

Food and Drug Administration
Rockville MD 20857

April 13, 2009

B, 2

RECEIVED
REGION 1
2009 APR 14 AM 10:42

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

RE: Final Radiological Status Survey Report for 12720 Twinbrook Parkway,
Building 2, Rockville, MD
Food and Drug Administration
License No. 19-07538-01
Docket No. 030-04544

Dear Sir or Madam:

Enclosed is the Final Status Survey Report for the Food and Drug Administration's Center for Devices and Radiological Health (FDA/CDRH) laboratory facility located at 12720 Twinbrook Parkway, Building 2 in Rockville, Maryland and other supporting documents related to the final status survey process.

Upon satisfactory review of the information provided, FDA/CDRH requests an amendment to its license under the provisions specified in Title 10, Code of Federal Regulations, Part 20.1402 to release 12720 Twinbrook Parkway, Building 2 for unrestricted use.

Clym Environmental had been contracted by the U.S. Food and Drug Administration (FDA) to perform these surveys. The point of contact at the firm is Mr. Charles Watts who can be reached by phone at (301) 694-6000 or by email at cwatts@clymenvironmental.com .

We look forward to hearing from you regarding the Final Status Survey Report. If you have any questions, please contact me at either phone (240) 276-3285 or email at [petro.shandnlk\(i-ii,fda.hhs.gov\)](mailto:petro.shandnlk(i-ii,fda.hhs.gov)).

143643

RUSS/DCM 11 000000 000

Page 2

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Petro Shandruk". The signature is fluid and cursive, with a large, stylized initial "P".

Petro Shandruk, RSO
Chief, Radiation Programs Branch
DMQRP, OCER (HFZ-240)
Center for Devices and
Radiological Health, FDA
1350 Piccard Drive
Rockville, MD 20850

Enc: License amendment
Final Radiological Status Survey Report
(2 copies of each)

cc: Lillian J. Gill
Senior Associate Director, CDRH

APPLICATION FOR MATERIAL LICENSE

Estimated burden per response to comply with this mandatory collection request: 1.4 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, MISSISSIPPI, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION, REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, A. MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TX 76011-4005

03004544

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 19-07538-01
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850

3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

12720 Twinbrook Parkway, Bldg. 1, Rockville, MD 20857
10903 New Hampshire Ave., Silver Spring, MD

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

PETRO SHANDRUK

TELEPHONE NUMBER

(240) 276-3285

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

- a. Element and mass number; b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT.

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

LICENSE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY Exempt Federal AMOUNT ENCLOSED \$ 0.00

13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Petro Shandruk, Radiation Safety Officer, CDRH

SIGNATURE

Petro Shandruk

DATE

4/15/05

FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
APPROVED BY			\$	DATE	

143643

U. S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

REQUEST FOR AMENMENT OF LICENSE 19-07538-01

DELETION OF: -FACILITY LOCATION

This request employs the number format used on the NRC MATERIALS LICENSE, Form 374. The additions will be preceded in the request by the italicized word *Add*.

Licensee:

1. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
2. DMQRP/OCER (HFZ-240)
1350 Piccard Drive
Rockville, MD 20850-4307

Item to be amended in this renewal:

Page

Conditions 10.....1

CONDITIONS

10. *Delete* 12720 Twinbrook Parkway, Building 2, Rockville, MD

For additional information, please contact:

Petro Shandruk
Radiation Safety Officer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
HFZ-240
1350 Piccard Drive
Rockville, MD 20850

Telephone: 240-276-3285
FAX: 240-276-3282
Email: petro.shandruk@fda.hhs.gov

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10 Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Department of Health & Human Services Food and Drug Administration Center for Devices and Radiological Health</p> <p>2. DMQRP/OCER (HFZ-240) 1350 Piccard Drive Rockville, Maryland 20850-4307</p>	<p>In accordance with the letter dated May 29, 2007.</p> <p>3. License number 19-07538-01 is amended in its entirety to read as follows:</p> <p>4. Expiration date June 30, 2015</p> <p>5. Docket No. 03004544 Reference No.</p>
--	--

<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Hydrogen 3</p> <p>B. Carbon 14</p> <p>C. Phosphorus 32</p> <p>D. Sulfur 35</p> <p>E. Any byproduct material with atomic numbers 3 through 83</p> <p>F. Plutonium 239</p> <p>G. Americium 241</p> <p>H. Americium 241</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p> <p>C. Any</p> <p>D. Any</p> <p>E. Sealed Sources</p> <p>F. Plated Sources</p> <p>G. Sealed Sources (Texas Nuclear Corporation, custom source)</p> <p>H. Sealed sources (Photon source, New England Nuclear Model NES-128S)</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. 100 millicuries</p> <p>B. 85 millicuries</p> <p>C. 100 millicuries</p> <p>D. 300 millicuries</p> <p>E. 1 millicurie per source and 5 millicuries total</p> <p>F. 4 microcuries</p> <p>G. 14 millicuries per source and 28 millicuries total</p> <p>H. 8 microcuries</p>
---	--	---

9. Authorized use:

- A. through D. Research and development as defined in 10 CFR 30.4.
- E. through G. Calibration, standardizing and testing of the licensee's instruments.
- H. For storage incident to disposal.

CONDITIONS

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
19-07538-01Docket or Reference Number
030-04544

Amendment No. 38

10. Licensed material may be used at the licensee's facilities located at 12720 Twinbrook Parkway, Buildings 1 and 2; Rockville, Maryland; and 10903 New Hampshire Avenue, Silver Spring, Maryland.
11.
 - A. Licensed material in items 6.A. through 6.D. shall be used by, or under the supervision of Peter Goering, Abiy B. Desta, or Michael D. O'Hara, Ph.D., or
 - B. Licensed material in items 6.A., 6.B., and 6.D. shall be used by, or under the supervision of Thotnas H. Umbreit, Ph.D.
 - C. Licensed material in items 6.E. through 6.H. shall be used by, or under the supervision of, Mary **3**. Walker or Peter Goering.
 - D. The Radiation Safety Officer for this license is Petro Shandruk.
12. Licensed material shall not be used in or on human beings.
13. The licensee shall not use licensed material in field applications where activity is released except as provided otherwise by specific condition of this license.
14.
 - A. Sealed sources shall be tested for leakage and/or contamination at intervals not to exceed the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State.
 - B. Notwithstanding Paragraph A of this Condition, sealed sources designed to primarily emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed 3 months.
 - C. Each sealed source fabricated by the licensee shall be inspected and tested for construction defects, leakage, and contamination prior to any use or transfer as a sealed source.
 - D. In the absence of a certificate from a transferor indicating that a leak test has been made within the intervals specified in the certificate of registration issued by the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or under equivalent regulations of an Agreement State, prior to the transfer a sealed source received from another person shall not be put into use until tested and the test results received.
 - E. Sealed sources need not be tested if they contain only hydrogen-3; or they contain only a radioactive gas; or the half-life of the isotope is 30 days or less; or they contain not more than 100 microcuries of beta- and/or gamma-emitting material or not more than 10 microcuries of alpha-emitting material.
 - F. Sealed sources need not be tested if they are in storage and are not being used; however, when they are removed from storage for use or transferred to another person and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

19-07538-01

Docket or Reference Number

030-04544

Amendment No. 38

- G. The leak test shall be capable of detecting the presence of 0.005 microcurie (185 becquerels) of radioactive material on the test sample. If the test reveals the presence of 0.005 microcurie (185 becquerels) or more of removable contamination, a report shall be filed with the U.S. Nuclear Regulatory Commission in accordance with 10 CFR 30.50(c)(2), and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Commission regulations.
- H. Tests for leakage and/or contamination, including leak test sample collection and analysis, shall be performed by the licensee or by other persons specifically licensed by the U.S. Nuclear Regulatory Commission or an Agreement State to perform such services.
- I. Records of leak test results shall be kept in units of microcuries and shall be maintained for 5 years.
15. Sealed sources or detector cells containing licensed material shall not be opened or sources removed from source holders by the licensee.
16. The licensee shall not acquire licensed material in a sealed source or device unless the source or device has been registered with the U.S. Nuclear Regulatory Commission pursuant to 10 CFR 32.210 or equivalent regulations of an Agreement State.
17. The licensee shall conduct a physical inventory every six months, or at other intervals approved by the U.S. Nuclear Regulatory Commission, to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for 5 years from the date of each inventory and shall include the radionuclides, quantities, manufacturer's name and model numbers, and the date of the inventory.
18. Maintenance, repair, cleaning, replacement, and disposal of foils contained in detector cells shall be performed only by the device manufacturer or other persons specifically authorized by the Commission or an Agreement State to perform such services.
19. A. Detector cells containing a titanium tritide foil or a scandium tritide foil shall only be used in conjunction with a properly operating temperature control mechanism which prevents the foil temperatures from exceeding that specified in the certificate of registration referred to in 10 CFR 32.210.
- B. When in use, detector cells containing a titanium tritide foil or a scandium tritide foil shall be vented to the outside.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
19-07538-01Docket or Reference Number
030-04544

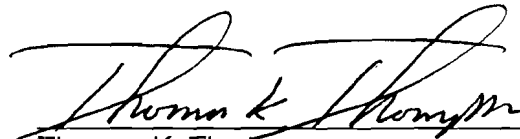
Amendment No. 38

20. The licensee is authorized to hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee:
- A. Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detect on survey meter set on its most sensitive scale and with no interposed shielding; and
 - B. Removes or obliterates all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee; and
 - C. Maintains records of the disposal of licensed materials for 3 years. The record must include the date of disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the disposal.
21. The licensee is authorized to transport licensed material in accordance with the provisions of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material."
22. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The U.S. Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application dated January 27, 1998 (ML070160180)
 - B. Letter dated April 2, 1998 (ML070120466)
 - C. Letter dated January 6, 2000 (ML003678663)
 - D. Letter dated April 16, 2003 (ML031260073)
 - E. Letter dated August 5, 2004 (ML042190374)
 - F. Letter dated January 25, 2005 (ML050380492)
 - G. Application dated April 16, 2007 (ML071130143)

For the U.S. Nuclear Regulatory Commission

Date August 17, 2007

By

Thomas K. Thompson
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Friday, August 17, 2007 8:45:34 AM

FINAL RADIOLOGICAL STATUS SURVEY REPORT

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
Building T2
12720 Twinbrook Parkway Rockville, MD**

FINAL REPORT

March 2009

Table of Contents

1.	Background.....	page 6
2.	Radiological Surveys.....	page 7
2.1	Field Measurements, Methods and Instrumentation.....	page 9
2.2	Laboratory Analysis of Smear Samples.....	page 10
2.3	Activity Determination At or Above Investigative Levels.....	page 11
3.	Final Status Survey Plan.....	page 11
3.1	Determining the Number of Data Points for Statistical Tests.....	page 11
3.1.1	Contaminants Not Present in Background.....	page 11
3.1.1.1	Calculate Relative Shift.....	page 12
3.1.1.2	Determination of Sign P.....	page 12
3.1.1.3	Determination of Decision Error Percentiles.....	page 12
3.1.1.4	Determine the number of Data Points for the Sign Test.....	page 12
3.1.2	Contaminants Present in Background.....	page 12
3.1.2.1	Scenario A.....	page 12
3.1.2.1.1	Calculate the Relative Shift.....	page 12
3.1.2.1.2	Determination of Pr.....	page 12
3.1.2.1.3	Determination of Decision Error Percentiles.....	page 13
3.1.2.1.4	Determine the Number of Data Points for the WRS Test.....	page 13
4.	Final Status Survey.....	page 13
4.1	Summary of Statistical Tests.....	page 13
4.1.1	Contaminants Not Present in Background.....	page 13
4.1.2	Contaminants Present in Background.....	page 14
5.	Quality Assurance.....	page 14
5.1	Daily operational Checks for Portable Survey Instruments.....	page 14
6.	Disposition of Materials and Waste.....	page 15
7.	Findings.....	page 15
8.	Conclusion.....	page 15

ATTACHMENTS

Attachment 1	DandD Occupancy Scenario Reports
Attachment 2	Resrad-Build Report
Attachment 3	Reference Matrices and Associated Measurements
Attachment 4	Reference Maps of Individual Laboratories/Areas
Attachment 5	Data Measurements
Attachment 6	Daily Operational Checks of Portable Survey Instruments

Abbreviations

ALARA	As Low As Reasonably Achievable
CDRH	Center for Devices and Radiological Health
CLYM	Clym Environmental Services, LLC
CPM	Counts per minute
DCGL	Derived Concentration Guideline Level
DPM	Disintegrations per minute
FDA	Food and Drug Administration
FSS	Final Status Survey
GCPM	Gross counts per minute
LBGR	Lower bound of the gray region
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MDC	Minimum detectable concentration
NIDCR	Minimum Detectable Count Rate
NCPM	Net counts per minute
NRC	Nuclear Regulatory Commission
QA	Quality Assurance

References

1. NUREG-1507, "Minimum Detectable Concentrations With Typical Radiation Survey Instruments for Various Contaminants and Field Conditions", NRC-Washington, DC, June 1998
2. NUREG-1575, "Multi-Agency Radiological Survey and Site Investigation Manual, Revision 1", August 2000
3. NUREG-1757, Vol. 1, "Consolidated NMSS Decommissioning Guidance. Decommissioning Process for Materials Licenses", Final Report, NRC-Washington, DC, September 2002
4. NUREG-1757, Vol. 2, "Consolidated NMSS Decommissioning Guidance, Decommissioning Process for Materials Licenses", Final Report, NRC-Washington, DC, September 2003
5. NUREG-CR-5512, Vol. 2, SAND2001-0822P, "Residual Radioactive Contamination From Decommissioning, Users Manual DandD, Version 2.1", NRC-Washington, DC, April 2001
6. DandD, Version 2.1 computer code
7. Resrad-Build, Version 3.4 computer code
8. Title 10, Code of Federal Regulations

1. Background

The Food and Drug Administration is part of the Executive Branch of the United States Government within the Department of Health and Human Services. The Food and Drug Administration (FDA) is a Nuclear Regulatory Commission (NRC) radioactive materials licensee. The possession, use and storage of these radioactive materials at this facility are authorized by the U.S. Nuclear Regulatory Commission (NRC) via a broadscope Radioactive Materials license, number 19-07538-01 (with 31 attachments). This license provides a limited scope of use directly associated with research activities. The FDA operated research laboratories at a facility located in Rockville, MD. This facility address is 12720 Twinbrook Parkway. The FDA occupant has been the Center for Devices and Radiological Health (CDRH). CDRH is one of six product-oriented centers that carry out the mission of the Food and Drug Administration. CDRH has and continues to conduct research employing various radiolabeled compounds and radioactive sealed sources.

There are five, one story buildings located at the facility. The principal places of use/storage were buildings 1 and 2 (T1 and T2). Buildings 3 thru 5 have been released from radiological control as referenced in license Amendment 28. The FDA has relocated research operations to another facility in the Washington, DC metropolitan area.

Building T1 consists of 19,229 square feet of mixed laboratory and office space. Building T2 consists of 5,121 square feet of laboratory space. The facility located at 12720 Twinbrook Parkway is presently owned and managed by Avalonbay Communities, Inc. located at 2400 Research Blvd., Suite 120 in Rockville, MD 20850. The facility is managed by Cassidy Pinkard Colliers Property Management, with offices located at 9801 Washingtonian Blvd., Suite 550, Gaithersburg, MD 20878. The building owner has designated the facility for major renovation after the FDAICDRH vacates the premises.

There were research protocols that involved the use of radioactive materials in sealed form. Unsealed form material was occasionally stored in Building T2 when not in use. These materials were procured, used and stored at 12720 Twinbrook Parkway, Building T2 under the FDAICDRH broad scope radioactive materials license.

The FDAICDRH, as an NRC licensee, is required to demonstrate that the facility located at 12720 Twinbrook Parkway located in Rockville, MD is acceptable for release in accordance with the requirements and conditions specified by the NRC. The FDAICDRH wants to remove Building T2 from their license as an authorized place of use in order to facilitate other remedial operations. The FDAICDRH has retained the services of Clym Environmental Services, LLC (CLYM) to assist in the decommissioning process. All decommissioning related activities (scoping

surveys, characterization surveys, remediation and waste disposal) were conducted under the authority of the current FDA/CDRH radioactive materials license.

2. Radiological Surveys

The Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) assigns a greater level of effort on surveys conducted in areas that have, or had, the highest potential for contamination. Areas are classified based on the radiological characteristics. Those areas that have no reasonable potential or extremely low probability of residual contamination are classified as non-impacted. Areas with some potential for residual contamination are classified as impacted.

There are nine laboratories/areas in Building T2, identified as 200, 201, 204, 205, 206, 208, 209, 210 and 212. There is a safe located in area 204 in Building T2. This safe was constructed from battleship grade steel and was used to store radioactive materials. The FDAICDRH Radiation Safety Officer stated that he could not recall a sealed source ever having leaked. The contents of the safe included a 100gram bottle of uranyl acetate, along with several sources and lead pigs. It was soon realized the interior surfaces of the safe as well as the lead pigs were contaminated and that several small sources were leaking. The interior surfaces of the safe and lead pigs were evaluated for total and removable surface contamination. The contaminants identified as a result of this survey were ^{137}Cs , ^{133}Ba and ^{241}Am .

The next step was to determine the Derived Concentration Guideline Levels (DCGL's) and select the Final Status Survey method in order to demonstrate compliance with the provisions specified in 10 CFR Part 20 for releasing the facility for unrestricted use.

Screening values for surface contamination were obtained using the values provided in NUREG-1757, Volume 1, Table B.1 in Appendix B. DandD Version 2.1 was used to obtain screening values for $^{238}\text{U}+\text{C}$ and ^{241}Am , not provided in Table B.1. Copies of the DandD Building Occupancy Scenario reports are provided as Attachment 1. The Resrad-Build computer code, version 3.4, was used to obtain a screening value for ^{133}Ba . A copy of the Resrad-Build report is provided as Attachment 2. A listing of the adopted screening values for building/surface contamination at Building T2 has been provided in Table 1.

The Final Status survey would designate each survey unit for surface scans and static measurement. The scoping survey was designed to meet the requirements of the Final Status survey. All laboratory and administrative space in Building 2 were designated as impacted.

The lower wall area was defined as the surface area from the floor to a height of eight feet. Surface scans were designated to cover 100% of accessible floor and 50% of accessible lower wall areas. Surface scans were designated to cover 10% of upper wall and ceiling areas. Scoping surveys were designed to evaluate levels of 1) total surface activity using surface scans as well as static measurements, and 2) removable surface contamination using smear samples. Smear sample locations were determined using the surveyor's professional judgment. These surveys would focus on surfaces deemed "high risk areas" e.g. floors, sinks and lower walls. Any area found to have residual surface contamination was designated for further evaluation as outlined below;

Surface Scans –any surface area found to be greater than twice the reference background for the surface matrices in beta mode, or 2 cpm above the reference background for the matrices being evaluated in the alpha mode.

Smears – any activity detected above the minimum detectable level.

Any area found to be at the investigative level for surface scans would be designated for evaluation in both alpha and beta mode. Further evaluations would be made using static measurements and smears to quantify the level of the contamination and better define the area. Any area where residual activity is identified at the investigative level would be sufficient cause to designate the area as a usage area. thereby increasing the coverage area for surface scans.

Table 1

Radionuclide	Symbol	Acceptable Screening Levels (dpm/100cm ²)
137-Cesium	¹³⁷ Cs	2.4E+04
133-Barium	¹³³ Ba	5.5E+04
241-Americium	²⁴¹ Am	26
238Uranium+C	²³⁸ U	250

Survey instruments were selected based on the detection sensitivities to the radiations of concern. The detection sensitivity of large area gas proportional detectors was evaluated to ensure detection levels are within acceptable parameters (10%-50% of the DCGL). These detectors were equipped with 0.4mm thick windows. This meant the detector could be operated in an alpha or beta mode. The DCGL's for ²³⁸U and ²⁴¹Am are low compared to the other contaminants. In order to meet the acceptable detection parameter of 10% to 50% of the DCGL, alpha must be evaluated independently. The strategy for evaluating residual surface contamination with ¹³³Ba as a possible contaminant was to scale the ¹³³Ba to the total activity and calculate a gross activity DCGL determined

using the ratio of contaminants identified in Table 2 and applying it using formula 4-4 as found in NUREG-1575 (December 1997).

Table 2

Radionuclide	Ratio
137-Cesium	96%
133-Barium	4%

The DCGL_{weighted} (DCGL_w) was found to be 24,558 dpm/100cm². One half the DCGL_w would be 12,278 dpm/100cm². One half the DCGL_w was next determined to be 6,860 cpm/100cm² by converting from a unit of radioactivity to counts per minute using a value of 0.096 for E_{weighted, total}. The total efficiency (E) was weighted according to the relative ratios. The surface efficiency (E_s) of 0.5 is applied for greater than 0.4 MeV beta emitting radionuclides.

$$E_{\text{weighted, total}} = (0.2 \times 0.5 \times 96\%) + (0 \times 4\%)$$

The active probe surface area of 582 cm² was also used in converting the DCGL_w from a unit of radioactivity to cpm.

The gross alpha DCGL_{weighted} (DCGL_w) was found to be 89 dpm/100cm². One half the DCGL_w would be 44 dpm/100cm². One half the gross alpha DCGL_w was next determined to be 12 cpm/100cm² by converting from a unit of radioactivity to counts per minute using a value of 0.045 for E_{weighted, total}. The total efficiency (E) was weighted according to the relative ratios. The surface efficiency (E_s) of 0.25 is applied for alpha emitting radionuclides.

$$E_{\text{weighted, total}} = (0.18 \times 0.25 \times 79\%) + (0.18 \times 0.25 \times 21\%)$$

The active probe surface area of 582 cm² was also used in converting the DCGL_w from a unit of radioactivity to cpm.

2.1 Field Measurements, Methods and Instrumentation

Surface scans and static measurements for beta emitting radionuclides were made using scaler/rate meters equipped with large area gas proportional detectors (Ludlum model 43-37 and 43-68). Variations in background readings of up to 400cpm in beta mode were found throughout the building. The contributing factors were determined to be 1) variations in the composition of surface matrices as well as 2) the presence of radon.

The Scan MDC for a 43-37 detector on a concrete floor surface was determined to be 614 dpm/100cm² using an averaged background of 934 cpm. The Scan MDC is well below the DCGL_w of 24,558 dpm/100cm². The following variables were used in determination of the Scan MDC for

the "ideal" surveyor; 1) a background count rate of 934 cpm, 2) $E_{\text{weighted, total}}$ of 0.096 and 3) the active area of the probe is 582 cm². A minimum detectable count rate (MDCR) of 1,292 cpm was determined for the ideal surveyor during the first scanning stage using an index of sensitivity (d') of 1.51 and a 2 second observation interval (NUREG 1575, 6.7.2.1 (6-8, 6-9)).

Surface scans and static measurements for alpha emitting radionuclides were conducted using a 43-37 large area gas proportional detector. The averaged ambient background for this detector in the alpha mode was found to be 1cpm. One half of the gross alpha DCGI_w (89 dpm/100cm²) is 44 dpm/100cm² or 11 cpm/100 cm² using a total weighted efficiency of 0.045. The probability of detecting two or more counts when passing over 44dpm/100cm² was determined to be 3% (NUREG-1575, 6.7.2.2 (6-14)) using a probe dimension of 15 'cm and a scan rate of 4cm/s. The time interval a surveyor should hold over a suspect area was determined to be 4 seconds (NUREG 1575, 6.7.2.2 (6-13)).

Reference areas for were located in Building T1 for each type of matrices identified in Building T2 laboratories/areas. These reference areas are identified as follows; room number 102, 106, 108, 128, 151A, 159 and the janitorial closet located next to the restrooms. A listing of the reference matrices and associated measurement for each portable survey instrument used has been provided as Attachment 3.

The detector was employed on the scanned surface at no greater than the prescribed speed as indicated below;

43-68, alpha/beta mode ½ a probe width per second (2inches/sec)

43-68, alpha mode ¼ a probe width per second (1inch/sec)

43-37, alpha/beta mode ½ a probe width per second (3inches/sec)

43-37, alpha mode ¼ a probe width per second (1.5inches/sec)

The minimum observational interval or hold time over a suspect area is as specified for the first stage scan: Beta - 2 seconds, Alpha - 4 seconds.

Surface scans were systematically conducted on accessible surfaces in each survey area as to ensure the 100% coverage in usage areas and 50% in non-usage areas. Special attention was made to joints, cracks, seams, etc. in any accessible survey area.

2.2 Laboratory Analysis of Smear Samples

The evaluation of removable surface activity was conducted using a dry paper wipe, covering an area of 100 cm² while applying moderate pressure. A total of ninety smear samples were collected and analyzed, ten

from each of the nine laboratories/areas. Smear samples were analyzed by Clym Environmental Services, LLC (license nr. MD-21-035-01) for gross alpha and beta. Samples were analyzed using liquid scintillation counting techniques. A region of interest was established 0 to 1000 MeV. The typical minimum detectable activity for gross beta using a four minute count time was 28 dpm. This was calculated using a background of 28 cpm and an efficiency for tritium of 46%. Any sample found to have detectable activity in excess of the minimum detectable was designated for quantitative analysis

2.3 Activity Detected At or Above Investigative Levels

The evaluation of total and removable surface contamination identified no area of surface contamination at or above action levels.

3. Final Status Survey Plan

The Derived Concentration Guideline Levels and Final Status Survey method to demonstrate compliance with the provisions specified in Title 10 CFR part 20 for releasing the facility for unrestricted use were determined. All nine laboratories /areas in Building T2 were combined to form one Class 3 survey unit, identified as Survey Unit 1. The floor surface area in Survey Unit 1 was determined to be 402 m².

The Final Status Survey designated the survey unit for surface scans and static measurements. Surface scans were completed in each laboratory/area during scoping surveys to the required specifications as detailed in Section 2. The static measurements would be made using a predetermined count time of one minute in beta mode and twenty minutes in alpha mode.

3.1 Determining the Number of Data Points for Statistical Tests

This section details the determination process in the selection and implementation of statistical tests.

3.1.1 Contaminants Not Present in Background

The Sign Test was selected to compare beta emitting nuclides or those contaminants not present in background ¹³⁷Cs and ¹³³Ba. The objective of the Final Status Surveys is to demonstrate that the residual radioactivity levels meet the release criterion. Scenario A has been selected to demonstrate this objective for residual contamination on building/structure surfaces. In demonstrating that this objective is met the null hypothesis tested, H₀; is the median concentration of residual radioactivity in the survey unit is greater than the DCGL_w. The Type I error (α) was specified as 0.05 and a Type II decision error (β) was set at 0.05.

3.1.1.1 Calculate the Relative Shift

The lower bound of the gray region was determined to be 2,870. The standard deviation of the contaminants in the survey unit was found to be 36. If the relative shift was determined to be >3 the lower bound of the gray region was adjusted. The relative shift for the survey unit was determined to be 2.79.

3.1.1.2 Determination of Sign p

The value of the relative shift calculated in section 3.1.1.1 was used to obtain the corresponding value of Sign p using Table 5.4 as found in NUREG-1575 (December 1997).

3.1.1.3 Determination of Decision Error Percentiles

The determination of percentiles, $Z_{1-\alpha}$ and $Z_{1-\beta}$ was conducted by selecting the designated values using Table 5.2 as found in NUREG-1575 (December 1997).

3.1.1.4 Determine the Number of Data points for the Sign Test

The number of data points for each survey unit was determined by selecting the designated values using Table 5.5 as found in NUREG-1575 (December 1997). The number of data points for Survey Unit I was found to be 15.

3.1.2 Contaminants Present in Background

3.1.2.1 Scenario A

The Wilcoxon Rank Sum (WRS) Test was selected to compare those contaminants present in background, ^{238}U and ^{241}Am . In demonstrating the objective that the Final Status Survey has met the null hypothesis, H_0 tested is the median concentration of residual radioactivity in the survey unit exceeds that in the reference area by more than the DCGL. The Type I error (α) was specified as 0.05 and a Type II decision error (β) was set at 0.05.

3.1.2.1.1 Calculate the Relative Shift

The lower bound of the gray region was established at 1. The standard deviation was found to be 1.7. If the relative shift was determined to be >4 the lower bound of the gray region was adjusted. The relative shift Survey Unit I was determined to be 2.38.

3.1.2.1.2 Determination of P_r

The value of the relative shift calculated in section 3.1.2.1.1 was used to obtain the corresponding value of P_r using Table 5.1 as found in NUREG-1575 (December 1997).

3.1.2.1.3 Determination of Decision Error Percentiles

The determination of percentiles, $Z_{1-\alpha}$ and $Z_{1-\beta}$ was conducted by selecting the designated values using Table 5.2 as found in NUREG-1575 (December 1997).

3.1.2.1.4 Determine the Number of Data points for the WRS Test

The number of data points for the survey unit was determined by selecting the designated values using Table 5.3 as found in NUREG-1575 (December 1997). The number of data points in Survey Unit 1 was found to be 11.

4. Final Status Survey

A one meter square grid system was constructed in each area of the survey unit, to include the floors and lower wall areas.

The designation for each surface in a survey unit was identified using an alpha-numeric system. The survey unit was identified as Survey Unit 1 and subsidiary laboratories/areas identified by a unique identifying number. The Final Status sample points in each laboratory/area were physically identified using the alpha-numeric designation for the grid in which the sample point or location resides. Diagram maps of each laboratory/area in Survey Unit 1 have been provided as Attachment 4.

The reference areas for establishing background for the different matrices were identified in Building T1. Sample measurements were then made at various locations within each of the reference areas on each type of matrices (e.g. benchtop, floor, casework, etc.). Variations in "background" were encountered for each type of matrices throughout the facility.

Random sample points were selected by first assigning each point in the survey unit a sequential numerical value. A random number generator was utilized to select the sample points for each survey unit.

A floor diagram and designated sample points were provided to the surveyor. The results of static measurements made in each survey unit have been provided as Attachment 5.

4.1 Summary of Statistical Tests

The measurements made at discrete locations as a result of FSS were evaluated.

4.1.1 Contaminants Not Present in Background

The Sign Test was selected to compare contaminants not present in background ^{137}Cs and ^{133}Ra . The objective of the Final Status

Surveys is to demonstrate that the residual radioactivity levels meet the release criterion.

H: The median concentration of residual radioactivity in the survey unit is greater than the DCGL_w.

All measurements were found to be less than the DCGL_w. The average of the measurements made in each survey unit was determined. The measurement average in the survey unit, -54 dpm/100cm² was less than the DCGL_w. The Sign test did not need to be performed as the survey unit met the release criterion.

4.1.2 Contaminants Present in Background

The Wilcoxon Rank Sum (WRS) Test was selected to compare alpha emitting nuclides or those contaminants present in background, ²³⁸U and ²⁴¹Am. In demonstrating the objective of the Final Status Survey is met the null hypothesis, H₀ tested is the median concentration of residual radioactivity in the survey unit exceeds that in the reference area by more than the DCGL_w. The largest measurement recorded in the survey unit was found to be 28 dpm/100cm². The smallest measurement recorded in the reference area was -23 dpm/100cm². The difference between the two measurements was found to be 52 dpm/100cm². The difference is less than the DCGL_w, 89 dpm/100cm². The WRS test did not need to be performed as the survey unit met the release criterion.

5. Quality Assurance

The performance of decommissioning activities has been managed within a framework of policies and procedures, which assure the validity and quality of data. Procedures were established for activities requiring the application of standard and approved methods to ensure regulatory requirements were met. These procedures document the technical competence of the survey approach thus ensuring the use of effective processes. Procedures utilized by Clym are documented using program-specific applications.

5.1 Daily Operational Checks for Portable Survey Instruments

The purpose of these procedures was to ensure portable scaler/rate meters equipped with gas proportional detectors were in proper working condition prior to placement into service.

When an instrument failed an operational check, both the instrument and detector were removed from service until the discrepancy could be resolved.

Both source and background measurements must fall within the acceptable range established for the site and were performed as follows:

Prior to beginning the performance of data measurements and/or scanning for the day,

After the lunch or noon break,

Any time the detector is suspected of being contaminated and

Any time instrument operation is in question.

Daily checks included 1) a determination of operational readiness, 2) ambient background determination and verification that each reading is within $\pm 20\%$ of the average in beta mode and 200% of the average in alpha mode and 3) check source reproducibility determination.

The check source reproducibility determination involved obtaining the data necessary to calculate the average source count and verify that each section of the detector face was reading within $\pm 10\%$ of the average in beta and alpha mode. Additionally, the 20 and 30 values for the background and check source counts were calculated. The acceptable value for 30 was established at $\pm 10\%$ of the mean.

A copy of these daily checks has been provided as Attachment 6.

6. Disposition of Materials and Waste

All radioactive materials, including the safe have been transferred to another licensed FDA/CDRH facility.

7. Findings

The objective of the Final Status Survey to demonstrate that the survey met the release criteria was achieved.

8. Conclusion

The Final Status Surveys conducted by the FDA/CDRH demonstrate compliance with the provisions specified in Title 10 CFR Part 20 for releasing the Building T2 located at 12720 Twinbrook Parkway in Rockville, MD for unrestricted use.

ATTACHMENT 1



DandD Building Occupancy Scenario

DandD Version: 2.1.0

Run Date/Time: 11/20/2008 2:30:48 PM

Site Name: 12720 Twinbrook Pkwy

Description: DCGL Determination

FileName: C:\Documents and Settings\Finley Watts\My Documents\12720\12720 DCGL.mcd

Options:

Implicit progeny doses NOT included with explicit parent doses

Nuclide concentrations are distributed among all progeny

Number of simulations: 400

Seed for Random Generation: 8718721

Averages used for behavioral type parameters

External Pathway is ON

Inhalation Pathway is ON

Secondary Ingestion Pathway is ON

Initial Activities:

Nuclide	Area of Contamination (m ²)	Distribution
238U+C	UNLIMITED	CONSTANT(dpm/100 cm**2)
Justification for concentration. DCGL Determination		Value 2.50E+02

Site Specific Parameters:

General Parameters:

None

Correlation Coefficients:

None

Summary Results:

90.00% of the 400 calculated TEDE values are $< 2.32\text{E}+01$ mrem/year .

The 95 % Confidence Interval for the 0.9 quantile value of TEDE is $2.19\text{E}+01$ to $2.46\text{E}+01$ mrem/year



DandD Building Occupancy Scenario

DandD Version: 2.1.0

Run **Date/Time:** 11/20/2008 2:39:56 PM

Site Name: 12720 Twinbrook Pkwy

Description: DCGL Determination

FileName: C:\Documents and Settings\Finley Watts\My Documents\12720\12720 DCGL.mcd

Options:

Implicit progeny doses NOT included with explicit parent doses

Nuclide **concentrations** are distributed among all progeny

Number of simulations: 6400

Seed for Random Generation: 8718721

Averages used for behavioral type parameters

External Pathway is ON

Inhalation Pathway is ON

Secondary Ingestion Pathway is ON

Initial Activities:

Nuclide	Area of Contamination (m ²)	Distribution
241Am	UNLIMITED	CONSTANT(dpm/100 cm *2)
Justification for concentration: DCGL Determination		Value 2.60E+01

Site Specific Parameters:

General Parameters:

None

Correlation Coefficients:

None

Summary Results:

90.00% of the 6400 calculated TEDE values are $< 2.45\text{E}+01$ mrem/year .

The 95 % Confidence Interval for the 0.9 quantile value of TEDE is $2.42\text{E}+01$ to $2.49\text{E}+01$ mrem/year

ATTACHMENT 2

RESRAD-BUILD Table of Contents

RESRAD-BUILD Input Parameters.....	2
Building Information.....	3
Source Information.....	4
For time = 0.00E+00 yr	
Time Specific Parameters.....	5
Receptor-Source Dose Summary.....	6
Dose by Pathway Detail.....	7
Dose by Nuclide Detail.....	8
For time = 1.00E+00 yr	
Time Specific Parameters.....	9
Receptor-Source Dose Summary.....	10
Dose by Pathway Detail.....	11
Dose by Nuclide Detail.....	12
Full Summary.....	13

Title \ DCGI Determination 133Ba

Input File : C:\RESRAD_Family\BUILD\site1.bld

RESRAD-BUILD Input Parameters

Number of Sources : 1
 Number of Receptors: 1
 Total Time : 3.650000E+02 days
 Fraction Inside : 5.000000E-01

Receptor Information

Receptor	Room	x	y	z	FracTime	Inhalation	Ingestion(Dust)
		[m]	[m]	[m]		[m3/day]	[m2/hr]
1	1	1.000	1.000	1.000	1.000	1.80E+01	1.00E-04

Receptor-Source Shielding Relationship

Receptor	Source	Density	Thickness	Material
		[g/cm3]	[cm]	
1	1	2.40E+00	0.00E+00	Concrete

Title: DCGL Determination 133Ba

Input File : C:\RESRAD_Family\BUILD\site1.bld

===== Building Information =====

Building Air Exchange Rate: 8.00E-01 1/hr

Height[m]	Air Exchanges [m3/hr]	
Area [m2]		

		<=Q03: 6.03E+01
H3: 2.500	Room 3	Q30 : 6.00E+01
	* LAMBDA: 1.00E+00	
Area 36.000	* /\ N23: 0.00E+00	
	** *****	Q32 : 3.00E+01
	** *****	Q23 : 3.00E+01
		<=Q02: 6.00E+01
H2: 2.500	Room 2	Q20 : 6.00E+01
	* LAMBDA: 1.00E+00	
Area 36.000	* /\ N12: 0.00E+00	
		QLR : 0.00E+00
	** *****	Q12 : 0.00E+00
		<=Q01: 9.60E+01
H1: 2.500	Room 1	Q10 : 9.60E+01
	* LAMBDA: 1.07E+00	
Area 36.000		

Deposition velocity: 1.00E-02 [m/s] Resuspension Rate: 5.00E-07 [1/s]

Title': DCGL Determination 133Ba

Input File : C:\RESRAD_Family\BUILD\sitel.bld

Source Information

Source: 1

Location:: Room : 1 x: 0.00 y: 0.00 z: 0.00[m]

Geometry:: Type: Area Area:3.60E+01 [m2] Direction: x

Pathway ::

Direct Ingestion Rate: 0.000E+00 [1/hr]

Fraction released to air: 1.000E-01

Removable fraction: 5.000E-01

Time to Remove: 3.650E+02 [day]

Contamination::

Nuclide Concentration Dose Conversion Factor (Library: FGR 11)

		Ingestion Inhalation Submersion		
		[mrem/pCi]	[mrem/pCi]	[mrem/yr/ {pCi/m3}I
BA-133	2.500E+06	3.400E-06	7.810E-06	2.079E-03

Title': DCGI Determination 133Ba

Input File : C:\RESRAD_Family\BUILD\site1.bld

Evaluation Time: 0.0000000E+00 years

```
=====
|                                     |
|                                     |
|----- Assessment for Time: 1 -----|
|                                     |
|----- Time =0.00E+00 yr -----|
|                                     |
|-----|
|-----|
```

===== Source Information =====

Source: 1

Location:: Room : 1 x: 0.00 y: 0.00 z: 0.00 [m]

Geometry:: Type: Area Area:3.60E+01 [m2] Direction: x

Pathway ::

Direct Ingestion Rate: 0.000E+00 [l/hr]

Fraction released to air: 1.000E-01

Removable fraction: 5.000E-01

Time to Remove: 3.650E+02 [day]

Contamination::	Nuclide	Concentration
		[pCi/m2]
	BA-133	2.500E+06

RESRAD-BUILD Dose Tables	
--------------------------	--

Source Contributions to Receptor Doses

[mrem]

		Source	Total
		1	
Receptor	1	1.92E+01	1.92E+01
Total		1.92E+01	1.92E+01

Title : DCGL Determination 133Ba
Input File : C:\RESRAD_Family\BUILD\site1.bld
Evaluation Time: 0.00000000E+00 years

Pathway Detail of Doses

[mrem]

Source: 1							
Receptor	External	Deposition	Immersion	Inhalation	Radon	Ingestion	
1	1.79E+01	1.00E+00	5.01E-03	1.23E-01	0.00E+00	1	43E-01
Total	1.79E+01	1.00E+00	5.01E-03	1.23E-01	0.00E+00	1.4	31-01

Title : DCGL Determination 133Ba

Input File : C:\RESRAD_Family\BUILD\sitel.bld

Evaluation Time: 0.00000000E+00 years

Nuclide Detail of Doses

[mrem]

Source: 1

Nuclide	Receptor	Total
	1	
BA-133	1.92E+01	1.92E+01

Assessment for Time: 2
Time =1.00E+00 yr

Source Information

Source: 1

Location:: Room: 1 x: 0.00 y: 0.00 z: 0.00 [m]

Geometry:: Type: Area Area:3.60E+01 [m2] Direction: x

Pathway ::

Direct Ingestion Rate: 0.000E+00 [1/hr]

Fraction released to air: 1.000E-01

Removable fraction: 0.000E+00

Time to Remove: 3.650E+02 [day]

Contamination::	Nuclide	Concentration
		[pCi/m2]
	BA-133	1.172E+06

Title: DCGL Determination 133Ba

Input File : C:\RESRAD_Family\BUILD\site1.bld

Evaluation Time: 1.00000000 years

RESRAD-BUILD Dose Tables

Source Contributions to Receptor Doses

[mrem]

	Source	Total
	1	
Receptor 1	1.12E+01	1.12E+01
Total	1.12E+01	1.12E+01

Title': DCGL Determination 1338a

Input File : C:\RESRAD_Family\BUILD\site1.bld

Evaluation Time: 1.00000000 years

Pathway Detail of Doses

[mrem]

Source: 1

Receptor	External	Deposition	Immersion	Inhalation	Radon	Ingestion
1	1.12E+01	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00
Total	1.12E+01	0.00E+00	0.00E+00	0.00E+00	0.00E+00	0.00E+00

Title': DCGL Determination 133Ba
 Input File : C:\RESRAD_Family\BUILD\site1.bld
 Evaluation' Time: 1.00000000 years

Nuclide Detail of Doses

[mrem]

Source: 1

Nuclide	Receptor	Total
	1	
BA-133	1.12E+01	1.12E+01

Title : DCGL Determination 133Ba
Input File : C:\RESRAD_Family\BUILD\site1.bld
Full Summary

RESRAD-BUILD Dose (Time) Tables	
---------------------------------	--

Receptor Dose Received for the Exposure Duration

(mrem)

Evaluation Time [yr]	
0.00E+00	1.00E+00
1	1.92E+01 1.12E+01

Receptor Dose/Yr Averaged Over Exposure Duration

(mrem/yr)

Evaluation Time [yr]	
0.00E+00	1.00E+00
1	1.92E+01 1.12E+01

ATTACHMENT 3

REFERENCE MATRICES and ASSOCIATED MEASUREMENTS

Scaler/rate meter: L2241-2 Detector: 43-37B
 SN: 189777 SN: 149714

	Laminate surface horiz.	Metal surface vert.	Metal surface horiz.	Cinderblock wall (painted)	Wood over cinder block	Wood surface vert.	Ceiling tiles	Drywall	Drywall over cinder block	Vinyl tile 12x12	Carpet
Counts/minute	539 ± 30	478 ± 18	552 ± 25	934 ± 36	661 ± 31	505 ± 34	925 ± 18	565 ± 19	754 ± 32	532 ± 19	508 ± 26

	Concrete floor
Counts/minute	713 ± 19

Scaler/rate meter: L2241-2 Detector: 43-37A
 SN: 189777 SN: 149714

	Laminate surface horiz.	Metal surface vert.	Metal surface horiz.	Cinderblock wall (painted)	Wood over cinder block	Wood surface vert.	Ceiling tiles	Drywall	Drywall over cinder block	Vinyl tile 12x12	Carpet
Counts/minute	7 ± 2	7 f 2	7 f 1	14 ± 3	8 ± 2	8 ± 2	16 ± 3	6 f 2	8 k 2	6 f 2	7 f 2

	Concrete floor
Counts/minute	13 ± 2

Scaler/rate meter: L2241-2 Detector: 43-68A
SN: 196826 SN: 159011

Counts/minute

Scaler/rate meter: L2241-2 Detector: 43-68B
SN: 196826 SN: 159011

Counts/minute

ATTACHMENT 4

RADIATION SAFETY SURVEY REPORT	SURVEYOR NAME:	DATE:
	LAB: 200	TIME:

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B												
C												
D												
E												
F												
G												
H												
I												
J												
K												
L												
	1	2	3	4	5	6	7	8	9	10	11	12

Comments:

RADIATION SAFETY SURVEY REPORT				SURVEYOR NAME:					DATE:				
				LAB: 204					TIME:				
				1	2	3	4	5	6	7	8	9	10

A B C D E F G H I J K L M N O P Q											A B C D E F G H I J K L M N O P Q

				1	2	3	4	5	6	7	8	9	10
--	--	--	--	---	---	---	---	---	---	---	---	---	----

Comments:

RADIATION SAFETY SURVEY REPORT						SURVEYOR NAME:						DATE:																
						LAB: 205						TIME:																
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17																												
A							A7													A								
B							To 206		To 208													B						
C																								C				
D																			D16					D				
E																								E				
F																			To 209					F				
G																								G				
H																								H				
I																			To 210					I				
J	J1								J8															J				
K																												
L																								L				
M																								M				
N	To 204																				To 212					N		
O																								O				
P																								P				
Q							To 201		R8													Q						
R																								R				
S																								S				
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17																												
Comments:																												

RADIATION SAFETY SURVEY REPORT						SURVEYOR NAME:						DATE:		
						LAB: 206						TIME:		
1 2 3 4 5 6 7 8 9 10 11 12 13 14														
A	<p>F4</p> <p>F11</p> <p>To 208</p> <p>To 204</p> <p>To 205</p>													A
B														B
C														C
D														D
E														E
F														F
G														G
H														H
I														I
J														J
K														K
L														L
M														M
1 2 3 4 5 6 7 8 9 10 11 12 13 14														
Comments:														

RADIATION SAFETY SURVEY REPORT						SURVEYOR NAME:						DATE:		
						LAB: 208						TIME:		
<div style="display: flex; justify-content: space-between;"> 1234567891011121314 </div>														
A														A
B														B
C														C
D														D
E														E
F														F
G														G
H														H
I														I
J														J
K														K
L														L
<div style="display: flex; justify-content: space-between;"> 1234567891011121314 </div>														
Comments:														

RADIATION SAFETY SURVEY REPORT				SURVEYOR NAME:					DATE:	
				LAB: 209					TIME:	
<div style="display: flex; justify-content: space-around; width: 100%;"> 12345678910 </div>										
A										A
B										
C										
D										
E										
F										
G										
H										
I										
J										
K										
L										
M										
N										
O										
<div style="display: flex; justify-content: space-around; width: 100%;"> 12345678910 </div>										
Comments:										

RADIATION SAFETY SURVEY REPORT				SURVEYOR NAME:					DATE:				
				LAB: 210					TIME:				
				1	2	3	4	5	6	7	8	9	10

A											A
B											B
C											C
D											D
E											E
F											F
G											G
H											H
I											I
J											J
K											K
L											L
M											M
N											N

	1	2	3	4	5	6	7	8	9	10
--	---	---	---	---	---	---	---	---	---	----

Comments:

RADIATION SAFETY SURVEY REPORT				SURVEYOR NAME:							DATE:		
				LAB: 212							TIME:		
12													
A													A
B													B
C													C
D													D
E													E
F													F
G													G
H													H
I													I
J													J
K													K
L													L
M													M
N													N
12													
Comments:													

ATTACHMENT 5

FINAL STATUS SURVEY GROSS BETA MEASUREMENTS

Sample, Point	Bkg (counts)	Gross (counts)	Count time (in min)	Total Surface Activity ¹ in DPM/100cm ²		
				Gross Beta	Uncertainty ²	MDA
200 - F4	281	340	1	488	404	647
201 - L6	269	339	1	579	400	633
204 - A4	308	283	1	-207	394	677
205 - J1	256	256	1	0	367	618
205 - D16	256	212	1	-364	351	618
206 - F4	356	360	1	33	434	728
206 - F11	356	320	1	-298	421	728
208 - F12	256	228	1	-231	356	618
208 - I12	256	208	1	-397	349	618
209 - J6	356	301	1	-455	415	728
209 - N5	214	225	1	91	340	565
210 - E1	256	242	1	-116	362	618
212 - E4	356	378	1	182	439	728
212 - L4	256	251	1	-41	365	618
212 - F12	256	247	1	-74	363	618

¹ - $E_{\text{weighted, total}} = 0.096$, probe active area 126cm²

² - at the 95% confidence level

Averaged Activity

-54 (DPM/100cm²)

FINAL STATUS SURVEY UNIT GROSS ALPHA MEASUREMENTS

Sample Point	Bkg (counts)	Gross (counts)	Count time (in min)	Total Surface Activity ¹ in DPM/100cm2		
				Gross Alpha	Uncertainty ²	MDA
200 - F4	80	54	20	-22	19	37
201 - E6	40	51	20	9	16	27
204 - Q4	80	70	20	-8	20	37
204 - H4	100	134	20	28	25	41
205 - J8	40	69	20	24	17	27
205 - R8	80	66	20	-12	20	37
205 - A7	80	110	20	25	23	37
205 - D8	40	71	20	26	17	27
209 - J6	100	79	20	-18	22	41
209 - H5	100	51	20	-41	20	41
212 - L4	80	53	20	-23	19	37

¹ - $E_{\text{weighted, total}}$: 0.06, probe active area 126cm²

² - at the 95% confidence level

DPM/100cm2

28 Largest Survey Unit Measurement

-23 Smallest Reference Area Measurement

52 Difference

FINAL STATUS REFERENCE AREA
GROSS ALPHA MEASUREMENTS

Sample Point	Bkg (counts)	Gross (counts)	Count time (in min)	Total Surface Activity ¹ in DPM/100cm ²		
				Gross Alpha	Uncertainty ²	MDA
200 - F4	80	52	20	-23	19	37
201 - E6	40	46	20	5	15	27
204 - Q4	80	68	20	-10	20	37
204 - H4	100	97	20	-3	23	41
205 - J8	40	54	20	12	16	27
205 - R8	80	75	20	-4	20	37
205 - A7	80	102	20	18	22	37
205 - D8	40	62	20	18	16	27
209 - J6	100	82	20	-15	22	41
209 - H5	100	118	20	15	24	41
212 - L4	80	75	20	-4	20	37

¹ - $E_{\text{weighted, total}}$: 0.06, probe active area 126cm²

² - at the 95% confidence level

ATTACHMENT 6

Instrument:	Scaler/rate meter
Detector:	Gas proportional

Model:	Ludlum 2241	Serial Nr:	19682
Model:	Ludlum 43-1	Serial Nr:	159011

Calibration Date:	07/24/08
Calibration Date:	07/24/08

Date	Time	Technician	Background in CPM		Acceptable Range (CPM)		Source ID Nr.	Isotope	Source Reading in CPM		Acceptable Range (CPM)		Results
		Reviewer	X	- X	+20% -20%	+3σ -3σ			X	- X	+10% -10%	+3σ -3σ	
10/30/2008	0600	EW	346	346	415	414	1560	137Cs	11730	11730	12903	12180	Pass
		FW			277	279					10557	11280	
10/31/2008	0600	EW	359	347	417	412	1560	137Cs	11744	11731	12904	12169	Pass
		FW			278	283					10558	11292	
11/3/2008	0600	EW	366	349	419	412	1560	137Cs	11410	11716	12888	12179	Pass
		FW			279	286					10544	11253	
11/4/2008	0600	EW	335	348	417	409	1560	137Cs	11722	11716	12888	12169	Pass
		FW			278	286					10545	11264	
11/5/2008	0600	EW	341	347	417	406	1560	137Cs	11287	11698	12868	12195	Pass
		FW			278	288					10529	11202	
11/6/2008	0600	EW	319	345	414	405	1560	137Cs	11691	11698	12868	12184	Pass
		FW			276	285					10528	11212	
11/7/2008	0600	EW	320	344	413	404	1560	137Cs	12126	11715	12886	12238	Pass
		FW			275	284					10543	11191	
11/10/2008	0600	EW	356	345	413	403	1560	137Cs	12100	11729	12902	12277	Pass
		FW			276	286					10556	11181	
11/14/2008	0600	EW	289	341	410	408	1560	137Cs	11406	11717	12889	12277	Pass
		FW			273	275					10546	11157	

Instrument:	Scaler/rate meter
Detector:	Gas proportional

Model:	Ludlum 2241-2	Serial Nr:	196826
Model:	Ludlum 43-68A	Serial Nr:	148834

Calibration Date:	07/24/08
Calibration Date:	07/24/08

Date	Time	Technician Reviewer	Background in CPM		Acceptable Range (CPM)		Source ID Nr.	Isotope	Source Reading in CPM		Acceptable Range (CPM)		Results
			X	-	+200% -200%	+3σ -3σ			X	-	+10% -10%	+3σ -3σ	
10/30/2008	0600	EW FW	1 1	1 1	2 -2	2 -1	61	241Am	6559	6559	7214 5901	7154 5964	Pass
10/31/2008	0600	EW FW	1 1	1 1	2 -2	2 0	61	241Am	6511	6557	7213 5901	7138 5977	Pass
11/3/2008	0600	EW FW	0 1	1 1	2 -2	2 -1	61	241Am	6454	6552	7208 5897	7122 5983	Pass
11/4/2008	0600	EW FW	1 1	1 1	2 -2	2 -1	61	241Am	6575	6553	7209 5898	7110 5997	Pass
11/5/2008	0600	EW FW	1 1	1 1	2 -2	2 -1	61	241Am	6201	6539	7193 5885	7114 5964	Pass
11/6/2008	0600	EW FW	1 1	1 1	2 -2	2 0	61	241Am	6315	6530	7183 5877	7104 5955	Pass
11/7/2008	0600	EW FW	1 1	1 1	2 -2	2 0	61	241Am	6570	6531	7184 5878	7095 5968	Pass
11/10/2008	0600	EW FW	1 1	1 1	2 -2	2 0	61	241Am	6355	6525	7177 5872	7084 5965	Pass
11/12/2008	0600	EW FW	2 1	1 1	2 -2	2 0	61	241Am	6422	6521	7173 5869	7072 5970	Pass
11/13/2008	0600	FW	2	1	2 -2	2 0	61	241Am	6335	6515	7166 5863	7063 5966	Pass
11/14/2008	0600	EW FW	1 1	1 1	2 -2	2 0	61	241Am	6439	6512	7163 5861	7052 5972	Pass
11/17/2008	0600	EW FW	0 1	1 1	2 -2	2 -1	61	241Am	6265	6504	7155 5854	7048 5961	Pass
11/21/2008	0600	EW FW	1 1	1 1	2 -2	2 -1	61	241Am	6486	6504	7154 5853	7038 5969	Pass
11/24/2008	0600	FW	1	1	2 -2	2 0	61	241Am	6273	6497	7146 5847	7033 5960	Pass

Instrument:	Scaler/rate meter
Detector:	Gas proportional

Model:	Ludlum 2241-2	Serial Nr:	189777
Model:	Ludlum 43-37B	Serial Nr:	148745

Calibration Date:	07/21/08
Calibration Date:	07/21/08

Date	Time	Technician	Background in CPM		Acceptable Range (CPM)		Source ID Nr.	Isotope	Source Reading in CPM		Acceptable Range (CPM)		Results
		Reviewer	X	- X	+20% -20%	+3σ -3σ			X	- X	+10% -10%	-3σ	
10/30/2008	0630	<u>FW</u> FW	898	898	<u>1077</u> 718	<u>997</u> 799	1559	137Cs	24265	24265	<u>26691</u> 21838	<u>25599</u> 22931	Pass
10/31/2008	0630	<u>FW</u> FW	897	898	<u>1077</u> 718	<u>991</u> 804	1559	137Cs	24957	24287	<u>26716</u> 21858	<u>25637</u> 22937	Pass
11/3/2008	0630	<u>FW</u> FW	889	897	<u>1076</u> 718	<u>987</u> 807	1559	137Cs	25626	24329	<u>26762</u> 21896	<u>25791</u> 22867	Pass
11/5/2008	0630	<u>FW</u> FW	901	897	<u>1077</u> 718	<u>983</u> 811	1559	137Cs	25439	24363	<u>26799</u> 21926	<u>25885</u> 22840	Pass
11/6/2008	0630	<u>FW</u> FW	870	895	<u>1074</u> 716	<u>980</u> 811	1559	137Cs	25829	24406	<u>26846</u> 21965	<u>26039</u> 22772	Pass
11/7/2008	0630	<u>FW</u> FW	944	899	<u>1078</u> 719	<u>986</u> 811	1559	137Cs	25714	24428	<u>26871</u> 21985	<u>26072</u> 22784	Pass

Instrument: Scaler/rate meter			Model: Ludlum 2241-2			Serial Nr: 189777			tic D t 07/21/08				
Detector: Gas proportional			Model: Ludlum 43-37A			Serial Nr: 148745			tic Date: 07/21/08				
Date	Time	Technician	Background in CPM		Acceptable Range (CPM)		Source ID Nr.	Isotope	Source Reading in CPM		Acceptable Range (CPM)		Results
			X	- X	+200% -200%	+3σ -3σ			X	- X	+10% -10%	+3σ -3σ	
		Reviewer											
11/3/2008	0700	FW FW	4	4	9 -9	Z 2	61	241Am	6139	6139	6753 5525	6746 5532	Pass
11/5/2008	0700	FW FW	5	4	9 -9	Z 2	61	241Am	5984	6134	6748 5521	6736 5533	Pass
11/6/2008	0700	FW FW	4	4	9 -9	Z 2	61	241Am	6022	6131	6744 5518	6724 5537	Pass
11/7/2009	0700	FW FW	5	4	9 -9	Z 2	61	241Am	6018	6127	6740 5515	6714 5541	Pass
11/10/2008	0700	FW FW	5	4	9 -9	Z 2	61	241Am	6132	6127	6740 5515	6705 5550	Pass

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

4/13/2009, and to inform you that the initial processing which includes an administrative review has been performed.

☒ AMEND. 19-07538-d
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** 143643.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.