SIGNUM

Innovative Healthcare Solutions

NMSB2

April 14, 2008

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

03036545

Amendment request for NRC License #29-30906-01

Dear Sir/Madam,

Signum Bioscience requests an amendment to our radioactive material license. Please remove 1 Deer Park Drive as an authorized location of use. A decommissioning survey report is enclosed.

Thank you in advance for your time and effort. Do not hesitate to contact me at 732 329-6344 if you have any questions.

Sincerely,

Maxwell Stock

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NMSS/RGN1 MATERIALS-002

7 Deer park Drive, Suite H Monmouth Junction, NJ 08852 www.signumbiosciences.com office 732.329.6344 fax 732-329-8344

Decommissioning Survey
for
Signum Biosciences, Inc.

NRC License # 29-30906-01

March 2008

Prepared by
Scott Dennerlein & Associates, LLC
NRC License # 29-30366-01

Introduction

On March 19th, 2008 Scott Dennerlein & Associates, LLC, conducted a decommissioning survey for Signum Biosciences in their laboratories at 1 Deer Park Drive, Monmouth Junction, New Jersey. The intent of the survey was to document the final radiological conditions in two laboratories, formerly utilized for radioactive material research. A request to remove this facility from the existing license will accompany this report. In the year prior to the survey, all radiological work was limited to millicurie amounts of tritium, carbon-14, and sulfur-35. 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 contamination-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 leased space is situated in a research park comprised of several buildings along a commercial stretch of Route 1. The NRC license (29-30906-01) is a specific license, limited to non-volatile forms, and was issued approximately four years ago. Routine monthly surveys have not revealed any contamination in the labs. The licensee has no other (i.e, State of New Jersey) radioactive material license. There has been a single Radiation Safety Officer for the life of the license, and this final survey was conducted under his guidance.

Radionuclides of Concern

There are no alpha emitters listed on the license, and a review of the inventory, waste manifests, and package receipt surveys, indicate the only possible contaminants would be ^{3}H, ^{14}C, or ^{35}S. The intent of this survey is to release the facilities at 1 Deer Park Drive for unrestricted use.

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 Total 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 radionuclides are presented in Table 1, below.

Radionuclide	Surface Contamination ($dpm/100cm^2$)
^{3}H	5,290,000
^{14}C	158,000
^{35}S	1,340,000

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

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/100cm^2 ". Therefore the DCGL for this project will be 5,000 dpm/100cm^2, with the knowledge that this value would deliver a TEDE far below 3 mrem/y.

Survey Units

The affected laboratories were surveyed as a 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 the decommissioning. The use of ^{3}H, ^{14}C, and ^{35}S in these areas falls in to this category.

Class 1 areas are surveyed by scanning 100% of all horizontal surfaces, and vertical surfaces to a height of two meters. Stationary, time integrated measurements of surface activity and wipe sampling for removable contamination are conducted at random and selected locations in each survey unit. The number of measurements required in each unit is determined as specified below.

Survey Design

The number of data points necessary for a given survey unit in this survey plan is based on 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 likely contaminants fall into this category of radionuclides. In terms of data reduction, this means the survey units are not compared to a reference (i.e. background) area, but are compared directly to the DCGL. The equation below 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 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 cm^2 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;

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

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 6% efficiency for the detection of C-14 and a 120 cm^2 probe. This would make the gray region from 300 cpm to 150 cpm. Thirty percent of the DCGL would give a standard deviation of 90. The relative shift would then be;

$$\Delta/\sigma = (300\text{-}150)/90 = 1.66$$

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 into the above equation gives the number of data points, N 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 xenon gas 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. After the scanning survey, fixed location measurements were obtained with the same probe and a five minute integrated count at twenty four locations. These locations were chosen at random, and are approximately the same areas where removable contamination was sampled by wiping a one inch dry filter paper over one hundred square centimeters. A floor plan of the surveyed area is provided, indicating the measurement locations. Table 2 lists the field detector, laboratory equipment and their associated parameters.

Detector	Probe area (cm^2)	Background (cpm)	Efficiency (cpm/dpm) 4π	Approximate Sensitivity		
				L_c counts	L_D counts	MDC dpm/100 cm^2
44-26	120	320	0.06 (^{14}C)	41	86	1,194
Packard LSC 156-2000 keV	N/A	30	0.51 (^{3}H) 0.94 (^{14}C)	13	29	57

Table 2. Detection Sensitivities for Survey Instrumentation

Where ;

$$L_c = 2.33\sqrt{B} \qquad L_D = 3 + 4.65\sqrt{B} \qquad MDC = \frac{3 + 4.65\sqrt{B}}{T\,\varepsilon_T A}$$

*where T = integrated count time
ε_T = total efficiency
A = area of probe / 100 cm^2
B = background countrate

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

Statistical Test of Measurement Results

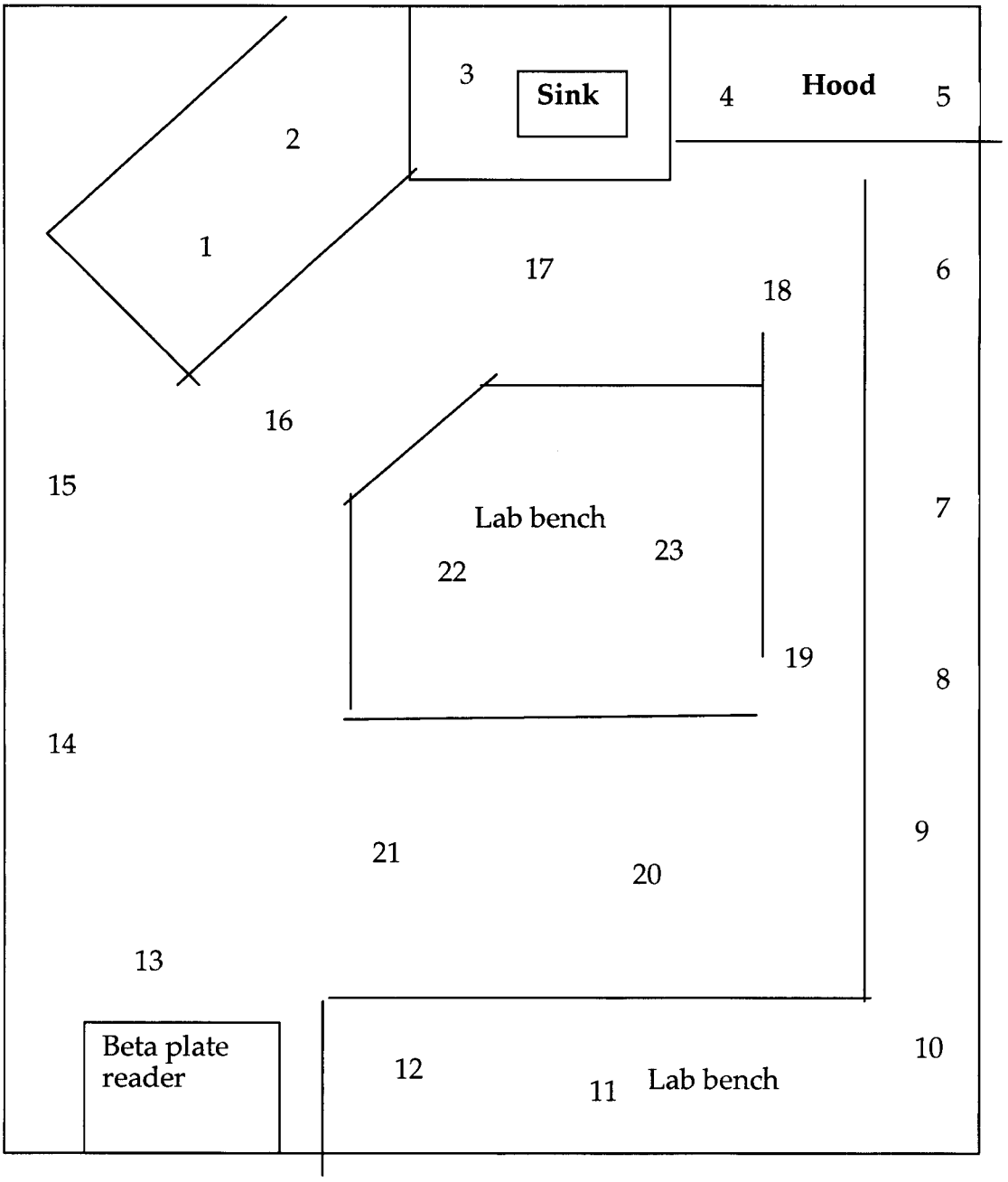
Summary of Statistical Tests

Location	Survey Type	N	S+	Critical Value	Meets Release Criteria?
Upstairs Lab	Total β	24	24	17	**YES**
Downstairs Lab	Total β	24	24	17	**YES**

These measurements would represent the total beta, 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.

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). Since the concept of negative disintegrations per minute is meaningless, values below the background count rate are assigned the value of 5,000 dpm, the release limit. 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 cm^2.

Upstairs Laboratory – Location of fixed and removable measurements



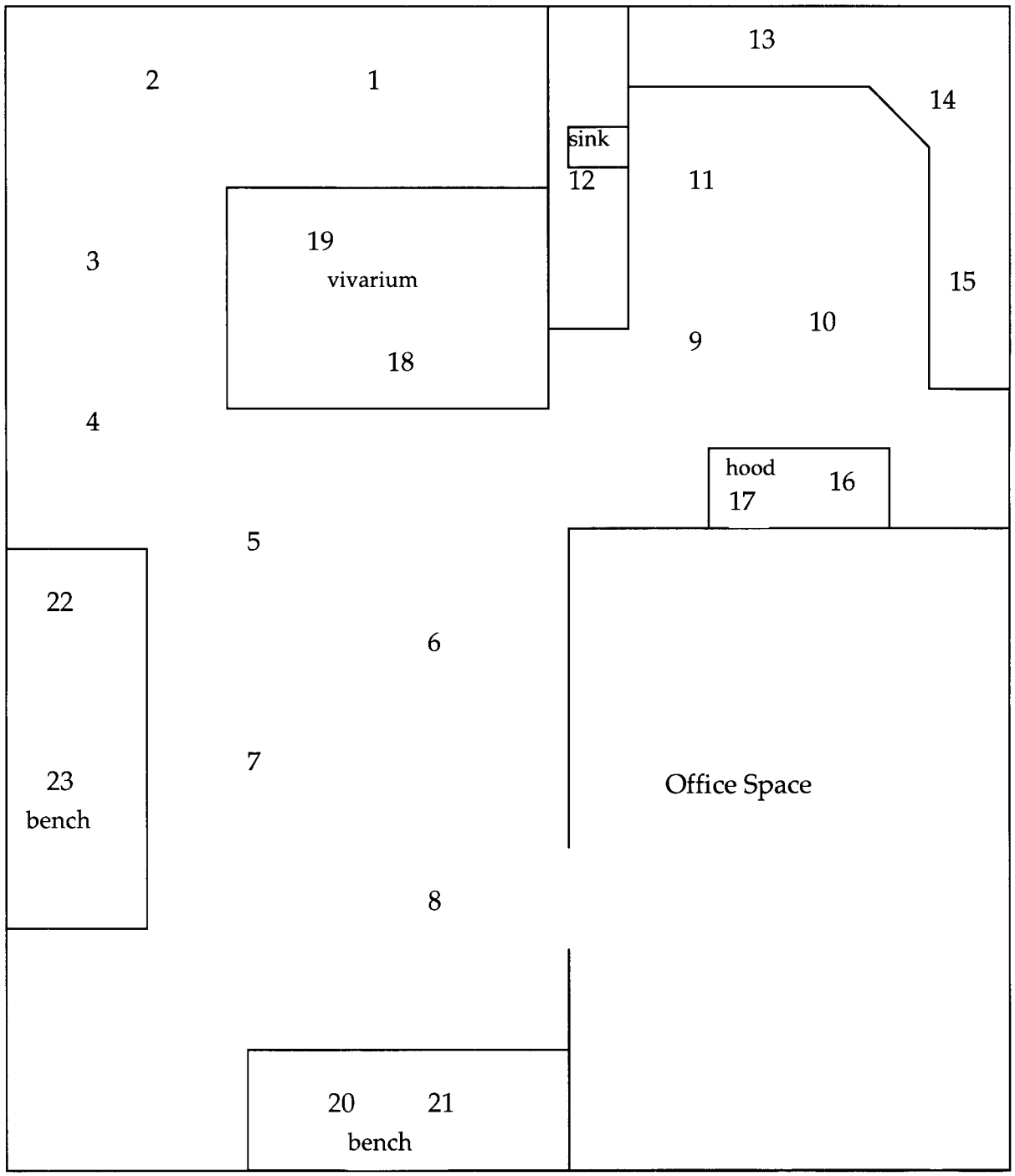
Upstairs laboratory

Location	Gross Counts	Net cpm	dpm/ 100 cm2	DCGL-data	Sign
1	380	60	794	4206	1
2	360	40	529	4471	1
3	360	40	529	4471	1
4	350	30	0	5000	1
5	350	30	397	4603	1
6	410	90	1190	3810	1
7	370	50	661	4339	1
8	370	50	661	4339	1
9	300	-20	-265	5000	1
10	320	0	0	5000	1
11	340	20	265	4735	1
12	290	-30	-397	5000	1
13	330	10	132	4868	1
14	370	50	661	4339	1
15	280	-40	-529	5000	1
16	330	10	132	4868	1
17	350	30	397	4603	1
18	310	-10	-132	5000	1
19	400	80	1058	3942	1
20	340	20	265	4735	1
21	360	40	529	4471	1
22	350	30	397	4603	1
23	410	90	1190	3810	1
sink	390	70	926	4074	1
Number of Positive Differences					24

Background (cpm)	320
Efficency	0.06
Probe Area/100 cm2	1.26
Count time	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.

Downstairs Laboratory – Location of fixed and removable measurements



Downstairs Laboratory - Total Beta measurements

Location	Gross Counts	Net cpm	dpm/ 100 cm2	DCGL-data	Sign		
1	384	64	847	4153	1		
2	362	42	556	4444	1		
3	363	43	569	4431	1		
4	350	30	0	5000	1		
5	357	37	489	4511	1		
6	410	90	1190	3810	1		
7	330	10	132	4868	1		
8	379	59	780	4220	1	Background (cpm)	320
9	301	-19	-251	5000	1	Efficency	0.06
10	328	8	106	4894	1	Probe Area/100 cm2	1.26
11	340	20	265	4735	1	Count time	1
12	290	-30	-397	5000	1		
13	370	50	661	4339	1		
14	370	50	661	4339	1		
15	280	-40	-529	5000	1		
16	330	10	132	4868	1		
17	350	30	397	4603	1		
18	310	-10	-132	5000	1		
19	350	30	397	4603	1		
20	340	20	265	4735	1		
21	360	40	529	4471	1		
22	400	80	1058	3942	1		
23	410	90	1190	3810	1		
24	370	50	661	4339	1		
sink	390	70	926	4074	1		
Number of Positive Differences					24		

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.

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*
380	350	8.2%
450	410	9.3%
410	380	7.6%
330	390	-16.7%
Average RPD =		2.1%

Table 3 - Reproducibility of Total Beta Measurements

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

Accuracy

Accuracy is a test of how close the meters response is to a known value. The hand held meters used for this project were calibrated to a standards set of five sources, with radioactivity levels certified by the National Institute of Standards and Testing. The efficiency for Carbon-14 was used for data reduction and sensitivity calculations. 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:

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

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.

Certificate of Calibration

Calibrated For: **Scott Dennerlein & Associates, LLC**

Meter: **Ludlum model 3 # 109793** Probe: **44-26 #073090**

Voltage Setting: 1400v **Background: 320 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	2,100	0.10
Tc-99 841-32-1	23,510	4,600	0.20
Cl-36 841-33-2	22,289	6,900	0.31
Sr/Y-90 841-35-2	22,711	17,000	0.38

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

Calibrated By: Scott Dennerlein **Date:** 6/3/2007

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. November1983

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

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

4/14/2008, and to inform you that the initial processing which includes an administrative review has been performed.

☑ AMEND. 29-30906-01
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** 142320.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader