
24	45	-15	-1429	3571	1	
25	52	-8	-762	4238	1	
26	57	-3	-286	4714	1	
27	52	-8	-762	4238	1	
28	59	-1	-95	4905	1	
29	53	-7	-667	4333	1	
30	64	4	381	4619	1	

Number of Positive Differences

29

The number of positive values exceeds the critical value of 17, (obtained from Table I.3 in MARSSIM) so the null hypothesis ("The residual radioactivity in the survey unit exceeds the release criterion") is rejected and it is concluded that the survey unit meets the release criterion.

Liquid Radioactive Waste Storage Area
Total Beta/Gamma Results (Pancake Probe Measurements)

Location	Gross Counts	Net cpm	dpm/100 cm2	DCGL-data	Sign	
1	50	-10	-952	4048	1	
2	65	5	476	4524	1	
3	61	1	95	4905	1	
4	59	-1	0	5000	1	
5	58	-2	-190	4810	1	
6	69	9	857	4143	1	
7	71	11	1048	3952	1	
8	68	8	762	4238	1	Background (cpm) 60
9	63	3	286	4714	1	Efficiency 0.07
10	68	8	762	4238	1	Probe Area/100 cm2 0.15
Number of Positive Differences					10	Count time 1

The number of positive values exceeds the critical value of 8, (obtained from Table I.3 in MARSSIM) so the null hypothesis ("The residual radioactivity in the survey unit exceeds the release criterion") is rejected and it is concluded that the survey unit meets the release criterion.

Quality Assurance Plan

Providing quality data for a decommissioning project is based on certain key elements as discussed in EPA guidance documents (EPA 504/G-93/071). These are known as PARRC (precision, accuracy, representativeness, completeness, and comparability) parameters. In addition, the sensitivity of measurements, expressed as the Minimum Detectable Activity (MDA) must be sufficiently low to detect contamination $\leq 25\%$ of the release criteria (NRC, 1992). The processes for assessing these parameters are discussed below.

Precision

Precision is a test of how closely one can replicate a measurement. Replicate measurements for total beta contamination were made by obtaining two one minute counts in sequence at the same location. At least 5% of the total measurements were duplicated in this manner. Since removable activity sampling is a destructive analysis it is not suitable for assessing precision. The formula below was used to determine the relative percent difference (RPD). One can expect measurements of contaminated areas at this site to be reproduced within \pm the RPD with similar instrumentation and count times.

Measurements		
Initial	Replicate	RPD*
62	59	5.0%
56	49	13.3%
49	51	-4.0%
57	50	13.1%
Average RPD =		6.8%

Table2. - Reproducibility of Total Beta Measurements

$$\text{*Relative Percent Difference} = \frac{\text{Measurement} - \text{Replicate Meas.}}{(\text{Measurement} + \text{Replicate Meas.}) / 2} \times 100\%$$

Accuracy

Accuracy is a test of how close the meters response is to a known value. The beta standards used for this project (the known value) were a set of five windowless sources (Carbon - 14 through Sr/Y-90, 156 – 2.1 MeV), with radioactivity levels certified by the National Institute of Standards and Testing. It is recognized that contamination on items may be in a geometry different from the calibration standard. (i.e. different size area, or not uniformly distributed). However, the difference between the meters efficiency for a point source and large areas of contamination is estimated to be less than 6% (NRC, 1995a).

To ensure continued accuracy in the field a check log was established at the beginning of the project. This is accomplished by counting the same source multiple times and plotting the average and two and three sigma values. A daily check of the meters, employing a radioactive source of known quantity, serves as the accuracy check. A source check "jig" was used to ensure the source and meter are always in the same position relative to one another. The value was plotted on the Quality Control chart against the average and standard deviations as determined previously. If an instruments is greater than plus or minus three standard deviations it is removed from use, and tagged "out of service" until repaired.

All recorded measurements in this final report were obtained with meters that met the criteria for usability.

Representativeness

Representative data would be that data which accurately reflects the environment where the measurement was obtained. One measurement of this parameter is to simply compare the number of times the premise the data is intended to show fails, compared to the number of times the premise is tested. For this project, the premise is elevated count rates with the meter indicates contamination. The equation used is:

$$\text{Representativeness} = (1-F/N) \times 100\%$$

For this project the goal is for data to be 100% representative. No hotspots were identified, so this parameter was not evaluated.

Completeness

Completeness is a measure of the amount of valid data obtained compared to the amount that was specified. For the purposes of evaluation, data defined as invalid through a QA review is subtracted from the complete data set to determine the number of valid data points. For this project, completeness was 100%..

Comparability

Comparability is a non quantitative evaluation of the agreement between different types of data sets which should be, intuitively, related to each other. For example, on this project, all locations exhibiting elevated fixed beta contamination would also exhibit some removable beta contamination. Again, no areas of elevated activity were encountered, so no evaluation of this parameter was attempted.

Sensitivity

To determine a meters suitability for a measurement, the minimum detectable concentration (MDC) is compared with the project specific release limits. The minimum detectable activity was calculated using an equation from NUREG-5849, and the average of the daily background and source checks. Meters and count times were adjusted so that the fixed activity MDC's were less than 20% of the release limits.

Data Reduction

All data was reported at the 95% confidence level. Basic parameters such as efficiency and background were evaluated from instrument check logs to determine if the values were within expected ranges. When several transformations of the data were required, a few values were traced from raw data to reported value to ensure continuity of data, and absence of transcription errors. Results in disintegration per minute (dpm) were only reported as whole numbers. Surface activity values were reported in dpm/100 cm².

Quality Assurance Conclusion

The equipment and methods employed for the collection of data in this report represent best industry practices for radiological decommissioning surveys. Detection sensitivities were 25% of the release criteria, and the self imposed release criteria itself was less than 10% of the allowable limits. The precision and accuracy of the data were evaluated, and found to be within prescribed industry standards.

The most current and accepted guidance document, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) was used for the survey design and data analysis.

The areas surveyed meet all applicable radiation protection standards, with the highest level of data confidence, and may be released for unrestricted use. This report should be maintained for review by the Nuclear Regulatory Commission.

References

U.S. Nuclear Regulatory Commission (NRC), NUREG/CR-5849, *Manual for Conducting Radiological Surveys in Support of License Termination*. Draft Report for Comment, June 1992

U.S. Nuclear Regulatory Commission (NRC), NUREG-1500 *Working Draft Regulatory Guide on Release Criteria for Decommissioning*. Draft Report for Comment, August 1994

U.S. Nuclear Regulatory Commission (NRC), NUREG-1505 *A Nonparametric Statistical Methodology for the Design and Analysis of Final Status Decommissioning Surveys*. Draft Report for Comment, August 1995

U.S. Nuclear Regulatory Commission (NRC), NUREG-1506 *Measurement Methods for Radiological Surveys in Support of New Decommissioning Criteria*. Draft Report for Comment, August 1995

U.S. Nuclear Regulatory Commission (NRC), NUREG-1507 *Minimum Detectable Concentrations with Typical Radiation Survey Instruments for Various Contaminants and Field Conditions*. Draft Report for Comment, August 1995

U.S. Nuclear Regulatory Commission (NRC) *Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material*., Policy and Guidance Directive FC 83-23. November 1983

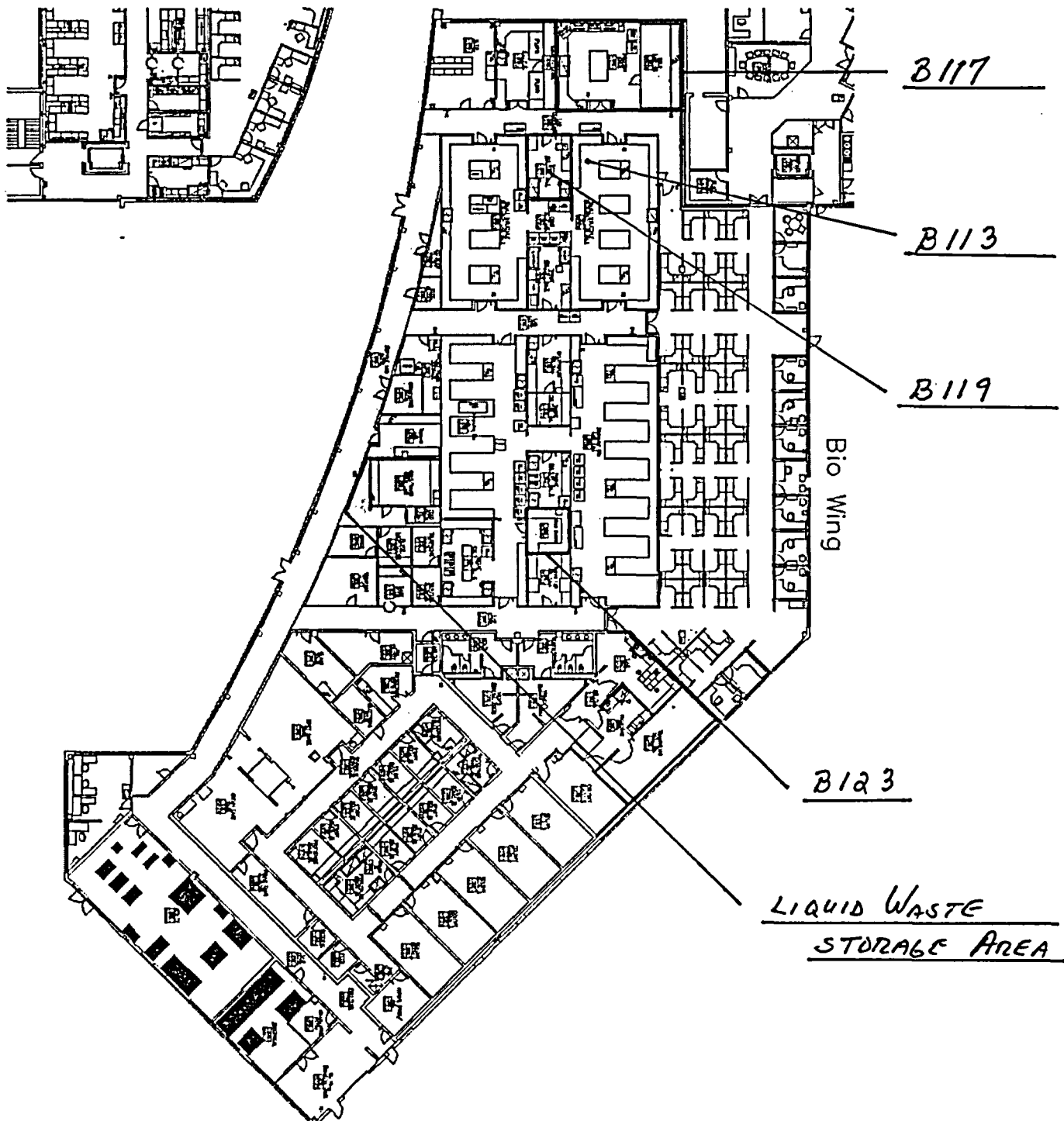
Environmental Protection Agency (EPA) EPA 540/G-93/071 *Data Quality Objectives Process for Superfund*. Washington, DC 1994

U.S. Nuclear Regulatory Commission (NRC), NUREG-1575 *Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)*

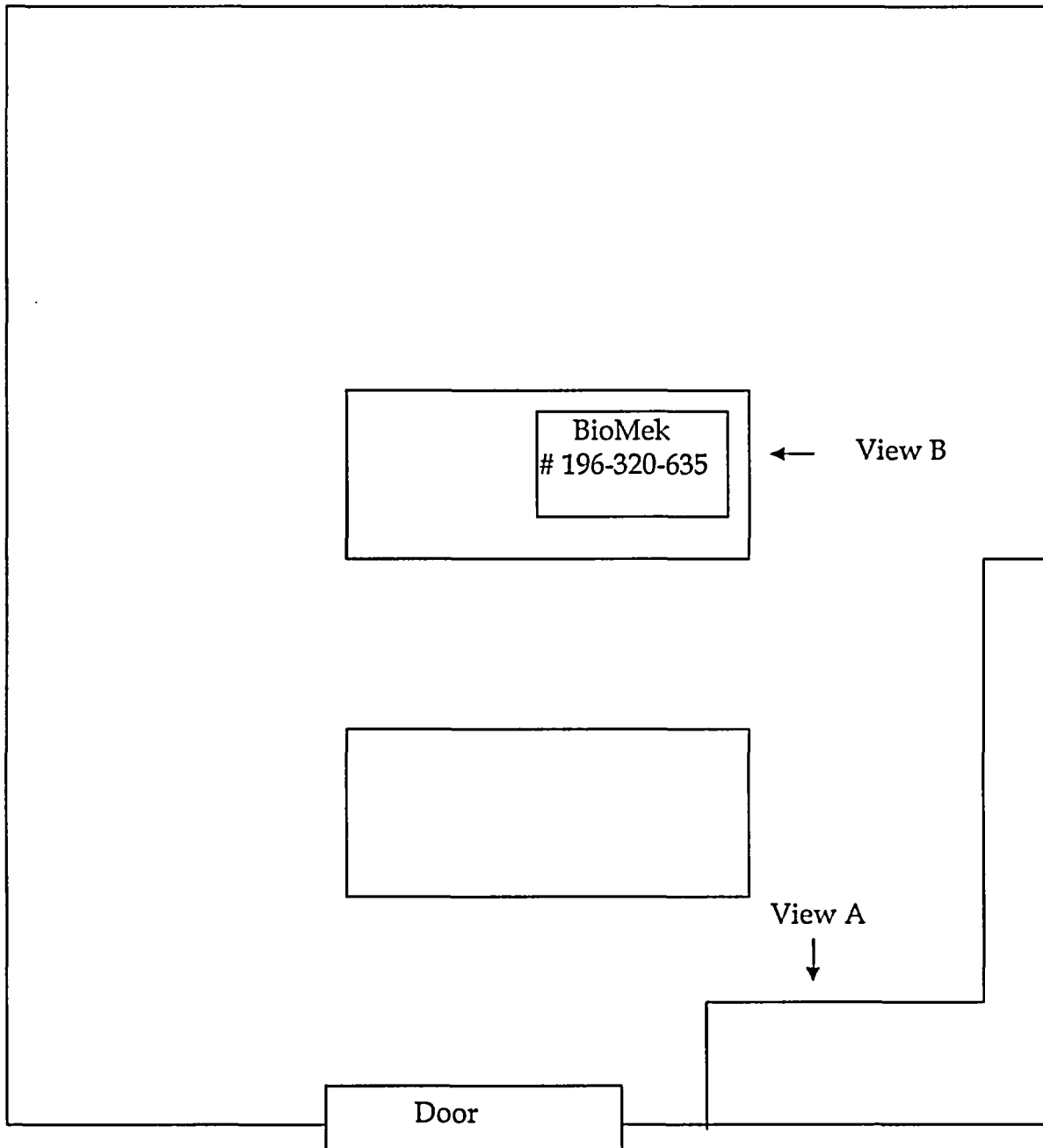
Appendix A

Photo-documentation of Sampling Locations and Room Diagrams

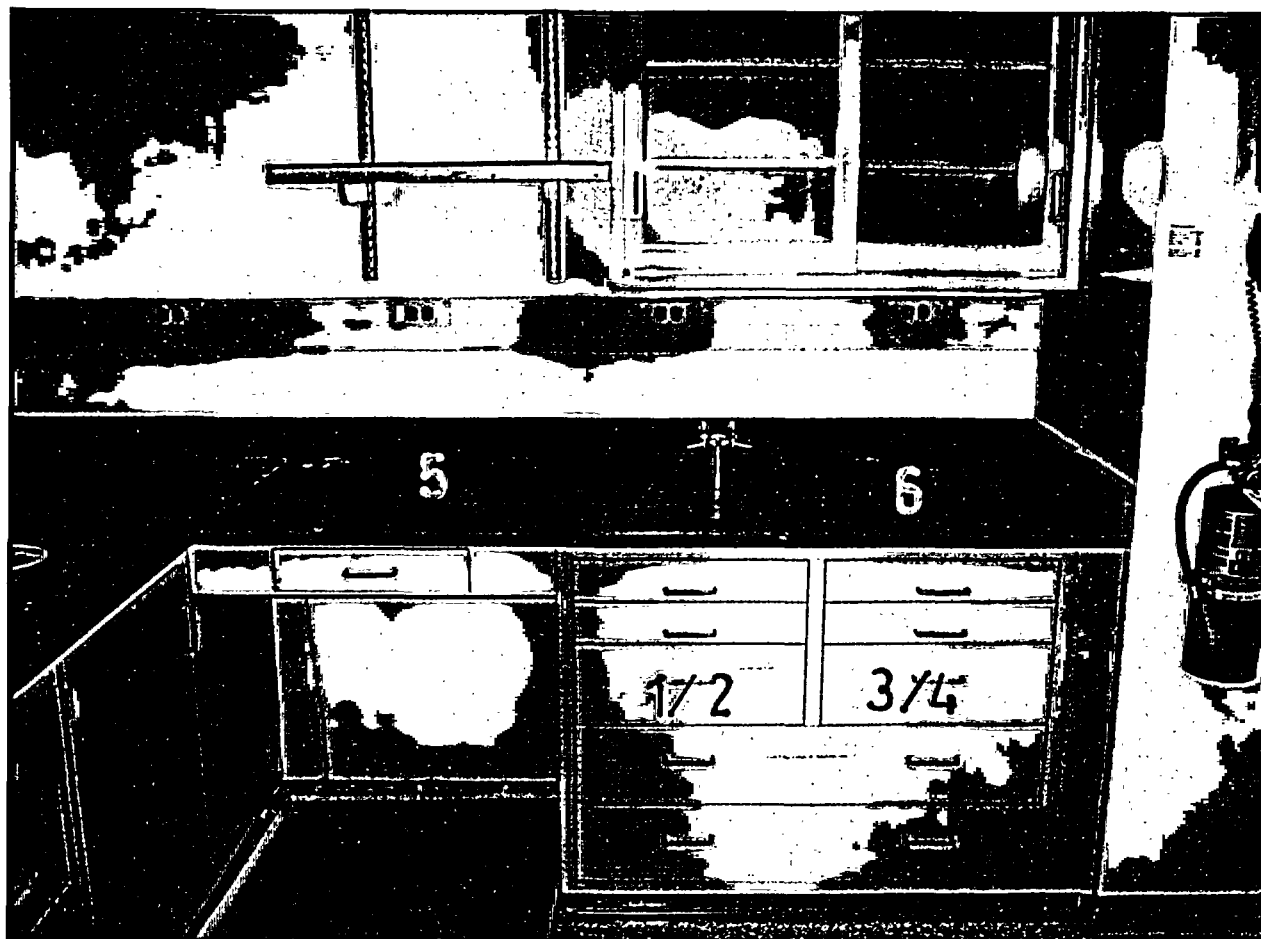
West Wing Diagram



B-113

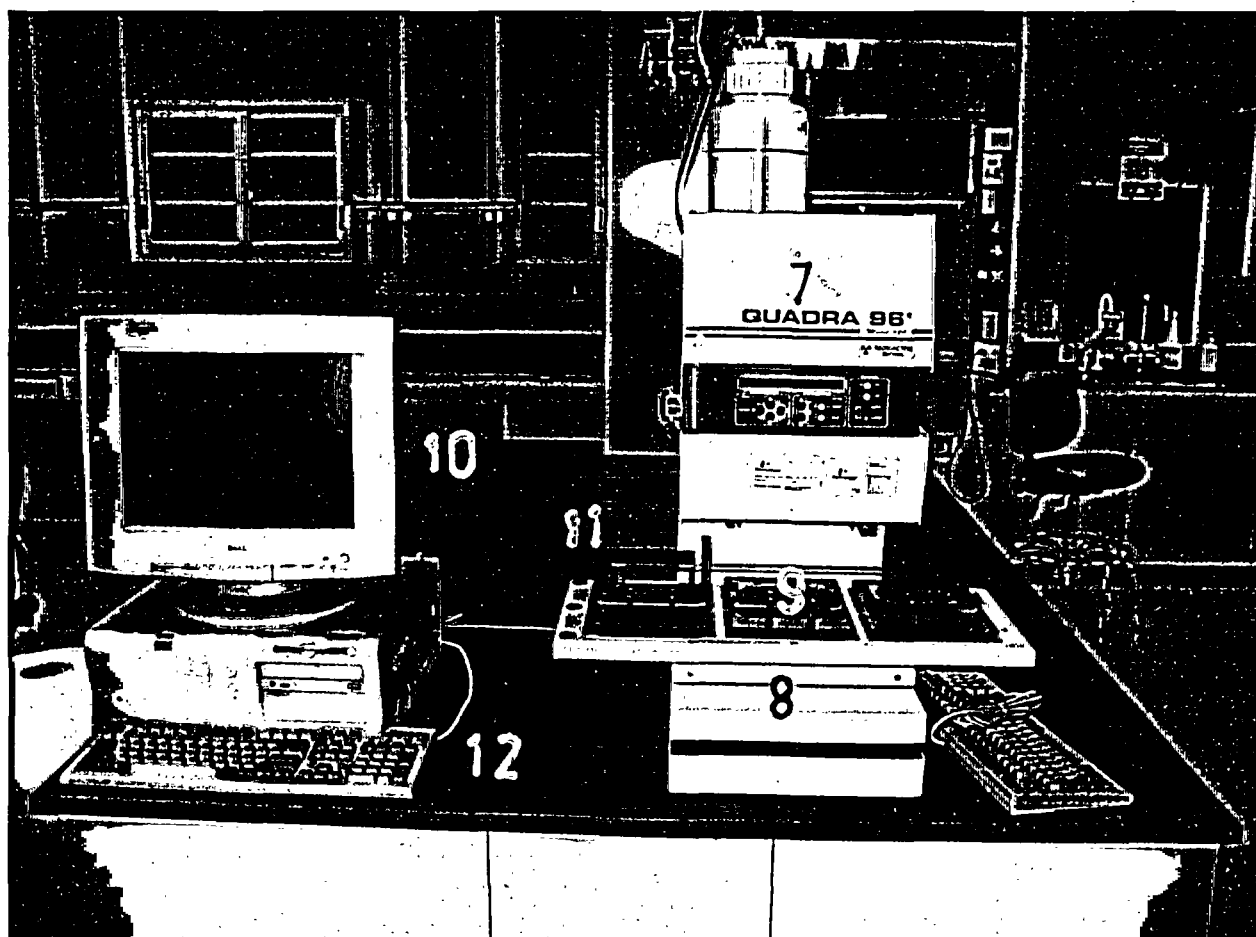


Only two small areas in this entire laboratory utilized radioactive material.



Laboratory B 113 - View A

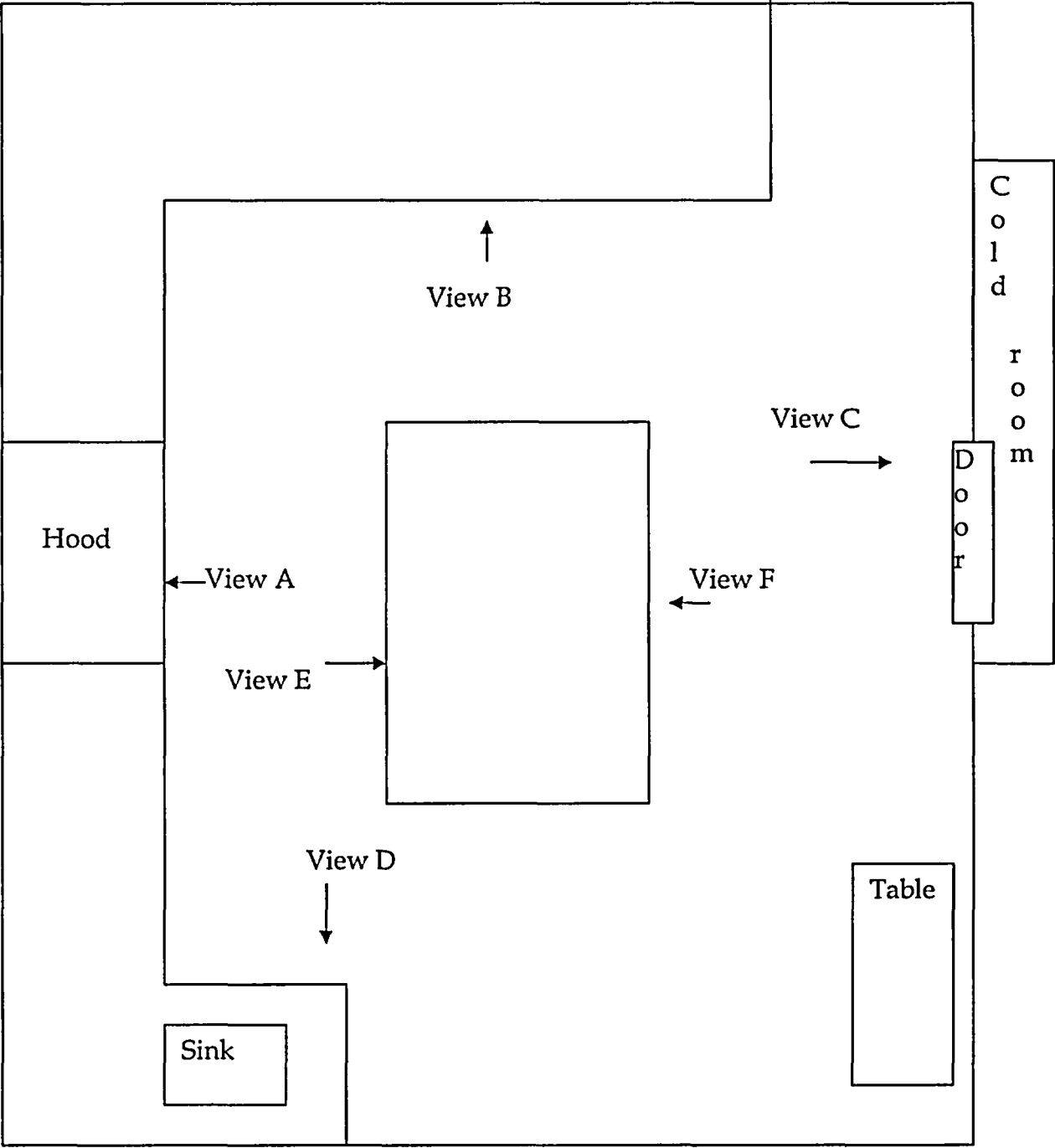
Measurement Locations

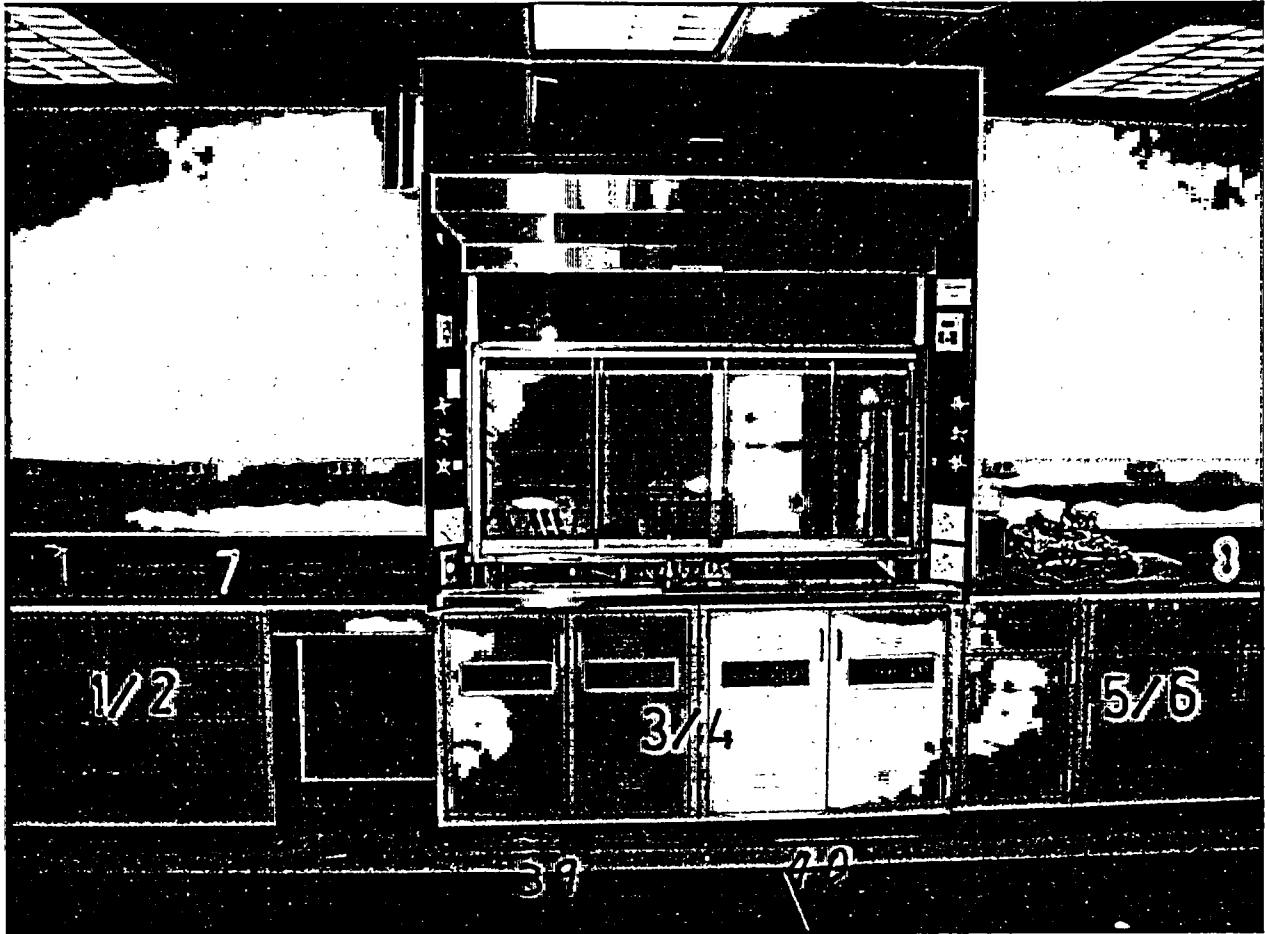


Laboratory B 113 - View B

Measurement Locations

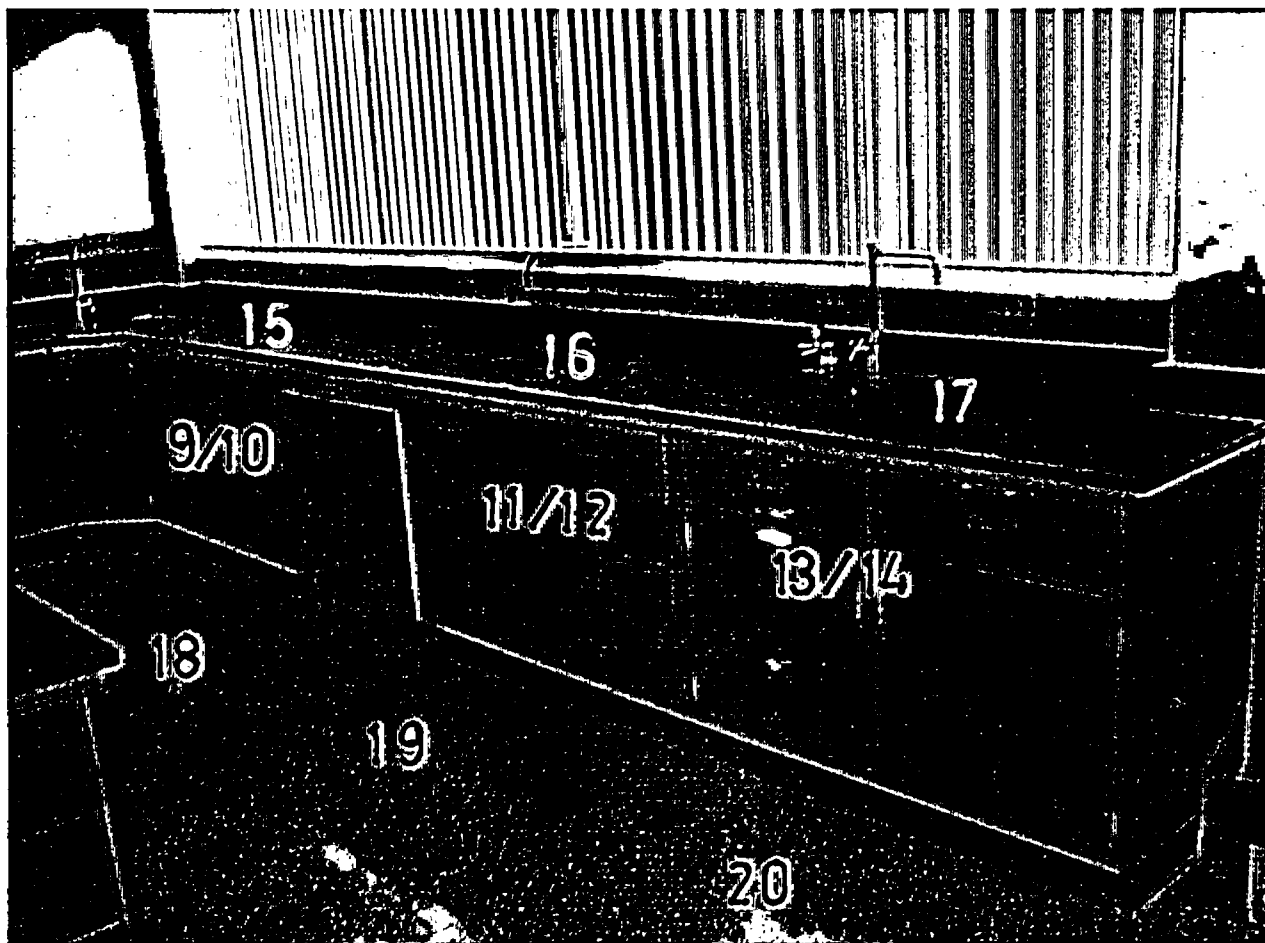
B-117





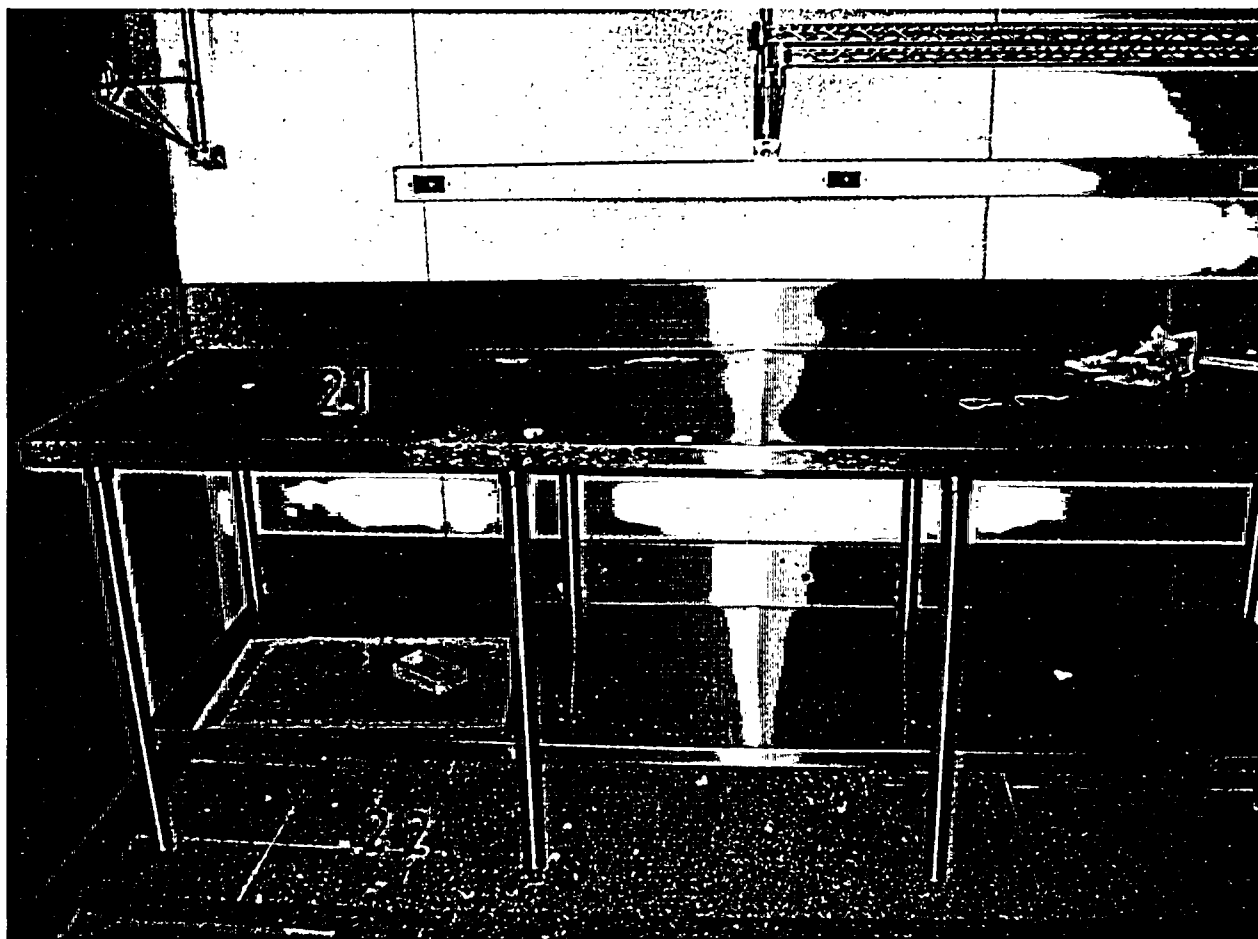
Laboratory B 117 - View A

Measurement Locations



Laboratory B 117 - View B

Measurement Locations



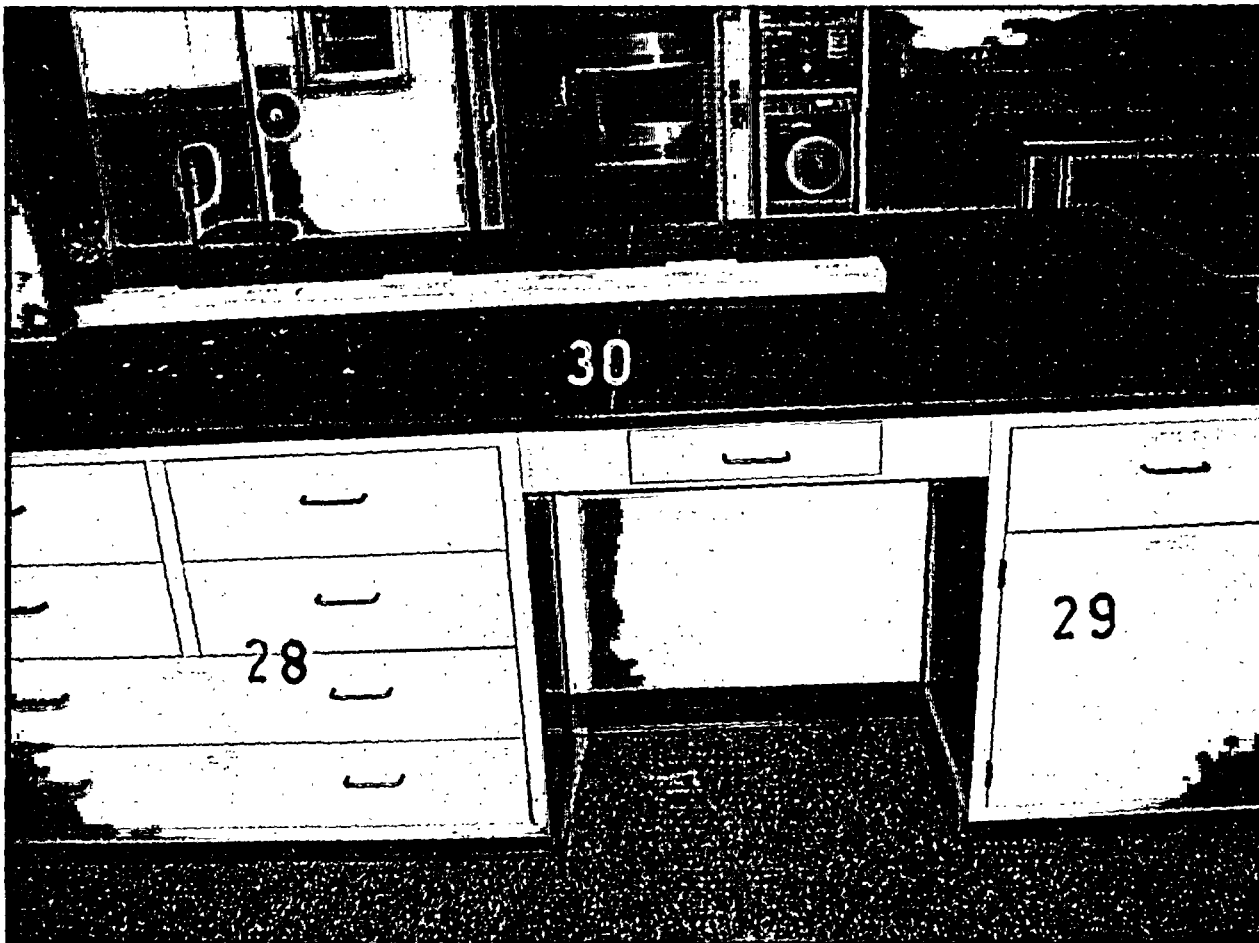
Laboratory B 117 - View C

Measurement Locations



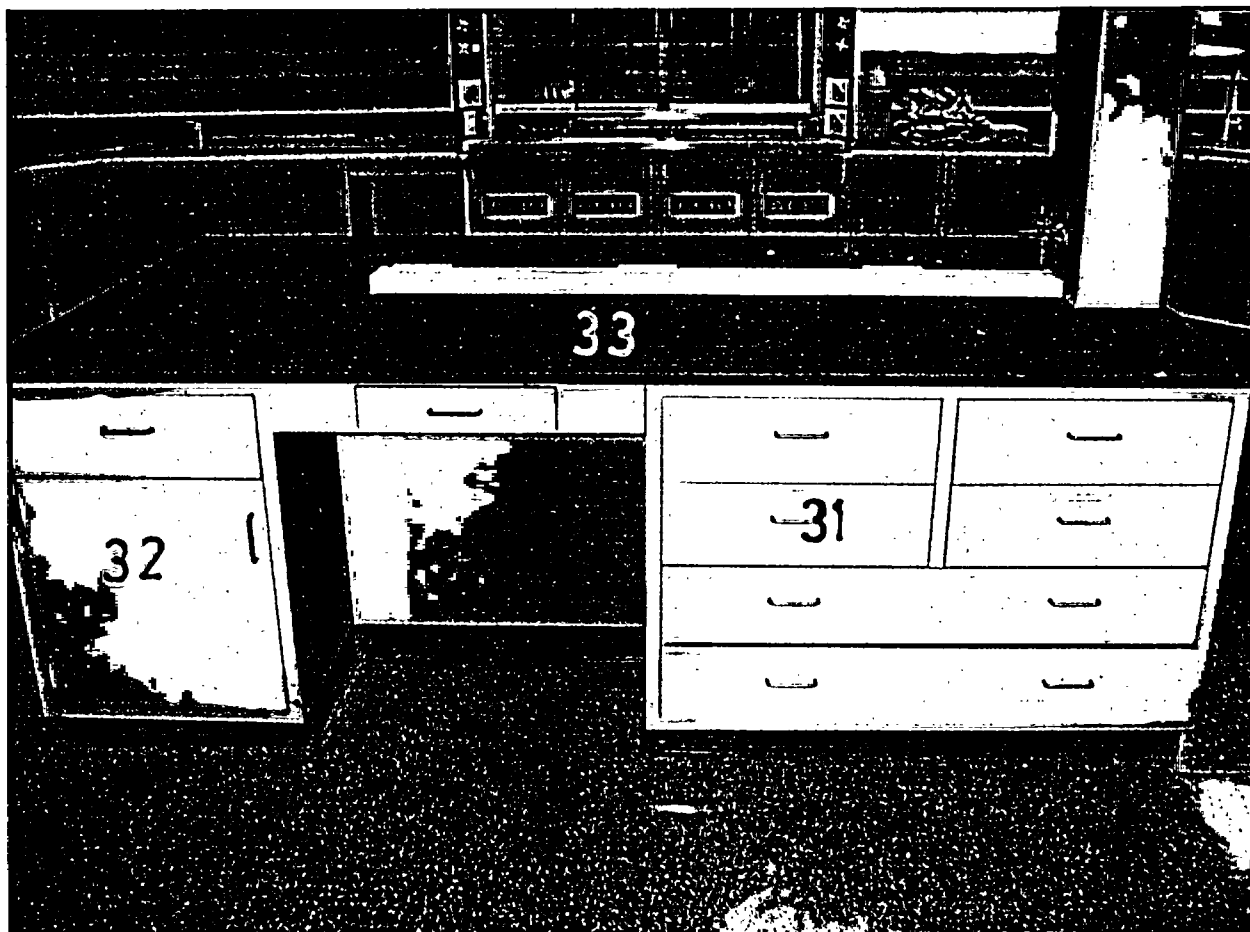
Laboratory B 117 - View D

Measurement Locations



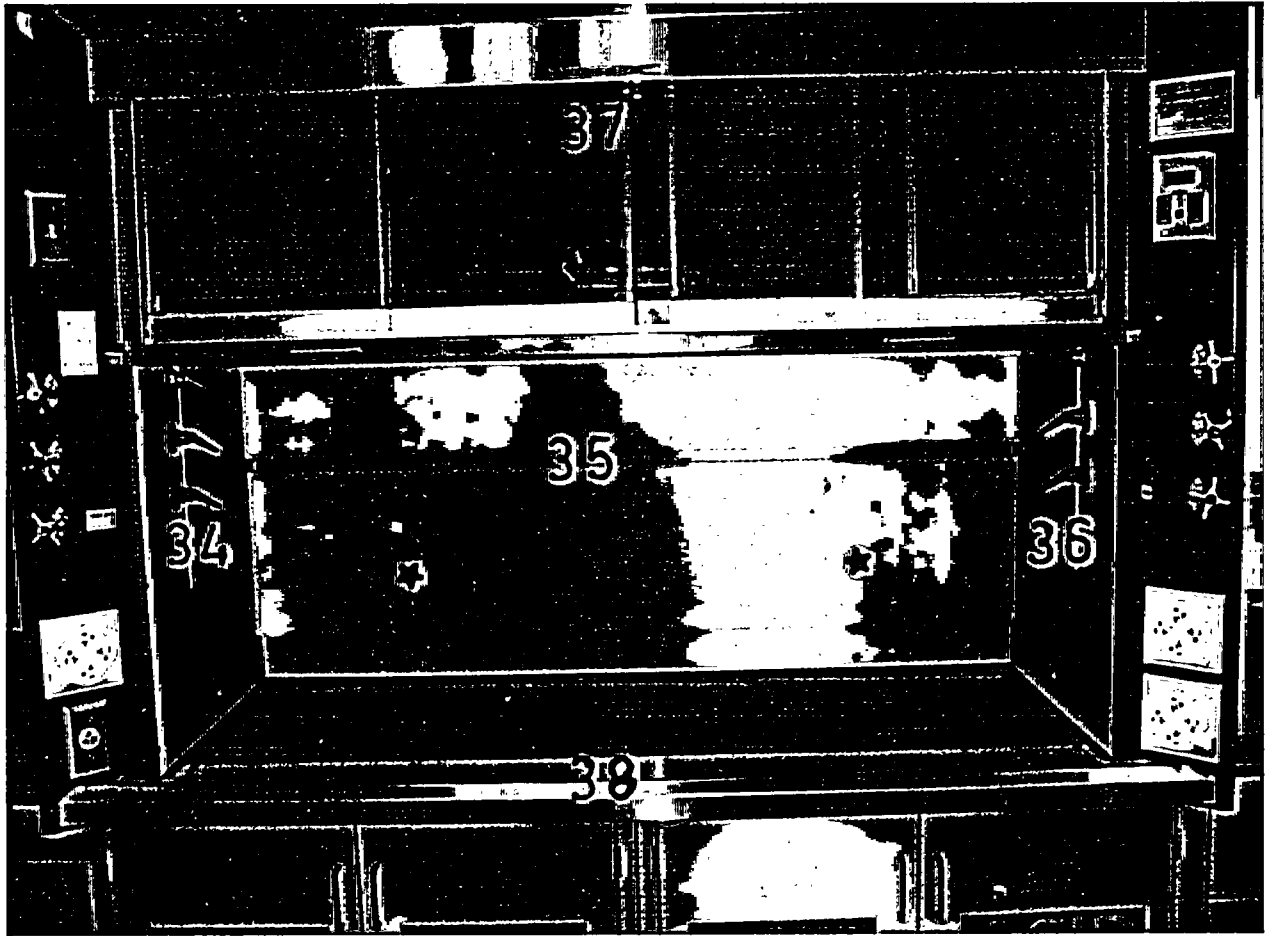
Laboratory B 117 - View E

Measurement Locations



Laboratory B 117 - View F

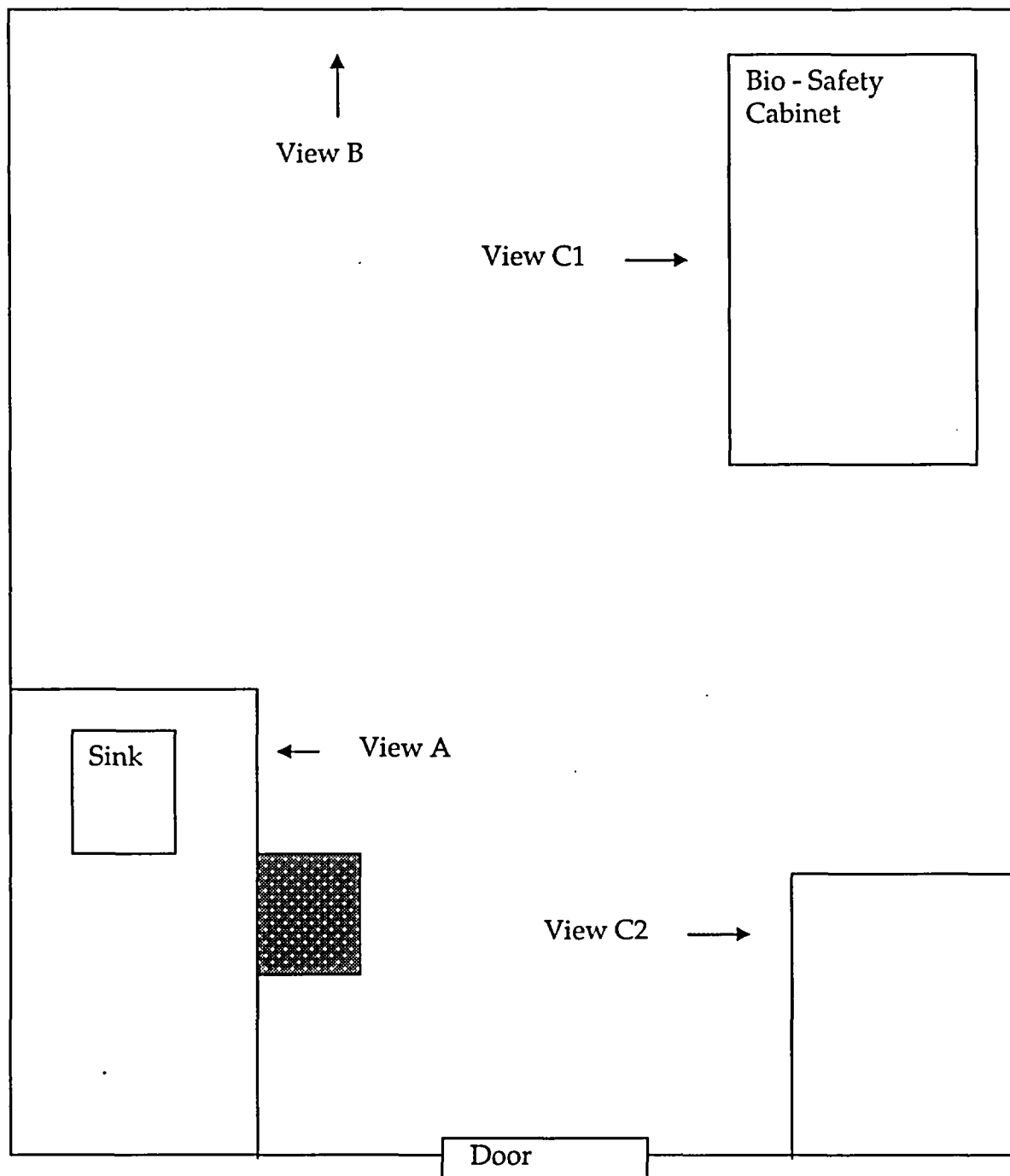
Measurement Locations

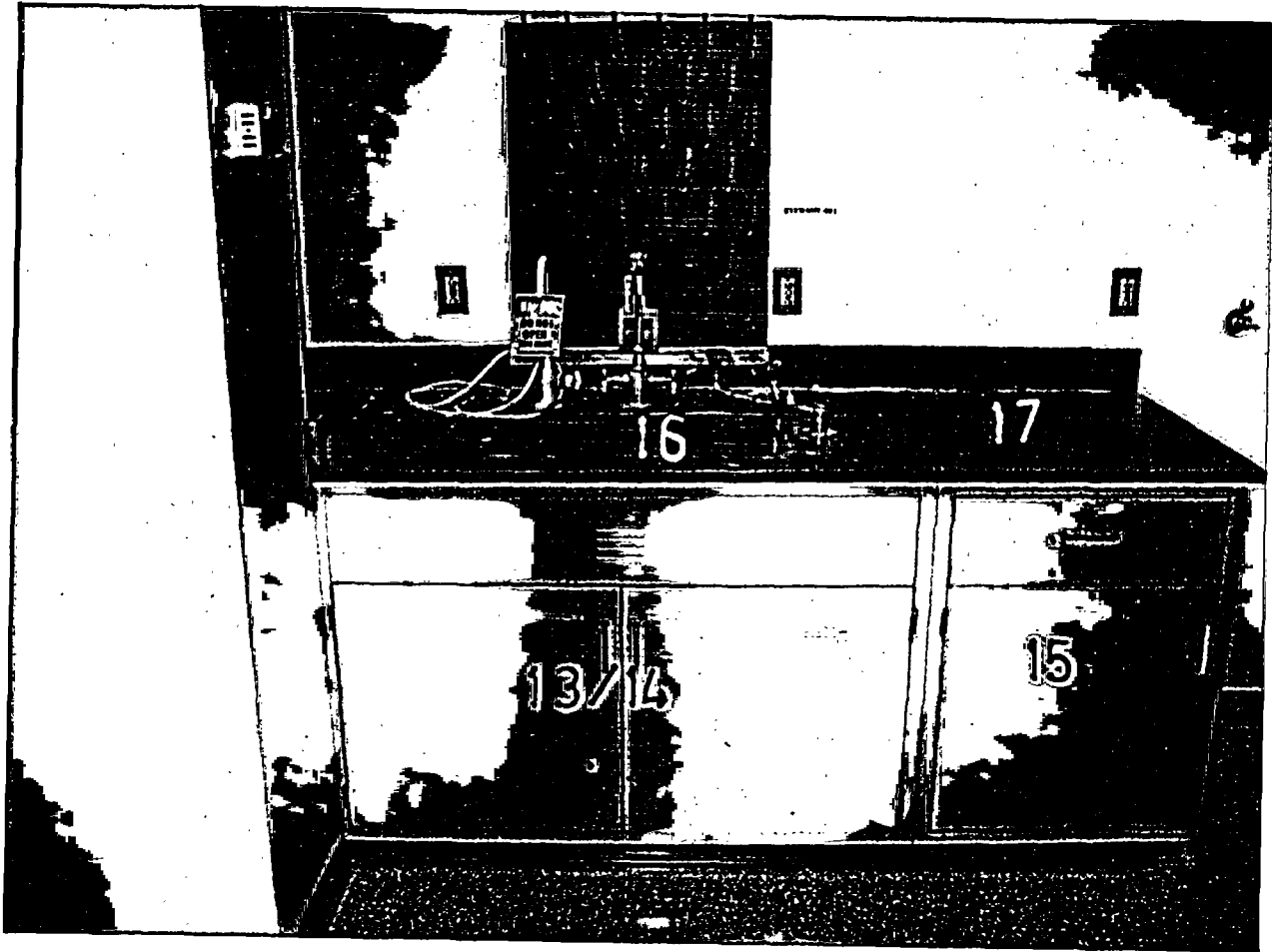


Laboratory B 117 - Hood

Measurement Locations

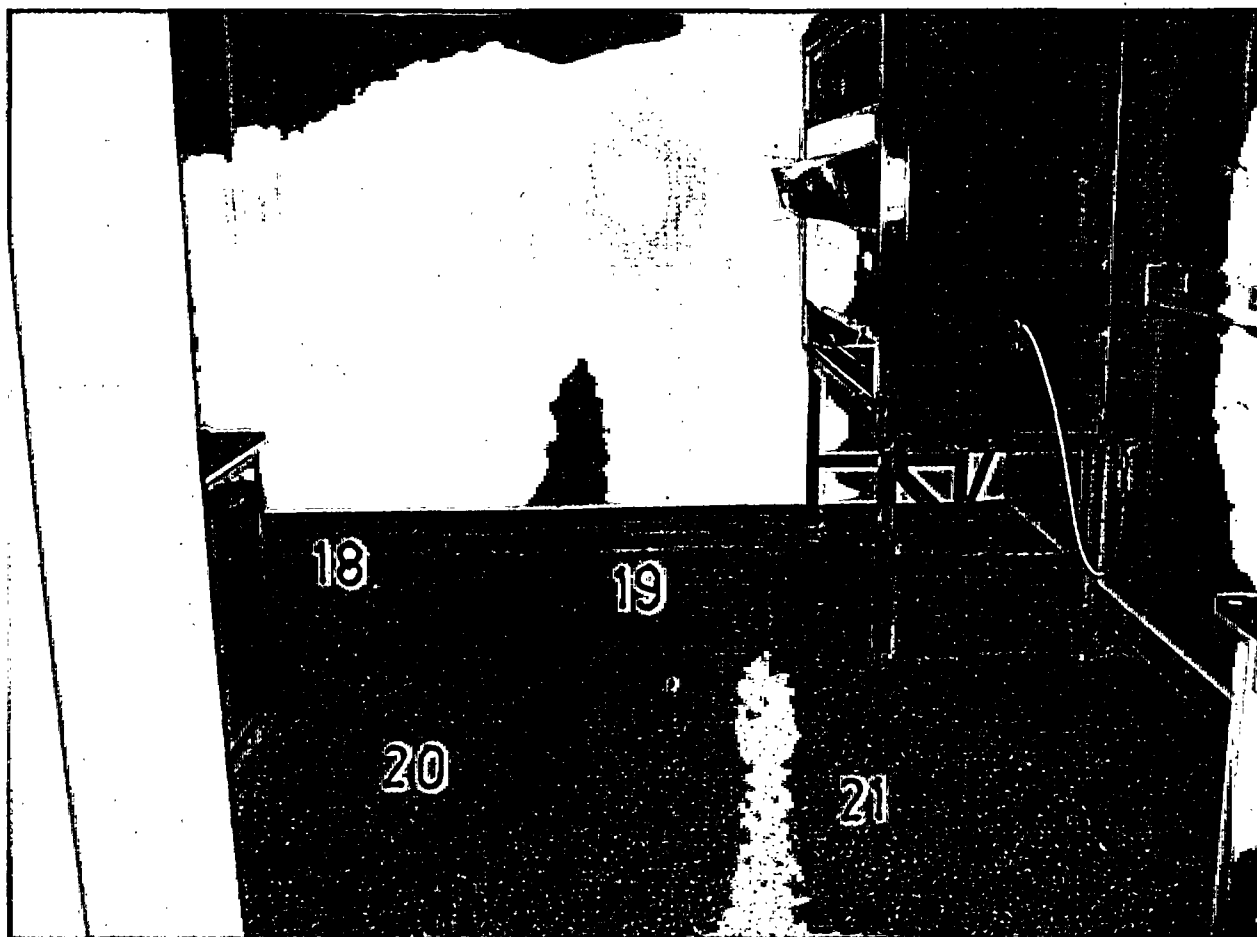
B-119





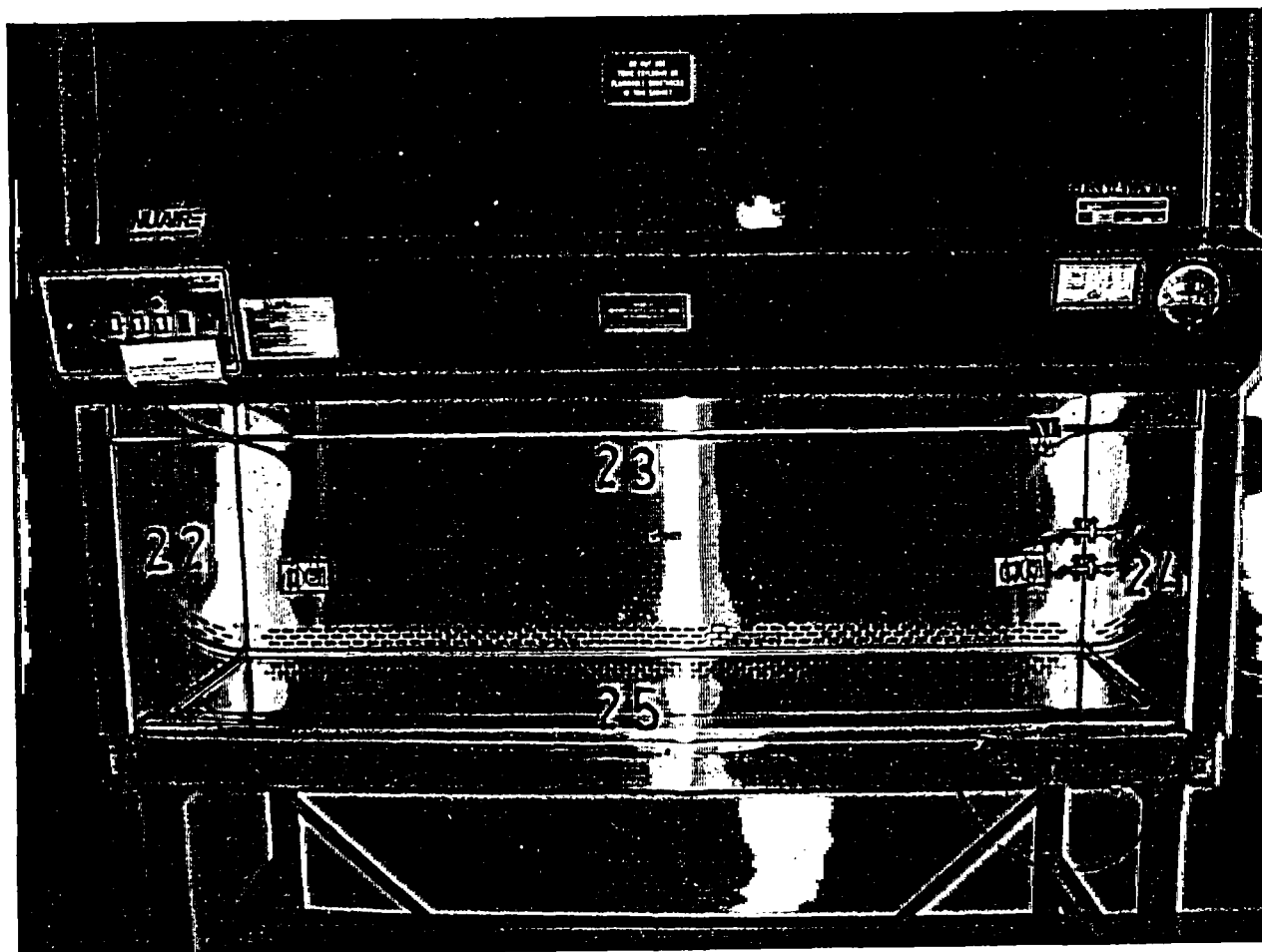
Laboratory B 119 - View A

Measurement Locations



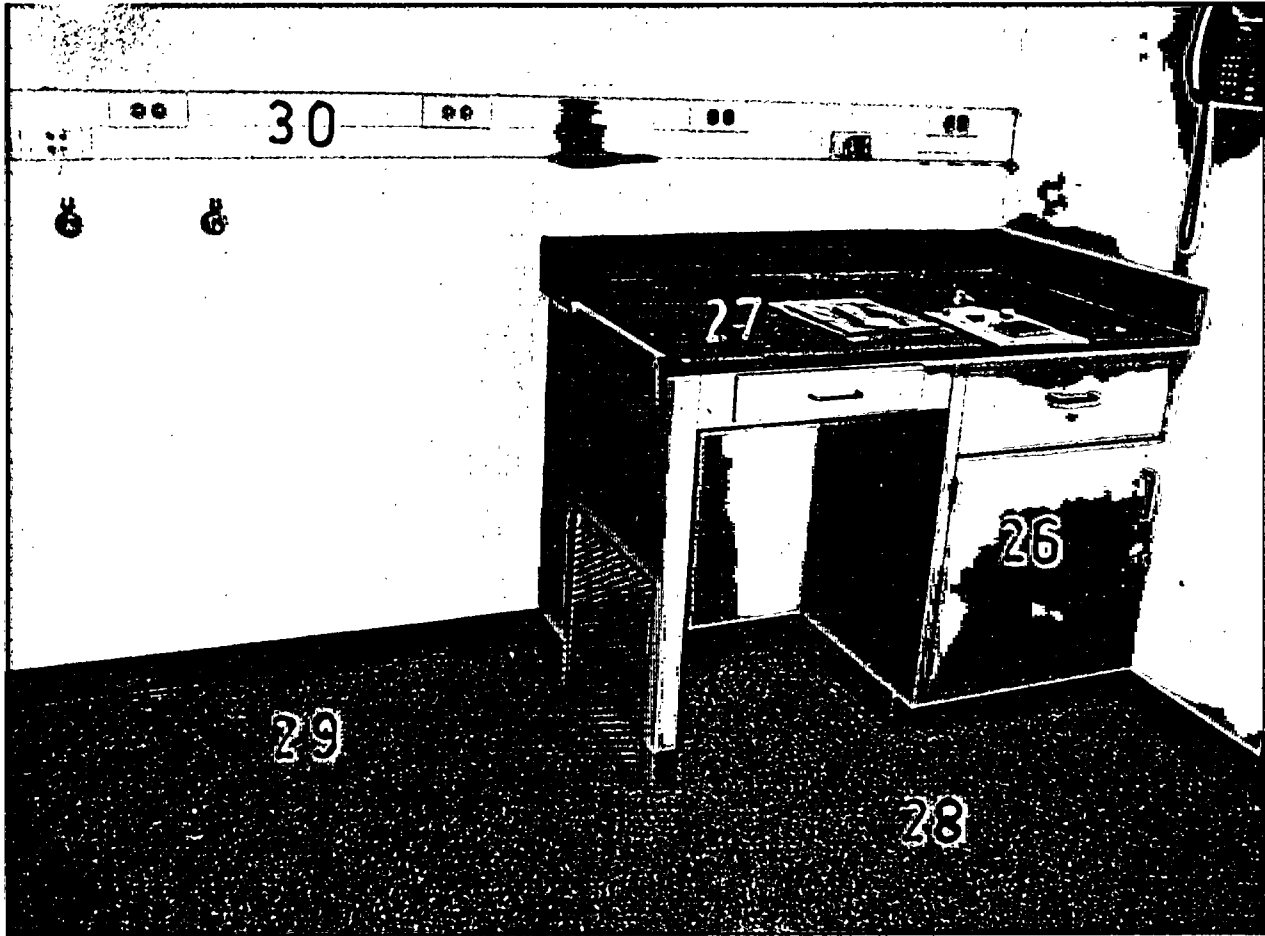
Laboratory B 119 - View B

Measurement Locations



Laboratory B 119 - View C1

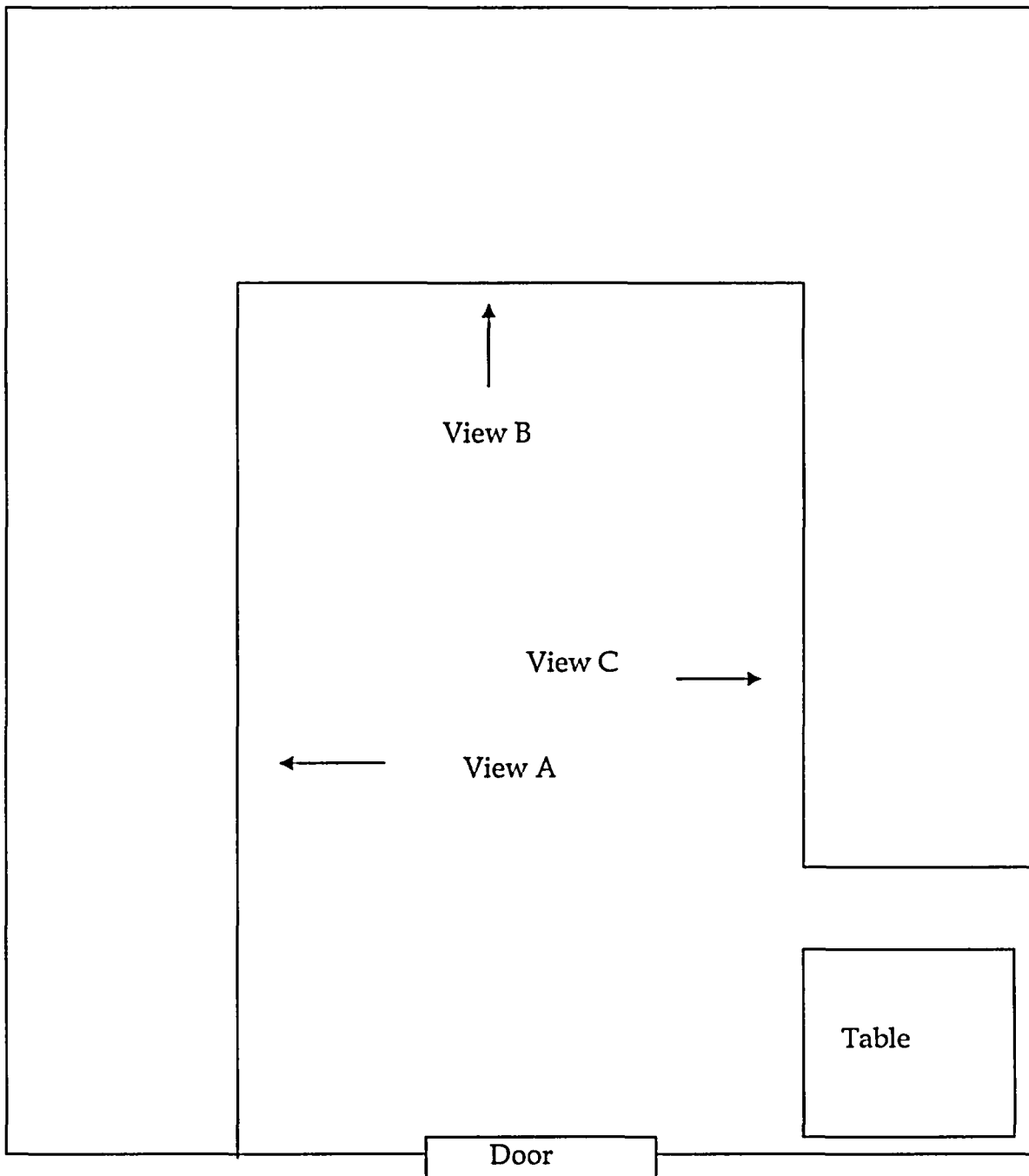
Measurement Locations

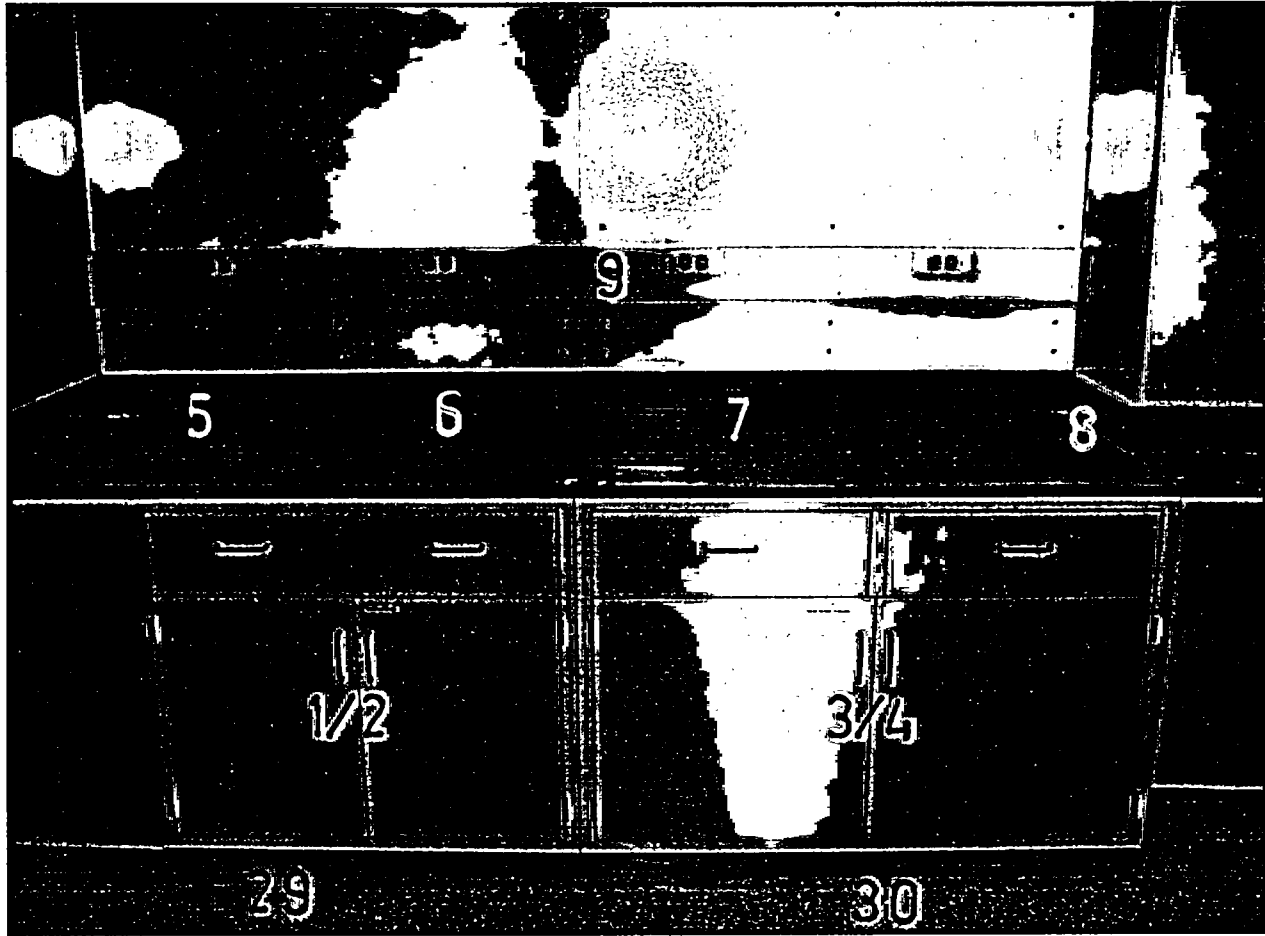


Laboratory B 119 - View C2

Measurement Locations

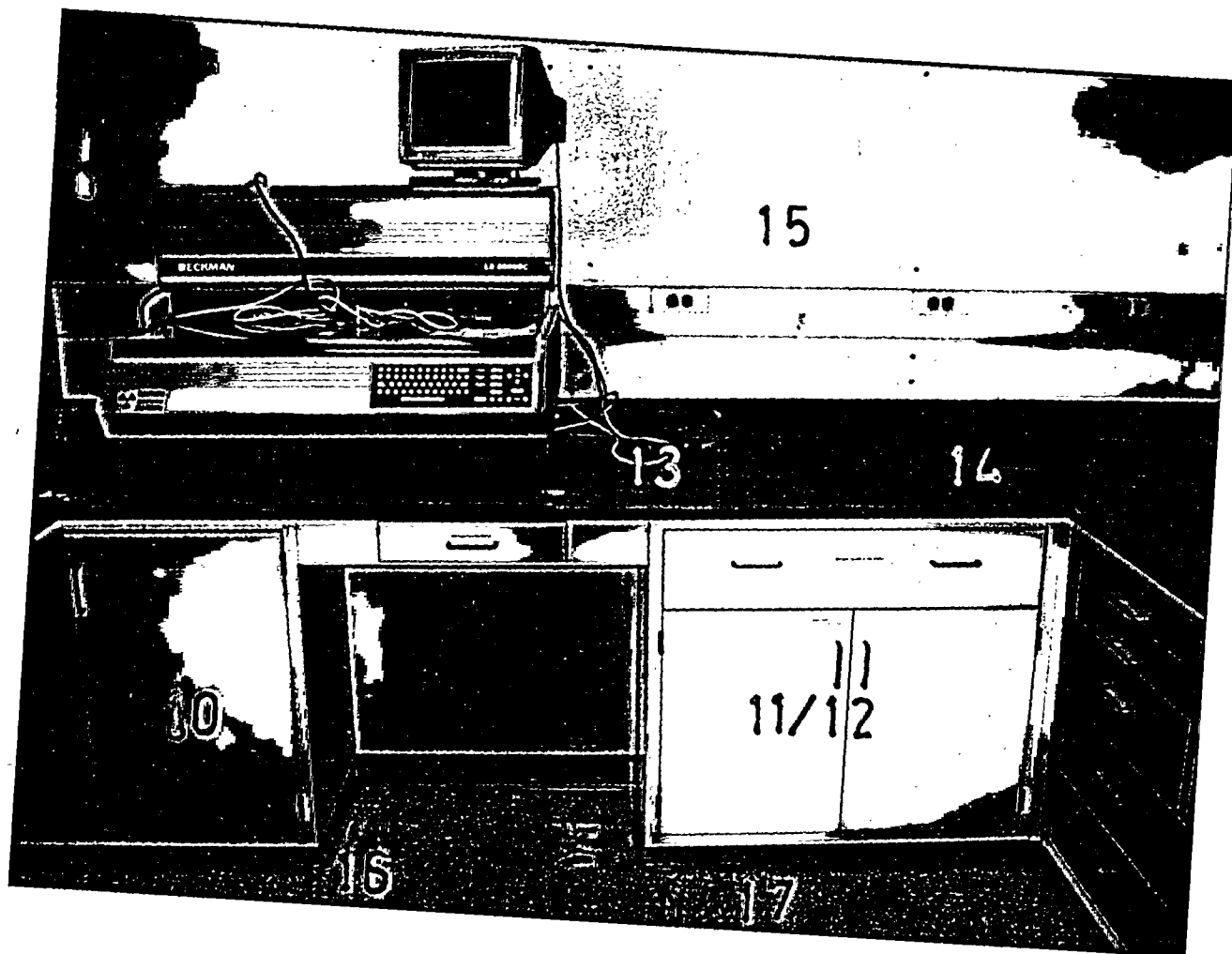
B-123





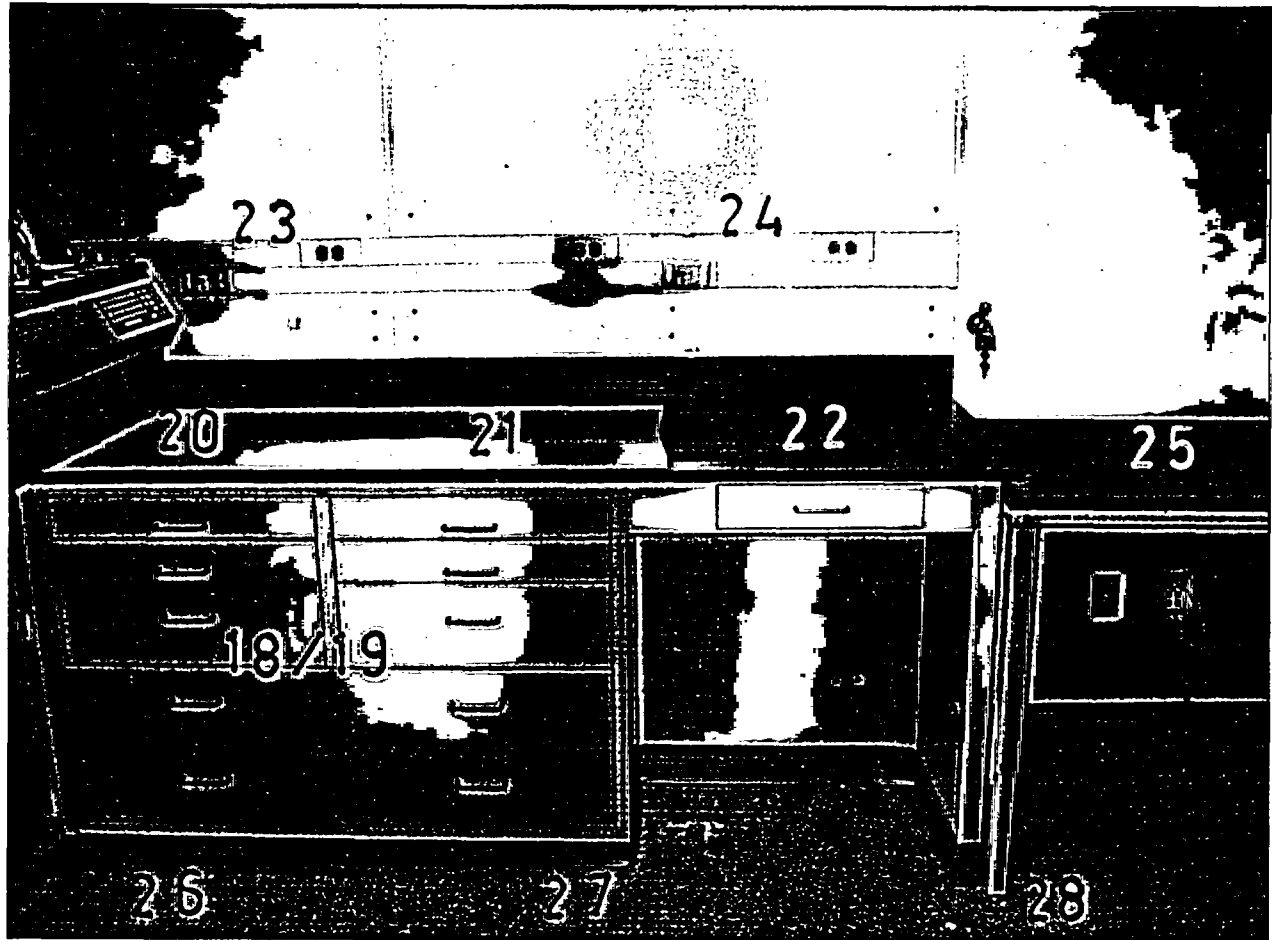
Laboratory B 123 - View A

Measurement Locations



Laboratory B 123 - View B

Measurement Locations

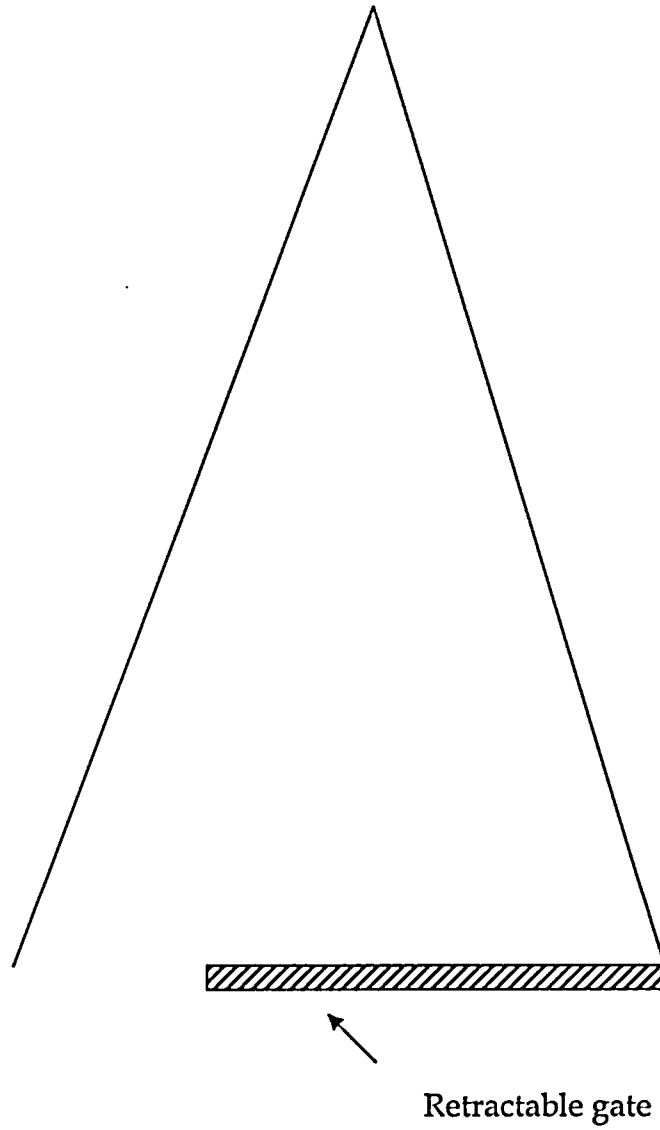


Laboratory B 123 - View C

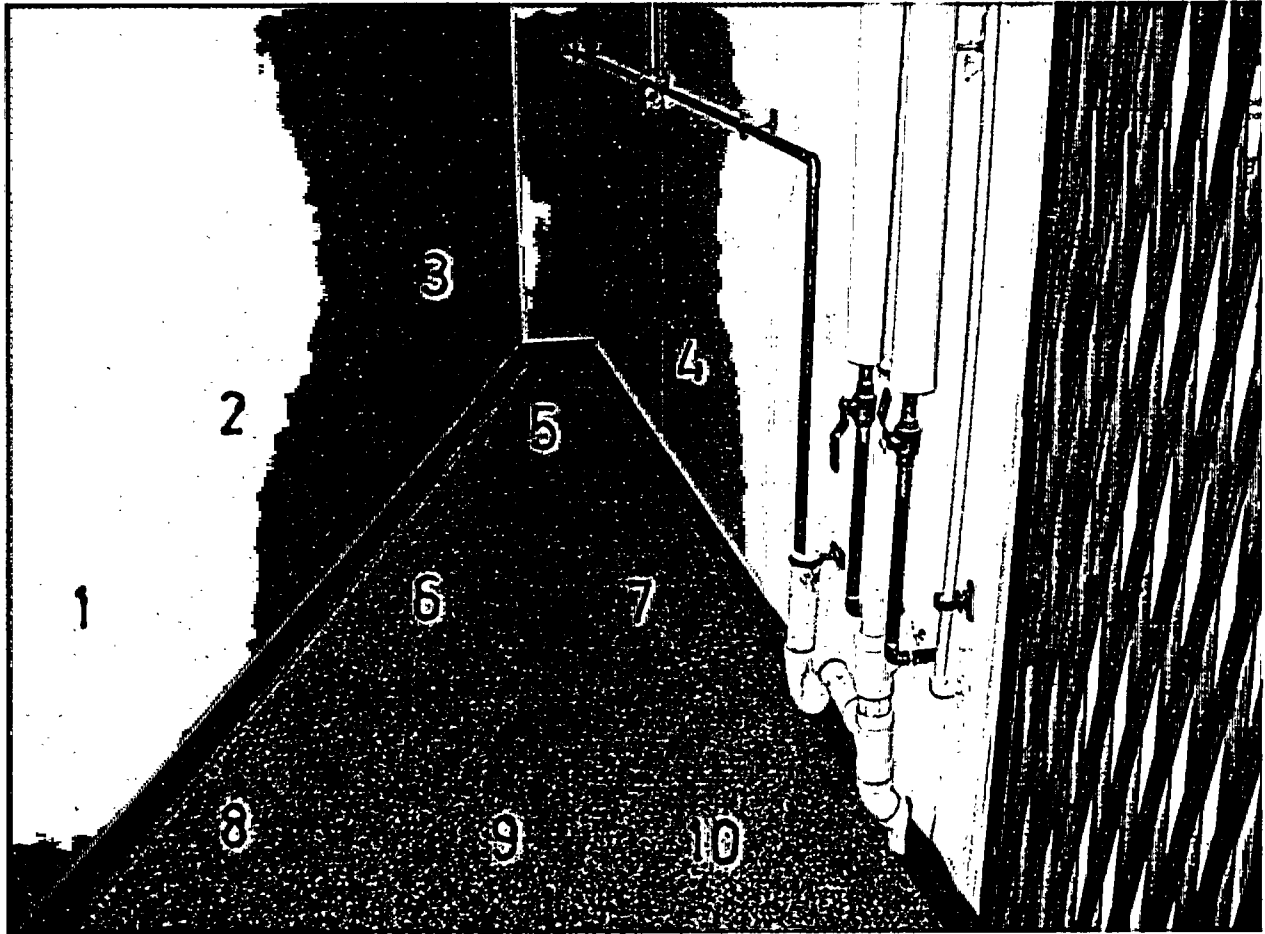
Measurement Locations

Bench covering was removed and LSC was relocated to survey bench-top underneath.

Liquid Radioactive Waste Storage



The Liquid Waste Storage area was a gated corner off a service corridor.



Liquid Radioactive Waste Storage Area

Measurement Locations

Appendix B

MicroBeta Counter Printouts

Liquid Scintillation Counter Log Sheet

Counter: Wallac Microbeta

Loaded By: S. Dennerlein Count Date 2/24/05

Sample Type: Wipes X Liquids Solids

[illegible]

Comments _____

c:\data\3h-swipes\A17_117.txt

RUN INFORMATION:

=====

Counting protocol no: 17

Thu 24-Feb-2005 11:36

Name: PACKAGE_AREA_SURVEYS

CPM normalization protocol no: -

*** DETECTORS NOT NORMALIZED

COLUMNS:

=====

SAMPLE	POS	CPM1
Unk_1	A01	50
Unk_2	A02	36
Unk_3	A03	41
Unk_4	A04	48
Unk_5	A05	41
Unk_6	A06	29
Unk_7	B01	39
Unk_8	B02	44
Unk_9	B03	43
Unk_10	B04	37
Unk_11	B05	40
Unk_12	B06	41
Unk_13	C01	35
Unk_14	C02	34
Unk_15	C03	38
Unk_16	C04	25
Unk_17	C05	33
Unk_18	C06	30
Unk_19	D01	35
Unk_20	D02	32
Unk_21	D03	29
Unk_22	D04	37
Unk_23	D05	35
Unk_24	D06	46
Unk_25	A01	35
Unk_26	A02	26
Unk_27	A03	31
Unk_28	A04	33
Unk_29	A05	31
Unk_30	A06	25
Unk_31	B01	31
Unk_32	B02	42
Unk_33	B03	35
Unk_34	B04	33
Unk_35	B05	38
Unk_36	B06	26
Unk_37	C01	36
Unk_38	C02	30
Unk_39	C03	34
Unk_40	C04	38
Unk_41	C05	36
Unk_42	C06	27
Unk_43	D01	33
Unk_44	D02	27
Unk_45	D03	27
Unk_46	D04	39
Unk_47	D05	35
Unk_48	D06	23
Unk_49	A01	38
Unk_50	A02	24
Unk_51	A03	28
Unk_52	A04	37
Unk_53	A05	31
Unk_54	A06	38
Unk_55	B01	27
Unk_56	B02	25
Unk_57	B03	33
Unk_58	B04	21
Unk_59	B05	32
Unk_60	B06	32
Unk_61	C01	30
Unk_62	C02	33

Unk_63	C03	35
Unk_64	C04	36
Unk_65	C05	73
Unk_66	C06	54
Unk_67	D01	28
Unk_68	D02	20
Unk_69	D03	34
Unk_70	D04	29
Unk_71	D05	26
Unk_72	D06	25
Unk_73	A01	30
Unk_74	A02	31
Unk_75	A03	31
Unk_76	A04	33
Unk_77	A05	31
Unk_78	A06	25
Unk_79	B01	32
Unk_80	B02	31
Unk_81	B03	34
Unk_82	B04	29
Unk_83	B05	30
Unk_84	B06	17
Unk_85	C01	27
Unk_86	C02	38
Unk_87	C03	45
Unk_88	C04	33
Unk_89	C05	31
Unk_90	C06	38
Unk_91	D01	48
Unk_92	D02	23
Unk_93	D03	30
Unk_94	D04	34
Unk_95	D05	37
Unk_96	D06	28
Unk_97	A01	30
Unk_98	A02	40
Unk_99	A03	34
Unk_100	A04	34
Unk_101	A05	34
Unk_102	A06	41
Unk_103	B01	40
Unk_104	B02	25
Unk_105	B03	48
Unk_106	B04	32
Unk_107	B05	36
Unk_108	B06	21
Unk_109	C01	40
Unk_110	C02	33
Unk_111	C03	34
Unk_112	C04	28
Unk_113	C05	41
Unk_114	C06	30
Unk_115	D01	37
Unk_116	D02	37
Unk_117	D03	29
Unk_118	D04	36
Unk_119	D05	42
Unk_120	D06	33

Total count rate: 4063.6 CCPM

Liquid Scintillation Counter Log Sheet

Counter: Wallac Microbeta

Loaded By: S. Dennerlein Count Date 12-28-04

Sample Type: Wipes X Liquids _____ Solids _____

[illegible]

Comments _____

c:\data\3h-swipes\A17_111.txt

RUN INFORMATION:

Counting protocol no: 17

Tue 28-Dec-2004 10:44

Name: PACKAGE_AREA_SURVEYS

CPM normalization protocol no: -

*** DETECTORS NOT NORMALIZED

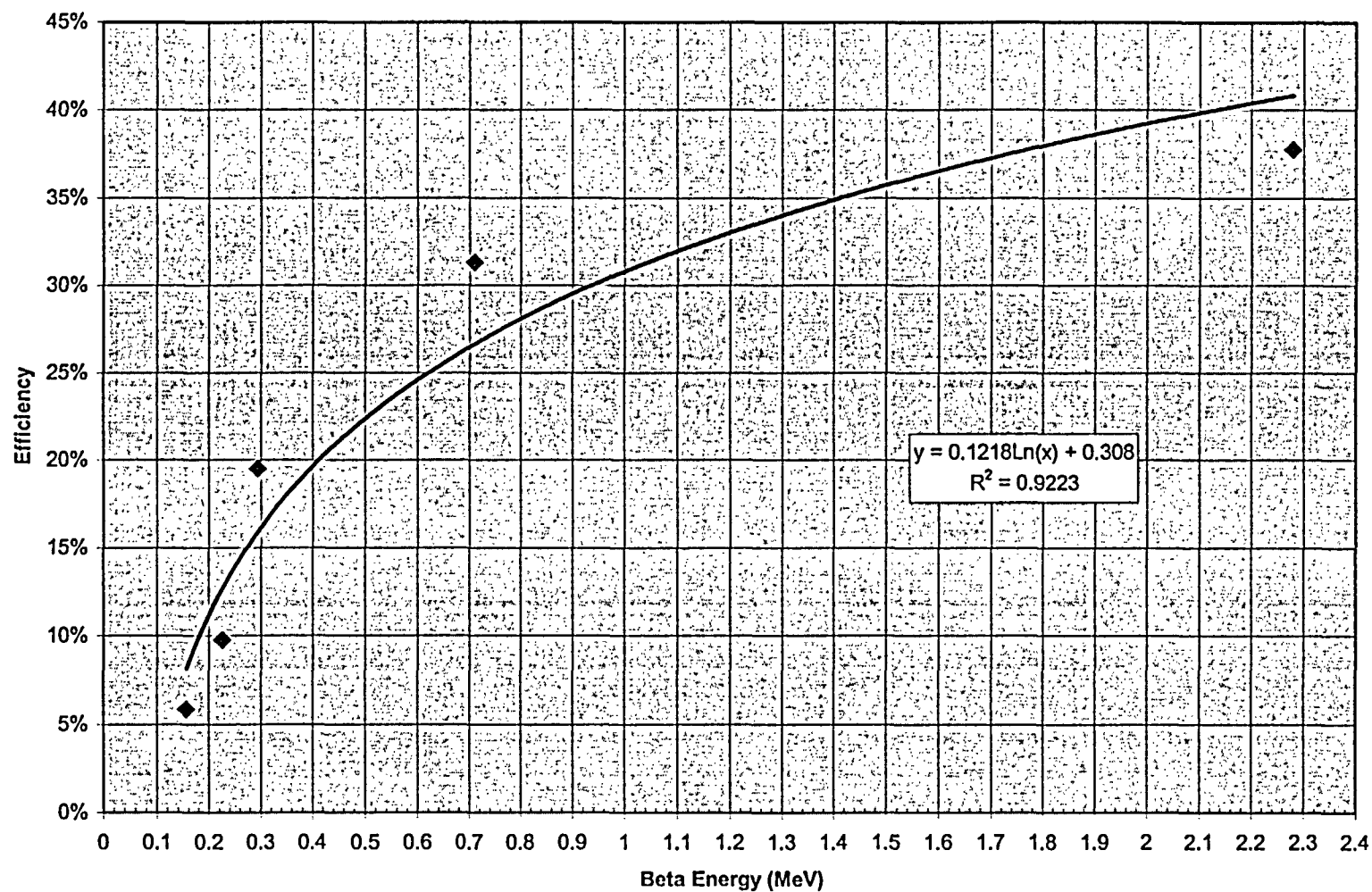
COLUMNS:

SAMPLE	POS	CCPM1
Unk_1	A01	47
Unk_2	A02	47
Unk_3	A03	38
Unk_4	A04	28
Unk_5	A05	31
Unk_6	A06	41
Unk_7	B01	38
Unk_8	B02	55
Unk_9	B03	41
Unk_10	B04	37
Unk_11	B05	44
Unk_12	B06	40
Unk_13	C01	25
Unk_14	C02	31
Unk_15	C03	25
Unk_16	C04	20
Unk_17	C05	24
Unk_18	C06	26
Unk_19	D01	21
Unk_20	D02	24
Unk_21	D03	19
Unk_22	D04	22
Unk_23	D05	16
Unk_24	D06	20

Appendix C

Instrument Calibration
Certificates

Efficiency vs. Energy Curve for Ludlum model 3 # 109793 w/44-9 probe # 073090



Certificate of Calibration

Calibrated For: Scott Dennerlein & Associates, LLC

Meter: Ludlum model 3 # 109793

Probe: 44-9 #073090

Voltage Setting: 900v

Background: 40 cpm

Linearity Test

Scale/Range	Calibration Point	As Found	As Calibrated	Calibration Point	As Found	As Calibrated
0-500	100	100	100	400	400	400
0-5k	1,000	1,000	1,000	4,000	4,000	4,000
0-50k	10,000	10,000	10,000	40,000	40,000	40,000
0-500k	100,000	100,000	100,000	400,000	400,000	400,000

Efficiency Determination

Isotope / serial#	NIST Activity	Net Counts	cpm/dpm 4π
C-14 841-31-3	224,442	13,000	0.06
Pm-147 841-36-2	21,674	2,129	0.10
Tc-99 841-32-1	23,510	4,532	0.20
Cl-36 841-33-2	22,289	6,910	0.31
Sr/Y-90 841-35-2	22,711	17,051	0.38

Comments: Check source (#1709) range 4,000 - 5,000 cpm

Calibrated By: Scott Dennerlein

Date: 1/15/2005

This is to acknowledge the receipt of your letter/application dated

4/21/2005, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amend 29-30698-01 There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned Mail Control Number 136944.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

: (FOR LFMS USE)
: INFORMATION FROM LTS
: -----
:
: Program Code: 03620
: Status Code: 0
: Fee Category: 3E 3M
: Exp. Date: 20120131
: Fee Comments: _____
: Decom Fin Assur Req'd: N
:

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED

Applicant/Licensee: PURDUE PHARMA, L.P.
Received Date: 20050426
Docket No: 3035882
Control No.: 136944
License No.: 29-30698-01
Action Type: Amendment

2. FEE ATTACHED

Amount: /
Check No.: /

3. COMMENTS

Signed Rebecca J. J. J.
Date 6/12/05

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered /__/)

1. Fee Category and Amount: _____

2. Correct Fee Paid. Application may be processed for:

Amendment _____
Renewal _____
License _____

3. OTHER _____

Signed _____
Date _____