REPORT OF RADIOLOGICAL SURVEY

For:

US Food and Drug Administration
Center for Food Safety and Applied Nutrition
Harvey W. Wiley Federal Building
5001 Campus Drive
College Park, MD 20740

December 2020

Prepared by:

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TABLE OF CONTENTS

ATTACHMENTS

Attachment One	Reference Matrices and Associated Measurements
Attachment Two	Reference Map of Facility and Survey Unit Area
Attachment Three	Results of Final Status Static Measurements
Attachment Four	Results of Wipe Samples - Final Status Survey
Attachment Five	Daily Operational Checks of Portable Survey Instruments, Calibration Certificate and Minimum Detectable Concentration Calculations
Attachment Six	Final Waste Shipment Manifest

ACRONYMS

ALARA	As Low As Reasonably Achievable
Clym	Clym Environmental Services, LLC
CF	Correction Factor
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
COC	Chain of Custody
CPM	Counts Per Minute
DCGL	Derived Concentration Guideline Level
DPM	Disintegrations Per Minute
DQA	Data Quality Assessment
DQO	Data Quality Objective
DSV	Default Screening Value
FDA	United States Food and Drug Administration
FSS	Final Status Survey
GCPM	Gross Counts Per Minute
HSA	Historical Site Assessment
LBGR	Lower Bound of the Gray Region
LSC	Liquid Scintillation Counter
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
MDC	Minimum Detectable Concentration
MDCR	Minimum Detectable Count Rate
NCPM	Net Counts Per Minute
NRC	United States Nuclear Regulatory Commission
QA	Quality Assurance
ROI	Region of Interest
RPP	Radiation Protection Program
RSO	Radiation Safety Officer
TEDE	Total Effective Dose Equivalent
TEI	Triumvirate Environmental, Inc.
Wiley	Harvey W. Wiley Federal Building, 5001 Campus Dr., College Park, MD 20740

1.0 INTRODUCTION

The U.S. Food and Drug Administration (FDA) is organized into centers specific to its research and regulatory focus. One of these is the Center for Food Safety and Applied Nutrition (CFSAN). In support of its mission, CFSAN has and continues to conduct research employing various radiolabeled compounds. One of CFSAN's facilities, the Harvey W. Wiley Federal Building (Wiley, 5001 Campus Drive, College Park, MD 20740) conducted research involving the possession, use and storage of radioactive materials authorized by the U.S. Nuclear Regulatory Commission (NRC) via Radioactive Materials license number No. 19-30771-01 (with 16 attachments, expiring December 31, 2025). This license provides a limited scope of use that is associated with life sciences research activities. Given that FDA is no longer pursuing the use of radioactive materials at the Wiley Building, this radioactive materials license is being amended to remove this building as an authorized location of use. In support of this request, decommissioning surveys and assessments are required. This report details the decommissioning surveys conducted and offers a conclusion derived from those surveys.

The NRC provides guidance on the radiological decommissioning of facilities such as the Wiley Building in the Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM). The FDA has engaged Clym Environmental Services, LLC (Clym) to assist in the implementation of the relevant steps of the MARSSIM process for the radiological assessment of the Wiley Building. The FDA has contracted Clym to perform this service through a subcontract with its hazardous, biological and radioactive waste management services provider, Triumvirate Environmental, Inc. (TEI). Clym is a State of Maryland radioactive materials licensee (MD-21-035-01, expiring 1/31/2027) and routinely provides such radiation safety support services to its customers. On site surveys and assessments were conducted by Clym under the authority of the CFSAN radioactive materials license. It is noted that Clym's Project Manager also serves as the contracted Radiation Safety Officer (RSO) for the CFSAN radioactive materials license.

2.0 SITE DESCRIPTION AND HSITORY

2.1 Historical Site Assessments

The MARSSIM process can be simply divided into four main phases of data collection and review: Planning, Conducting, Assessing and Decision Making. The first phase, Planning, incorporates the Historical Site Assessment. The HSA is later followed by other surveys ultimately leading to the Final Status Survey (FSS). The HSA is intended to collect existing data relevant to site activities involving the use of radioactive materials from the start of those activities to the present time. The intent of the HSA is further defined depending on the type of activities conducted. Given the limited scope of operations associated with FDA research at the Wiley Building, namely low activity toxin studies, the HSA is specifically intended to: identify potential and known sources of radioactive material and/or radioactive contamination based on existing data; assess the likelihood for

contaminant migration; provide useful information for designing scoping and characterization surveys; provide initial classification of the site, or survey units within the site, as impacted or non-impacted; and consider the areas and systems affected by the infrastructure improvements.

It should be noted that the initial classification is the catalyst for future phases and is critical to the ultimate surveys that follow. This initial classification can be further defined after the completion of scoping and characterization surveys and therefore is a very basic, first impression of the possibility for radioactive contamination in a given area. "Impacted" then is meant to describe any area within the Facility that has a reasonable opportunity for radioactive contamination to be present. The reasonableness of this assumption might include knowledge of past operations, lack of knowledge of past operations, storage strategies, contaminant migration potential, or the proximity of an area as compared to known areas of radioactive material use or storage. "Non-impacted" therefore is meant to define an area where there is no reasonable possibility, or an extremely low probability, for radioactive contamination.

2.2 Site Description

The FDA/CFSAN/Wiley Building at 5001 Campus Drive, College Park, MD is generally described as follows:

- Five-story building consisting of approximately 251,000 square feet of which CFSAN is the sole occupant

- The Wiley Building was commissioned in 2001 and has been occupied by CFSAN from that time until present day

- CFSAN plans to continue its occupancy and use of the facility in the future, but without the use of radioactive materials requiring specific licensure from the NRC

2.3 Site Ownership

The Wiley Building is presently owned by the U.S Government (General Services Administration).

2.4 Radionuclides of Concern

The radionuclides that were possessed and used by research staff at the Wiley Building include phosphorus-32 (^{32}P), sulfur-35 (^{35}S), hydrogen-3 (^{3}H or tritium) and carbon-14 (^{14}C). Given that ^{32}P and ^{35}S are short-lived radionuclides and have not been used in more than five years prior to this survey, the radionuclides of concern for this survey were limited to ^{3}H and ^{14}C.

2.5 Previous Radiological Surveys and Assessments

Periodic contamination surveys were conducted in all areas where radioactive materials were used or stored during the term of the current and previous radioactive materials licenses. The results of those surveys supported the designation of the radionuclides of concern as no other site contaminants were identified. It is noted that generally licensed sources of naturally occurring radioactive materials (specifically uranyl acetate) were used and stored in one laboratory on site (3EL14).

3.0 RADIOLOGICAL SURVEYS

The Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) provides procedures and calculations to provide statistically defensible evidence that survey results meet the current dose-based release criteria required by the Nuclear Regulatory Commission for facilities operating under radiological controls. This process culminates in the Final Status Survey (FSS). Inputs into the Final Status Survey design are from two sources: pre-release surveys and dose modeling. The pre-release surveys, including the historical site assessment, scoping survey, the characterization survey and the remedial action support survey, provide information into planning the FSS. The dose modeling provides Derived Concentration Guideline Levels (DCGLs) for both the statistical test used in qualifying the uniformly distributed residual radioactivity and for the elevated measurement comparison of localized residual radioactivity.

MARSSIM provides a standardized statistical approach to sampling and describes the statistical tools, tests and assumptions needed. The intent of the statistical approach is to develop a representation of the distribution of residual radioactivity in the survey unit utilizing the least number of samples. Non-parametric statistical tests are used by MARSSIM to minimize the dependence on normality since many of these sampling distributions are skewed by small areas of localized radioactivity that can result from remediation activities.

Sampling is required if a surface scan of adequate sensitivity cannot be obtained to show that the release criteria is met. Sampling and direct measurement cannot fully replace a 100% scan in terms of spatial coverage and therefore, the location of samples and the number of samples must provide enough information about the overall distribution of residual radioactivity to make a decision on releasing a survey unit.

Given the critical importance of sufficient data, scoping surveys must meet the following key objectives: conservative classification, thorough consideration of all surfaces and designed to meet Final Status requirements based on initial classification.

A scoping survey is performed to substantiate and better define potential radioactive contaminants including the general extent of any residual activity. These surveys usually

consist of surface scans and direct radiation level measurements at representative points. Samples of residues from surfaces and other areas of potential contamination should be analyzed to determine radionuclide specific activity. Should residual activity be detected, Clym proposed to proceed directly with characterization surveys.

Within any survey design, the unit to be surveyed must be defined by type and risk level. Clym has identified two subgroups of these units: building structures and building systems. Building structures consist of ceilings, upper walls, shelves, lower walls, casework and sinks, and floors. Building systems consist of sink traps and drain lines, and chemical fume hoods, ducting and exhaust blower motors, filters and fans. There are no systems associated with the waste storage module. All shelves, lower walls, grating and floors within the storage module are considered "high risk" units.

The percentage of any unit to be surveyed is based on the potential or known levels of residual contamination. The amount of coverage designated for each area classification has been provided in Table 1.

Table 1: Scoping Survey Percentage of Surface Area Surveyed

Area Classification	***Building Structures***					***Building Systems***	
	Ceiling	**Upper Walls**	**Lower Walls & Shelves**	**Casework**	**Floors**	**Traps & Drain Lines**	**Hoods & Ducts**
Impacted	10%	10%	50%	50%	50%	100% (traps)	100% (hoods)

All scans and sample collection activities were conducted in accordance with industry standard procedures and good work practices. Surface scans will be conducted with special attention afforded to cracks, joints and other areas where contamination may have accumulated. Wipe samples will be used to evaluate the presence of removable surface contamination. Surveys in all areas will focus on "high risk" surfaces. Survey units will be divided into square meters for sampling using a square shaped grid design.

MARSSIM assigns a greater level of effort on surveys conducted in areas that have, or had, the highest potential for contamination. The process by which an area is classified is based on the radiological characteristics. 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.

The history of radioactive materials possession, use and storage at the Wiley Building is detailed in license related documents. Additional information was obtained from a review of historical records and interviews with the operational personnel. Records indicated that long-lived, open-form radioactive materials that were used at the facility included:

Tritium and 14-Carbon (^{3}H and ^{14}C).

The Final Status survey was designed to designate each survey unit for surface scans and swipe samples. In an attempt to gain operational efficiency, the scoping survey was designed to meet the requirements of the Final Status Survey. The radioactive waste compartment of the waste storage module was designated as impacted. The contiguous hazardous waste compartment was also designated for survey.

Scoping surveys were designed to evaluate: 1) total surface activity using surface scans as well as static measurements, and 2) removable surface contamination using smear samples. These surveys would focus on surfaces deemed "high risk areas". The "lower walls" in known radioactive material usage areas was defined as the surface area from the floor to a height of approximately six feet. Surface scans were designated to cover 50% of accessible floor and 50% of accessible lower wall areas. Smear sample locations were determined using the surveyor's professional judgment. Any area found to have residual surface contamination was designated for further evaluation as outlined below:

(1) Surface Scans
Any surface area found to be greater than 20% above the established background for the matrices being evaluated.

(2) Smears
Any activity detected above the minimum detectable.

Any area found to be at the investigative level for surface scans would be designated for further evaluation. This evaluation would be made using static measurements and smears to quantify the level of the contamination and better define the area.

Based on the history of radioactive material use at the Wiley Building and the survey data available, scoping surveys were designed to meet final status survey requirements. This design would allow for the efficient collection of data and maximize outsourced labor. The next step was to determine the Derived Concentration Guideline Levels (DCGLs) and select the Final Status Survey method in order to demonstrate compliance with the provisions specified in NRC regulations for releasing the waste storage module for unrestricted use.

Surface contamination screening levels were obtained using the values provided in NUREG-1757, Volume 1, Appendix B, Table B.1. A listing of the adopted screening values for building/surface contamination is provided in Table 2.

Table 2: Surface Contamination Screening Values

Radionuclide	Symbol	Acceptable Screening Level (dpm/100cm^2)
Tritium	^{3}H	1.2e+08
14-Carbon	^{14}C	3.7e+06

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 0.4 mm thick windows. It was determined that tritium (^{3}H) would be evaluated independently, relying solely on smear samples to determine residual surface contamination. The DCGL was adjusted from 1.2e+08 dpm/100cm^2 to 1.2e+07 dpm/100cm^2 to reflect a swipe efficiency of ten percent (10%).

The DCGL for ^{14}C was found to be 3.7e+06 dpm/100cm^2. Minimum detectable concentration (MDC) for the selected instrumentation can be calculated at the 95% confidence level using a variation of common equations such as those found in NUREG 1507, "Minimum Detectable Concentrations with Typical Radiation Survey instruments for Various Contaminants and Field Conditions" Table 3.1 (Strom & Stansbury, 1992). A 25% surface efficiency was applied to the calibrated efficiency to account for attenuation for less than 0.4 MeV beta-emitting radionuclides.

A typical static MDC calculation for gas flow proportional detectors, for example, is provided here:

$$MDC_{static} = \frac{3 + 3.29\sqrt{B_R \cdot t_S \cdot (1 + \frac{t_s}{t_b})}}{t_S \cdot E_{tot} \cdot \frac{A}{100}}$$

Where:

MDC_{static}	=	minimum detectable concentration (dpm/100cm^2)
B_R	=	background count rate (counts per minute)
t_b	=	background count time (minutes)
t_s	=	sample count time (minutes)
E_{tot}	=	total detector efficiency for radionuclide of interest
A	=	detector probe area (cm^2)

Scanning MDC (95% confidence level) for the same instrument can be calculated using equations from MARSSIM (6-8, 6-9, 6-10). A typical MDC_{scan} calculation for gas flow proportional detectors is shown here:

$$MDC_{scan} = \frac{d' \sqrt{b_i} \left(\frac{60}{i}\right)}{\sqrt{p} \cdot E_{tot} \cdot \frac{A}{100cm^2}}$$

Where:

MDC_{scan}	=	minimum detectable concentration (dpm/100cm^2)
d'	=	desired performance variable (1.38)
b_i	=	background count during the residence interval (counts)
i	=	residence interval (seconds)
p	=	surveyor efficiency (0.5)
E_{tot}	=	total detector efficiency for radionuclide of interest
A	=	detector probe area (cm^2)

Wipe sample counting MDC (95% confidence level) can be calculated using a variation of common equations such as those found in NUREG 1507, "Minimum Detectable Concentrations with Typical Radiation Survey instruments for Various Contaminants and Field Conditions" Table 3.1 (Strom & Stansbury, 1992). An example for a typical liquid scintillation counter is shown here:

$$MDC_{wipe\ sample} = \frac{3 + 3.29\sqrt{B_r \cdot t_s \cdot \left(1 + \frac{t_s}{t_b}\right)}}{t_s \cdot E}$$

Where:

$MDC_{wipe\ sample}$	=	minimum detectable concentration (dpm/100cm^2)
B_R	=	background count rate (counts per minute)
t_b	=	background count time (minutes)
t_s	=	sample count time (minutes)
E	=	instrument efficiency for radionuclide of interest

3.1 Field Measurements, Methods and Instrumentation

Surface scans and static measurements were made using scaler/rate meters (Ludlum model 221) equipped with large area gas proportional detectors (Ludlum model 43-37 and 43-68). Variations in background readings were found throughout the survey area. The primary contributing factor was determined to be variations in the

composition of surface matrices. Reference areas were located in adjacent areas that had not housed radioactive materials previously.

As an example, the MDC_{static} for the 43-37 detector was determined to be 185 dpm/100cm^2 using an averaged background in air of 750 cpm. The Static MDC is well below the required fifty percent (50%) of the DCGL for ^{14}C. The MDC_{scan} was found to be 790 dpm/100cm^2 for the same matrix. These calculations for the encountered surface matrices are included with Attachment Five.

The minimum observational interval or hold time over a suspect area was specified for the first stage scan at 2 seconds. The detector was employed on the scanned surface at no greater than the prescribed speed as indicated below:

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

3.2 Laboratory Analysis of Smear Samples

The evaluation of removable surface activity was conducted using a dry paper wipe, covering an approximate area of 100 cm^2 while applying moderate pressure. A total of 9,218 smear samples were collected during scoping surveys. The number of samples collected was influenced by the volume of supplies, equipment and items that remained in storage in impacted areas. This data set is available upon request.

Clym Environmental Services, LLC analyzed the scoping survey smear samples using liquid scintillation counting techniques. A region of interest was established between 0 to 2000 keV. The typical minimum detectable activity for gross beta using a four-minute count time was 25 dpm. This was calculated using a background of 28 cpm and detection efficiency for tritium of 53%. Any sample found to have detectable activity in excess of the minimum detectable was designated for quantitative analysis.

It is noted that no scoping survey wipe sample was found to have activity greater than instrument MDA.

3.3 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.

4.0 FINAL STATUS SURVEY PLAN

All areas surveyed were combined into one (1) Class 3 survey unit, identified as Survey Unit One, totally approximately 4,500 square feet or 418 square meters. This survey unit includes the following rooms / areas: Basement Level (BEL02 – BEL19), First Floor (1D008

(LS Counting), 1D009, 1D011 (Rad Waste) and 1D012, Second Floor (None), Third Floor (3EL14), Fourth Floor (4EL13-4EL18) and all applicable contiguous areas for each.

Table 3 Survey Units

Survey Unit	*Approximate Area (m^2)*
One	418

The Final Status Survey required surface scans and one-minute static measurements within the survey unit. Surface scans were completed in the survey unit during scoping surveys to the required specifications as detailed in Section 3.

4.1 Determining the Number of Data Points for Statistical Tests

This section details the process of determining the selection and implementation of statistical tests required by MARSSIM.

4.1.1 Contaminants Not Present in Background

The Sign Test was selected to compare beta emitting nuclides, or those contaminants not present in background (^{3}H and ^{14}C). 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 is tested (H_o), namely is the median concentration of residual radioactivity in the survey unit greater than the DCGL? The alternative hypothesis, H_a, would result in the median concentration of residual radioactivity in the survey unit being less than the DCGL.

H_o: The median concentration of residual radioactivity in the survey unit is greater 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.

4.1.1.1 Calculate the Relative Shift

First, the DCGL, lower bound of the gray region (LBGR) and the standard deviation of the contaminants in each survey unit were used to calculate the relative shift. The LBGR was determined for each survey unit. Next, the standard deviation and relative shift were calculated for each survey unit.

If the relative shift was determined to be >3, the lower bound of the gray

region (LBGR) is to be adjusted. The relative shift for each survey unit was calculated and the LBGR adjusted to 3.

4.1.1.2 Determination of Sign p

The value of the relative shift calculated in section 4.1.1.1 was used to obtain the corresponding value of Sign p using Table 5.4 as found in NUREG-1575 (Revision 1, August 2000).

4.1.1.3 Determination of Decision Error Percentiles

The determination of percentiles, Z1-α and Z1-β was conducted by selecting the designated values using Table 5.2 as found in NUREG-1575 (Revision 1, August 2000).

4.1.1.4 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 (Revision 1, August 2000). The number of data points for the survey unit was determined to be 14. In following the recommendation of MARSSIM 5.5.2.2 the sample size was increased by 20% and rounded up to allow for potential data losses. Accounting for this increase, the total number of data points was 17.

5.0 FINAL STATUS SURVEY

A total of one (1) survey unit (Class 3) was designated for evaluation using Final Status Survey techniques. A one-meter square grid system was constructed in each survey area, to include the floors and lower walls. The designation for each surface in the survey unit was identified using an alphanumeric system. Diagrams of the areas included in the survey unit have been provided as Attachment Two.

For this survey, surface matrices were identified and references for establishing background for these matrices were collected. A copy of these results is included as Attachment One.

Random sample points were identified within the survey unit and a random starting point was determined. Sample points were designated using a random number generator after having assigned each grid coordinate a numerical value.

The results of static measurements made in the survey unit have been provided as Attachment Three. The results of swipe samples collected from the survey unit have been provided as Attachment Four.

5.1 Summary of Statistical Tests

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

5.1.1 Contaminants Not Present in Background

The Sign Test was selected to compare those contaminants not present in background (^{3}H and ^{14}C). The objective of the Final Status Survey is to demonstrate that the residual radioactivity levels meet the release criterion.

H_o: The median concentration of residual radioactivity in the survey unit is greater than the DCGL.

All measurements were found to be less than the DCGL. The average of the measurements made in each survey unit was determined. The measurement average in each survey unit was found to be less than the DCGL. The Sign test did not need to be performed as each survey unit met the release criterion.

6.0 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.

6.1 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/or
- ✓ Any time instrument's operation is in question.

Daily instrument checks included:

1) a determination of operational readiness,

2) ambient background determination, 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 ± 10%. Additionally, the 3σ values for the background and check source counts were calculated. A copy of these daily checks has been provided as Attachment Five.

6.2 Internal Quality Assurance Checks

Quality assurance evaluations were conducted for each surveyor. These evaluations involved verification measurements to confirm Final Status Survey measurements for total surface contamination. Measurements were made at two- (2) randomly selected Final Status Survey sample points from each survey unit. The procedures and techniques utilized to make these measurements were identical to those used in the FSS. Additionally, surface scans were conducted on what were deemed "high risk" surfaces in each survey unit. "High risk" surfaces included laboratory bench tops, chemical fume hoods, fixtures, including doorknobs and light switches. This evaluation was conducted assessing the measured values for each survey point (both verification and FSS) to determine if overlap occurred at the 95% confidence level.

7.0 DISPOSITION OF MATERIALS AND WASTE

All licensed radioactive waste was removed from the site as of November 14, 2018 (see Attachment Six). The source from the liquid scintillation counter was removed and transferred to the device manufacturer on September 30, 2019.

8.0 CONCLUSION

The Final Status Surveys conducted by Clym on behalf of the FDA's Center for Food Safety and Applied Nutrition (CFSAN) demonstrate compliance with the provisions specified in the CFSAN's radioactive materials license and associated NRC regulations for release of the Wiley Building for unrestricted use. Therefore, Clym recommends that CFSAN petition the NRC for immediate removal of the Wiley Building as an authorized place of use on its radioactive materials license and update the primary physical address to:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Muirkirk Road Complex
8301 Muirkirk Road
Laurel, MD 20708.

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. Title 10, Code of Federal Regulations

Attachment One

Reference Matrices
Background Measurements

ATTACHMENT ONE

Reference Background Measurements for Surface Matrices

Scaler / Ratemeter L221 (#147494)

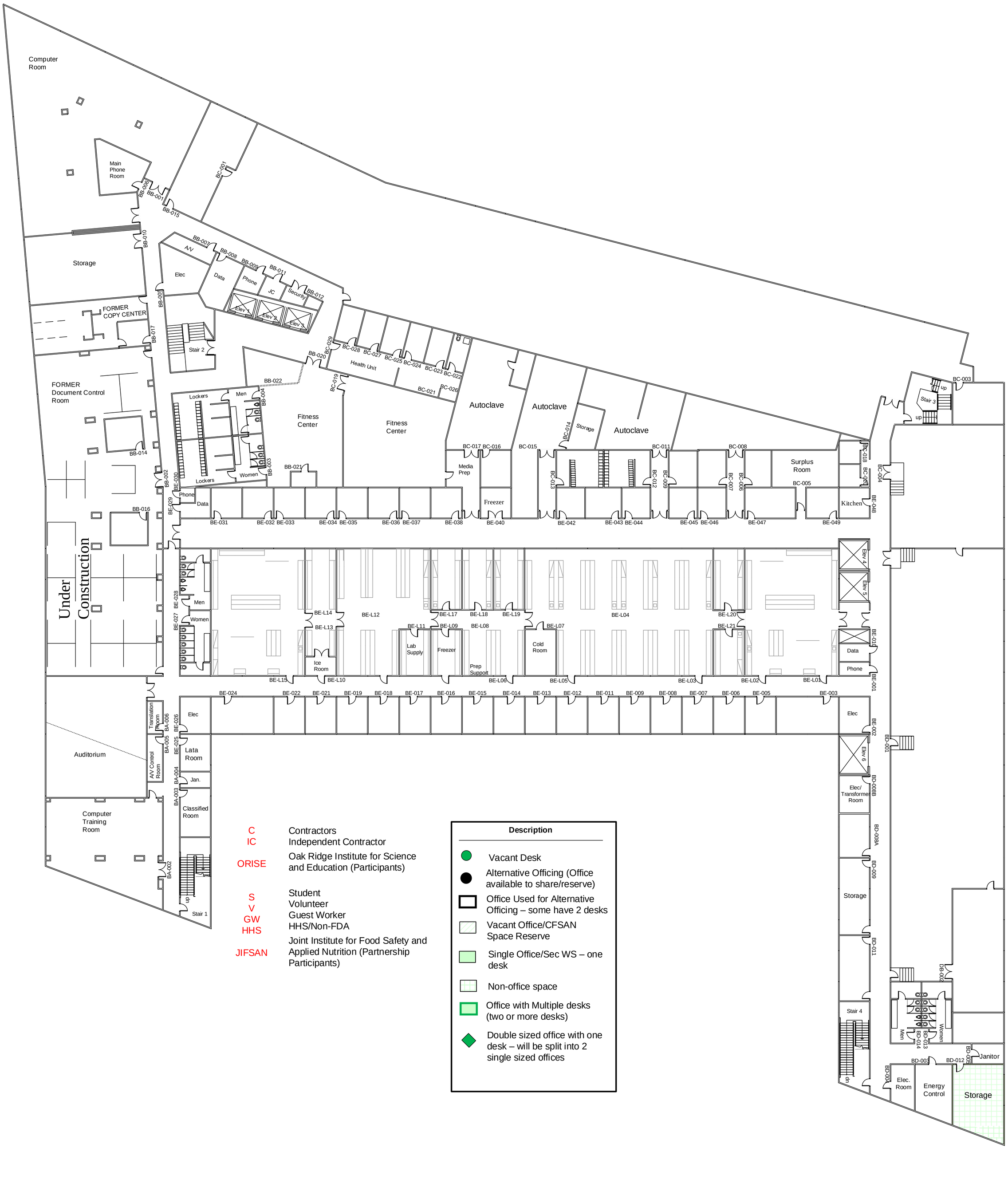
Detector 43-37 (#216994)

Matrix Description	Reference Area	MDC DPM/100cm^2	Average Background (CPM)	3 σ	Expected Background Range CPM (+/- 3 σ)		Individual One-Minute Static Measurements (CPM)									
Floor, vinyl	1D021	176	686	70	616	756	660	663	712	666	688	703	671	672	729	696
Casework, metal	1D021	163	571	58	513	630	541	576	597	547	557	587	588	556	580	584
Benchtop	1D021	177	677	62	616	739	663	695	662	684	653	703	687	708	657	660
Wood	1D021	142	613	58	555	671	591	587	629	623	606	649	623	610	619	593
Drywall	1D021	168	612	65	547	677	627	598	633	657	587	617	599	610	592	601

Attachment Two

Reference Maps
Facility and Survey Unit

CFSAN - College Park
Basement Floor

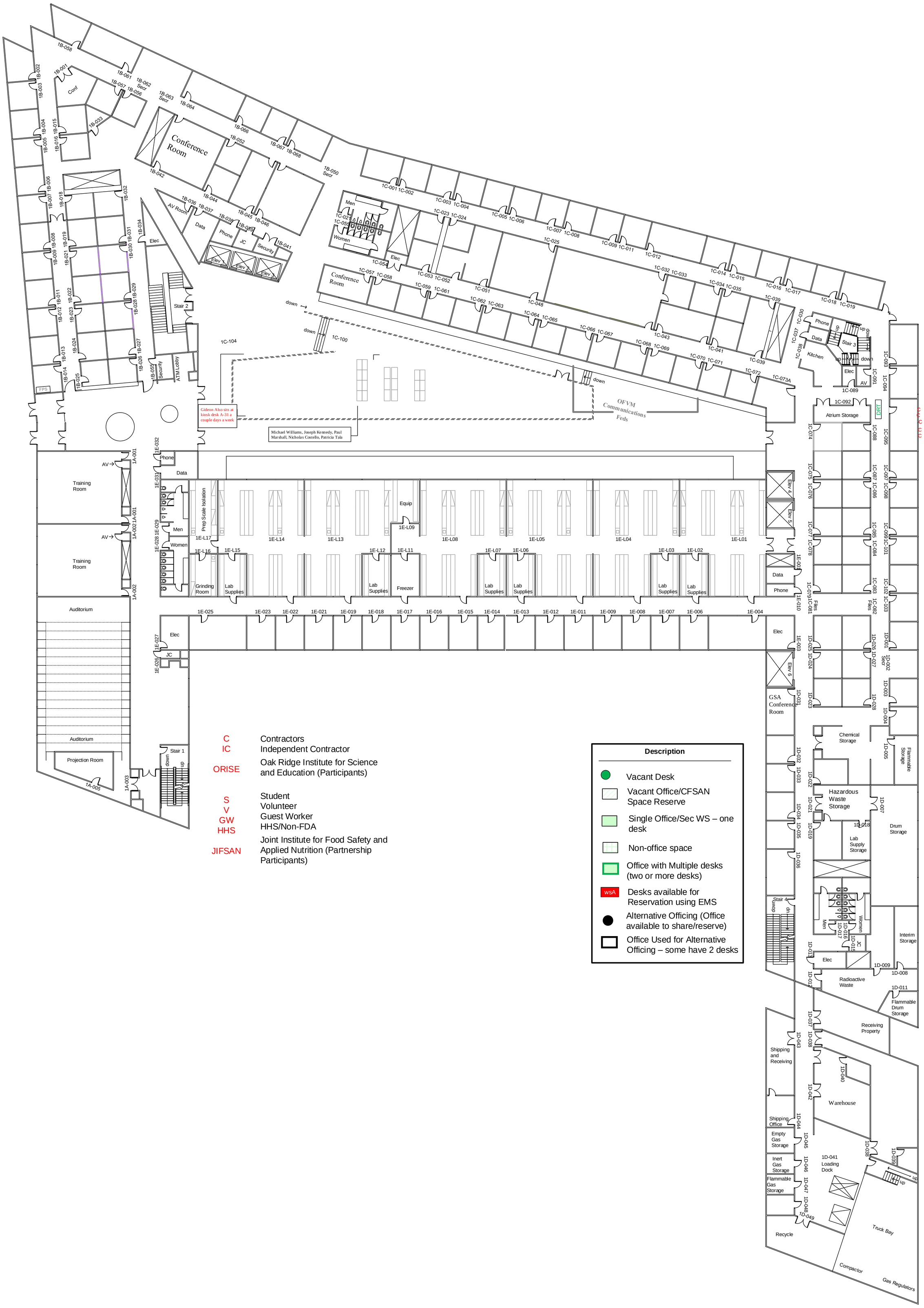


C	Contractors
IC	Independent Contractor
ORISE	Oak Ridge Institute for Science and Education (Participants)
S	Student
V	Volunteer
GW	Guest Worker
HHS	HHS/Non-FDA
JIFSAN	Joint Institute for Food Safety and Applied Nutrition (Partnership Participants)

Description

- Vacant Desk
- Alternative Officing (Office available to share/reserve)
- Office Used for Alternative Officing – some have 2 desks
- Vacant Office/CFSAN Space Reserve
- Single Office/Sec WS – one desk
- Non-office space
- Office with Multiple desks (two or more desks)
- Double sized office with one desk – will be split into 2 single sized offices

CFSAN - College Park
1st Floor



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- Non-office space
- Office with Multiple desks (two or more desks)
- wsA — Desks available for Reservation using EMS
- Alternative Officing (Office available to share/reserve)
- Office Used for Alternative Officing – some have 2 desks

CFSAN - College Park
2nd Floor

C	Contractors
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CFSAN - College Park
3rd Floor

OFFICE OF FOOD SAFETY (OFS)
OFFICE OF COMPLIANCE (OC)
OFFICE OF REGULATORY SCIENCE (ORS)
OFFICE OF NUTRITION, AND FOOD LABELING (ONFL)
OFFICE OF MANAGEMENT (OM)
OFFICE OF ANALYTICS AND OUTREACH (OAO)
OFFICE OF DIETARY SUPPLEMENT PROGRAMS (ODSP)

CFSAN Space Reserve

C Contractors
IC Independent Contractor

ORISE Oak Ridge Institute for Science and Education (Participants)

S Student
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GW Guest Worker
HHS HHS/Non-FDA

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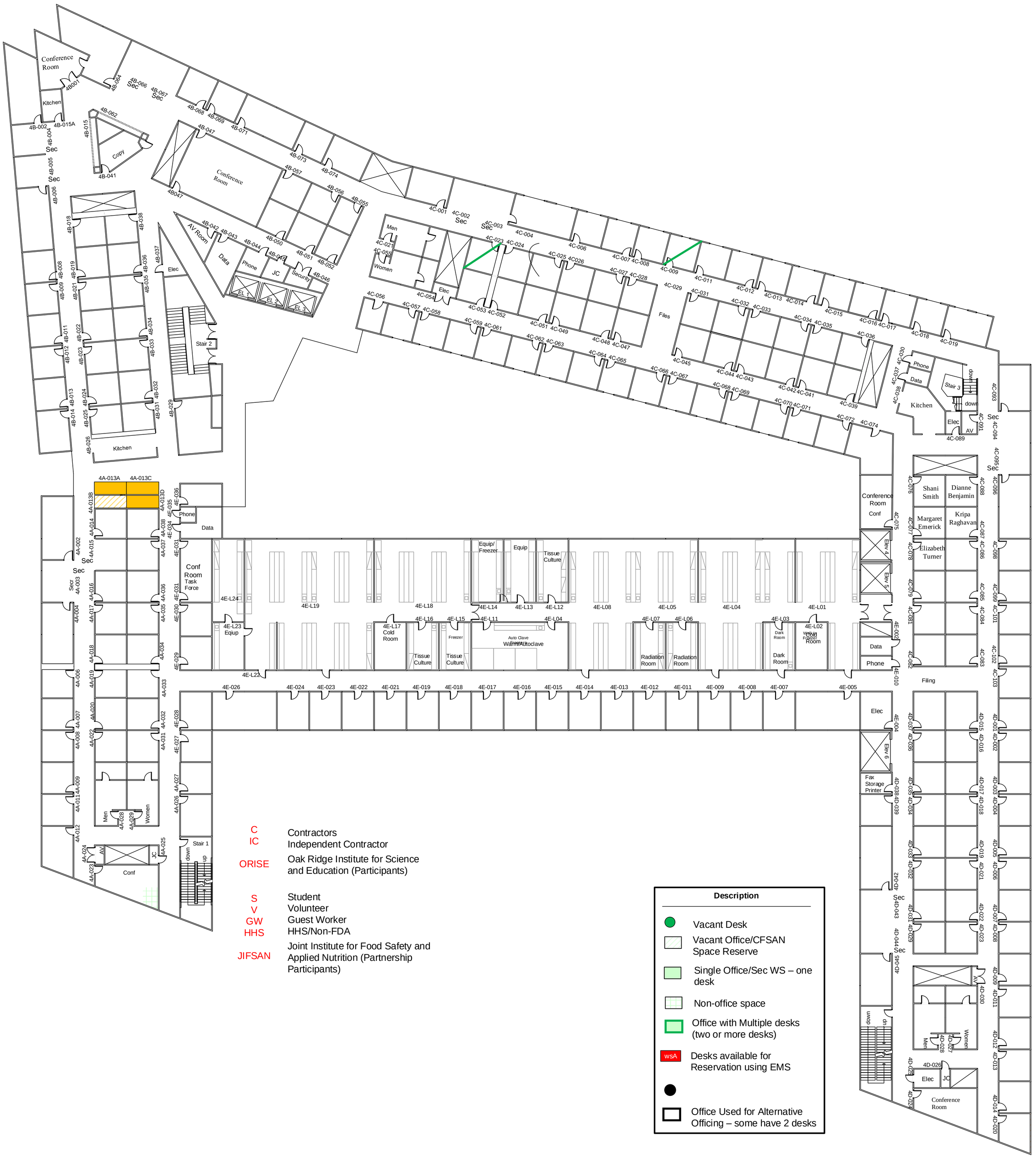
- Office with Multiple desks (two or more desks)
- wsA — Desks available for Reservation using EMS
- Alternative Officing (Office available to share/reserve)
- Office Used for Alternative Officing – some have 2 desks

CFSAN - College Park
4th Floor



C	Contractors
IC	Independent Contractor
ORISE	Oak Ridge Institute for Science and Education (Participants)
S	Student
V	Volunteer
GW	Guest Worker
HHS	HHS/Non-FDA
JIFSAN	Joint Institute for Food Safety and Applied Nutrition (Partnership Participants)

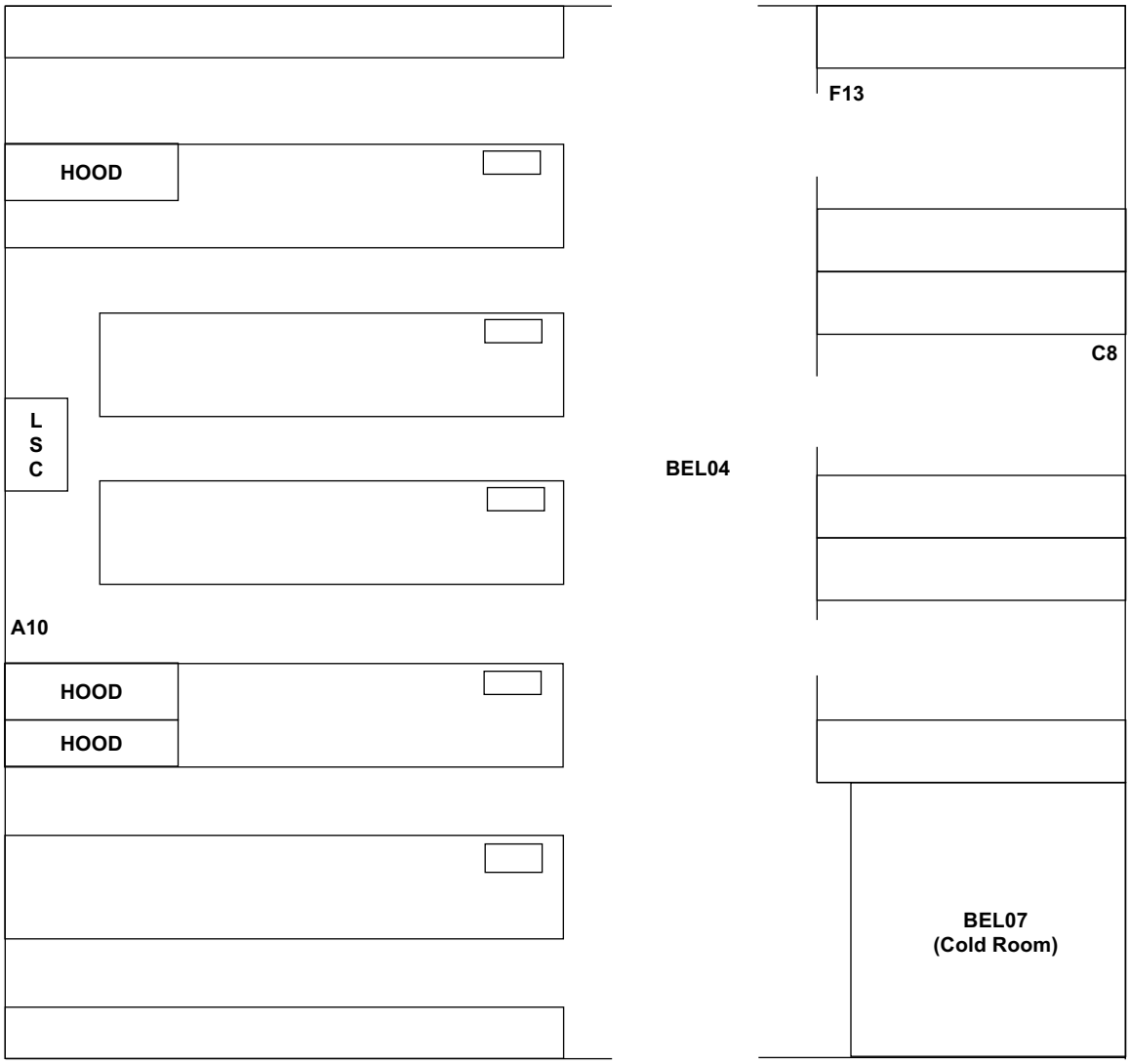
Description

- Vacant Desk
- Vacant Office/CFSAN Space Reserve
- Single Office/Sec WS – one desk
- Non-office space
- Office with Multiple desks (two or more desks)
- wsA — Desks available for Reservation using EMS
- Office Used for Alternative Officing – some have 2 desks

MONITORING AND SURVEY FORM

Surveyor:	Date:
Watts, C.	9/21/18
Client:	**Location:**
FDA Wiley Building	BEL04 Suite

Area Diagram:



Comments:
Drawing not to scale.
"E" = Ceiling, "F" = Floor
Approximate size 2,400 ft^2

Meter information

L2221 (#147494)
43-37 (#216994)
DOC: 4/12/18

Note(s):

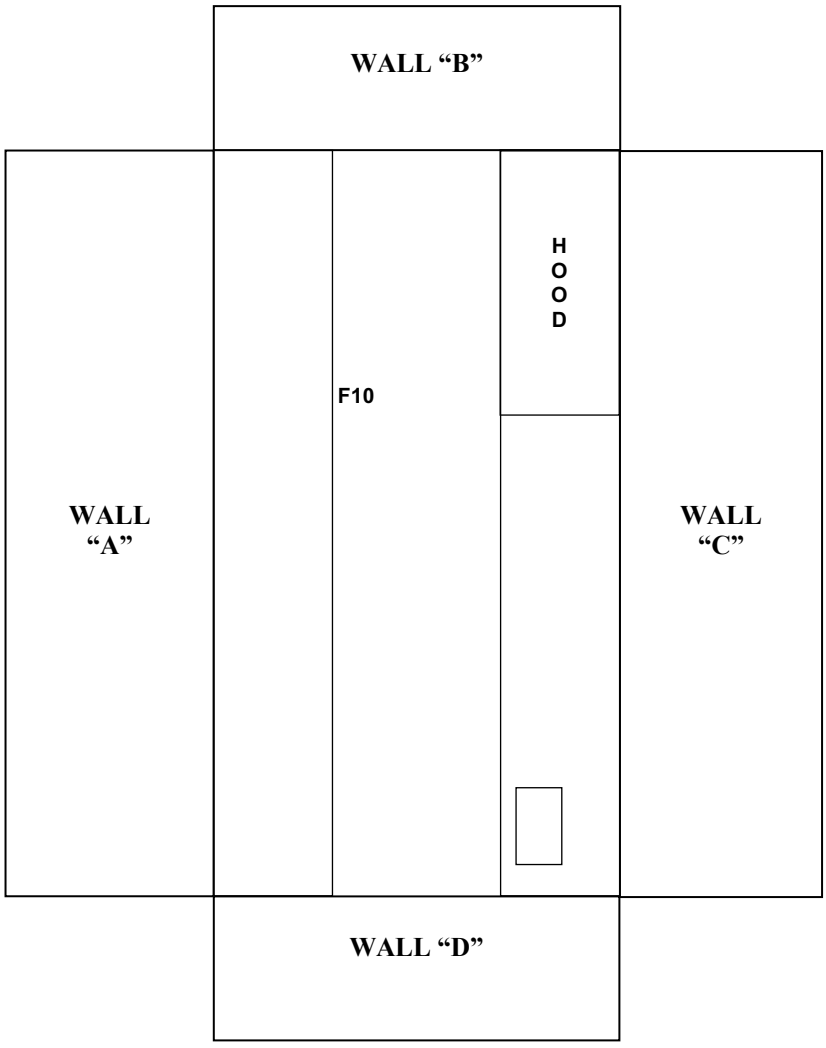
Final Status Points (Static result (cpm)):

BEL004: A10 (669)
BEL004: F13 (703)
BEL004: C8 (641)

MONITORING AND SURVEY FORM

Surveyor:	Date:
Watts, C.	9/21/18
Client:	**Location:**
FDA Wiley Building	BEL18

Area Diagram:



Comments:
Drawing not to scale.
"E" = Ceiling, "F" = Floor
Approximate size 450 ft^2

Note(s):

Final Status Points (Static result (cpm)):
BEL018: F10 (636)

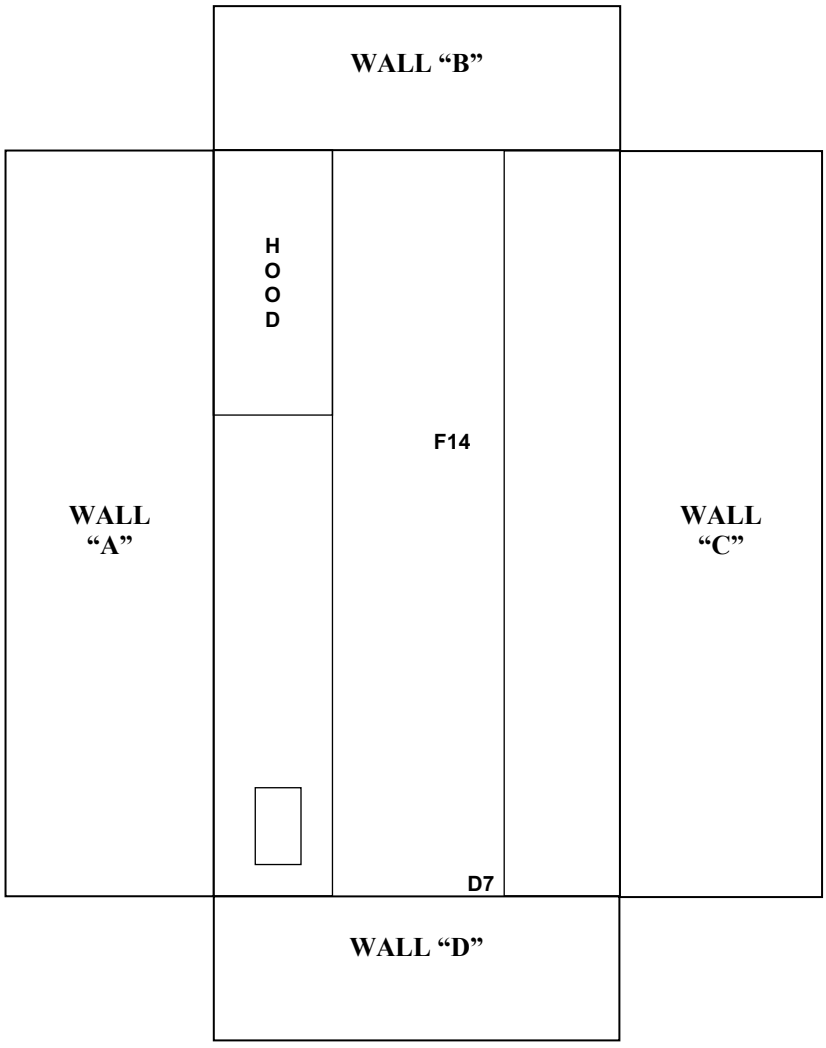
Meter information

L2221 (#147494)
43-37 (#216994)
DOC: 4/12/18

MONITORING AND SURVEY FORM

Surveyor:	Date:
Watts, C.	9/21/18
Client:	**Location:**
FDA Wiley Building	BEL19

Area Diagram:



Comments:
Drawing not to scale.
"E" = Ceiling, "F" = Floor
Approximate size 450 ft^2

Meter information

L2221 (#147494)
43-37 (#216994)
DOC: 4/12/18

Note(s):

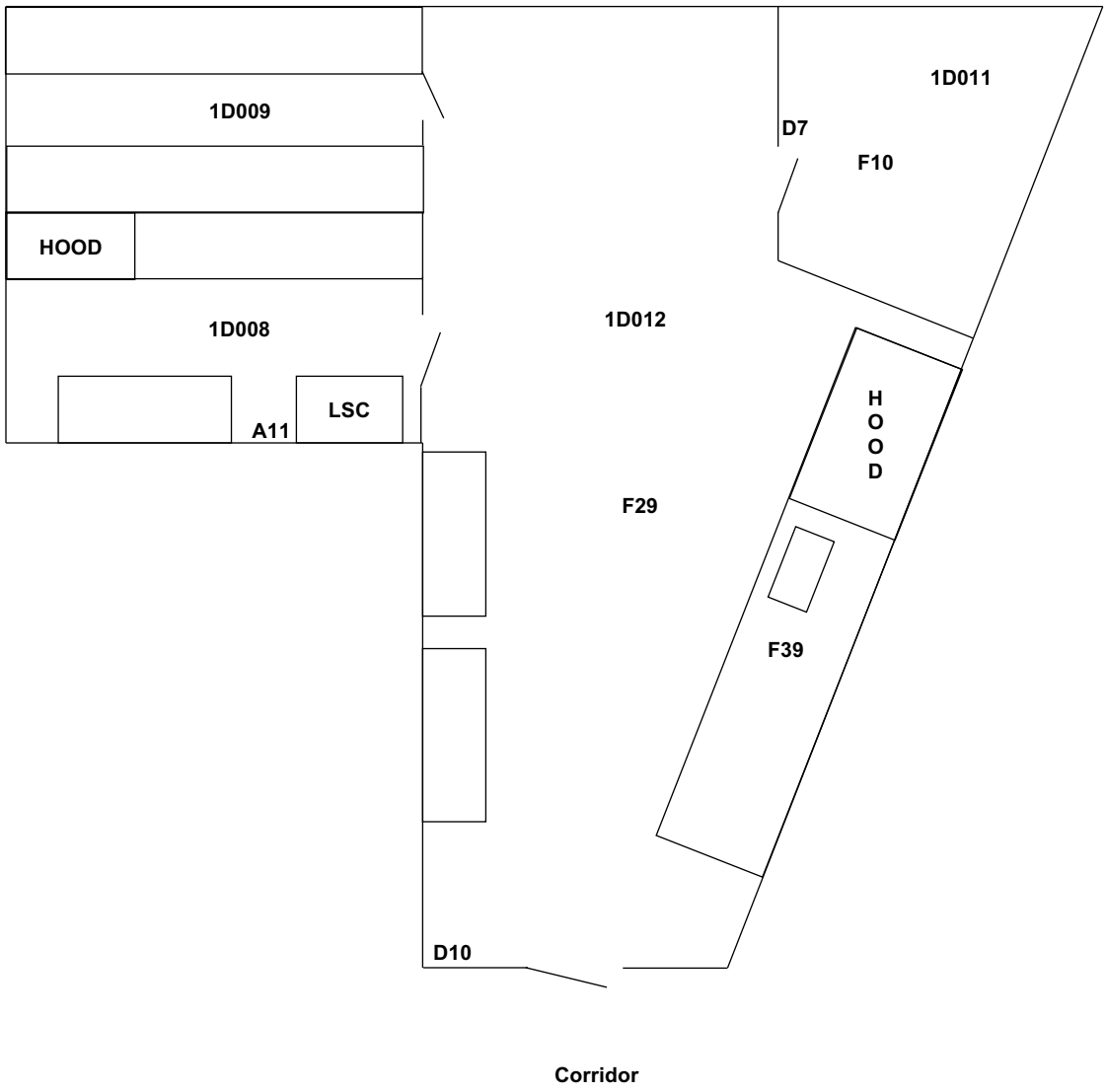
Final Status Points (Static result (cpm)):

BEL019: F14 (729)
BEL019: D7 (568)

MONITORING AND SURVEY FORM

Surveyor:	Date:
Watts, C.	9/21/18
Client:	**Location:**
FDA Wiley Building	1D012 Suite

Area Diagram:



Comments:
Drawing not to scale.
"E" = Ceiling, "F" = Floor
Approximate size 1,150 ft^2

Meter information

L2221 (#147494)
43-37 (#216994)
DOC: 4/12/18

Note(s):

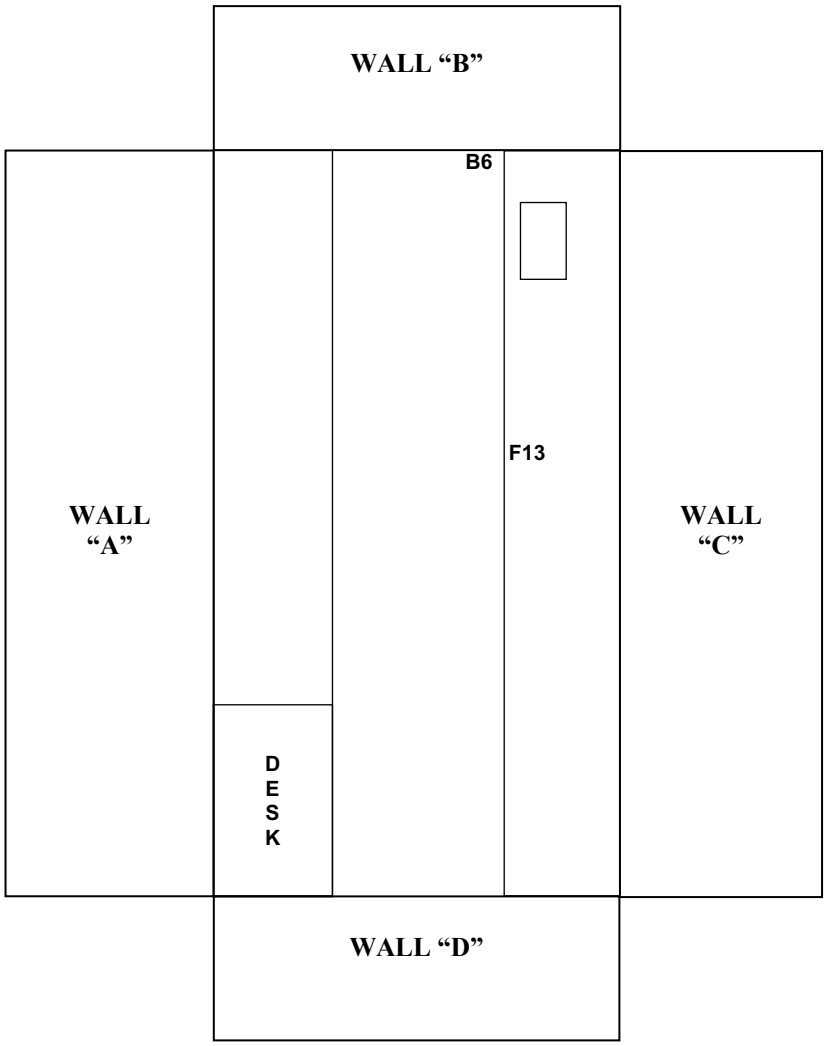
Final Status Points (Static result (cpm)):

1D008: A11 (610)
1D011: D7 (672)
1D011: F10 (688)
1D012: F29 (675)
1D012: F39 (577)
1D012: D10 (621)

MONITORING AND SURVEY FORM

Surveyor:	Date:
Watts, C.	9/21/18
Client:	**Location:**
FDA Wiley Building	3EL14

Area Diagram:



Comments:
Drawing not to scale.
"E" = Ceiling, "F" = Floor
Approximate size 450 ft^2

Meter information

L2221 (#147494)
43-37 (#216994)
DOC: 4/12/18

Note(s):

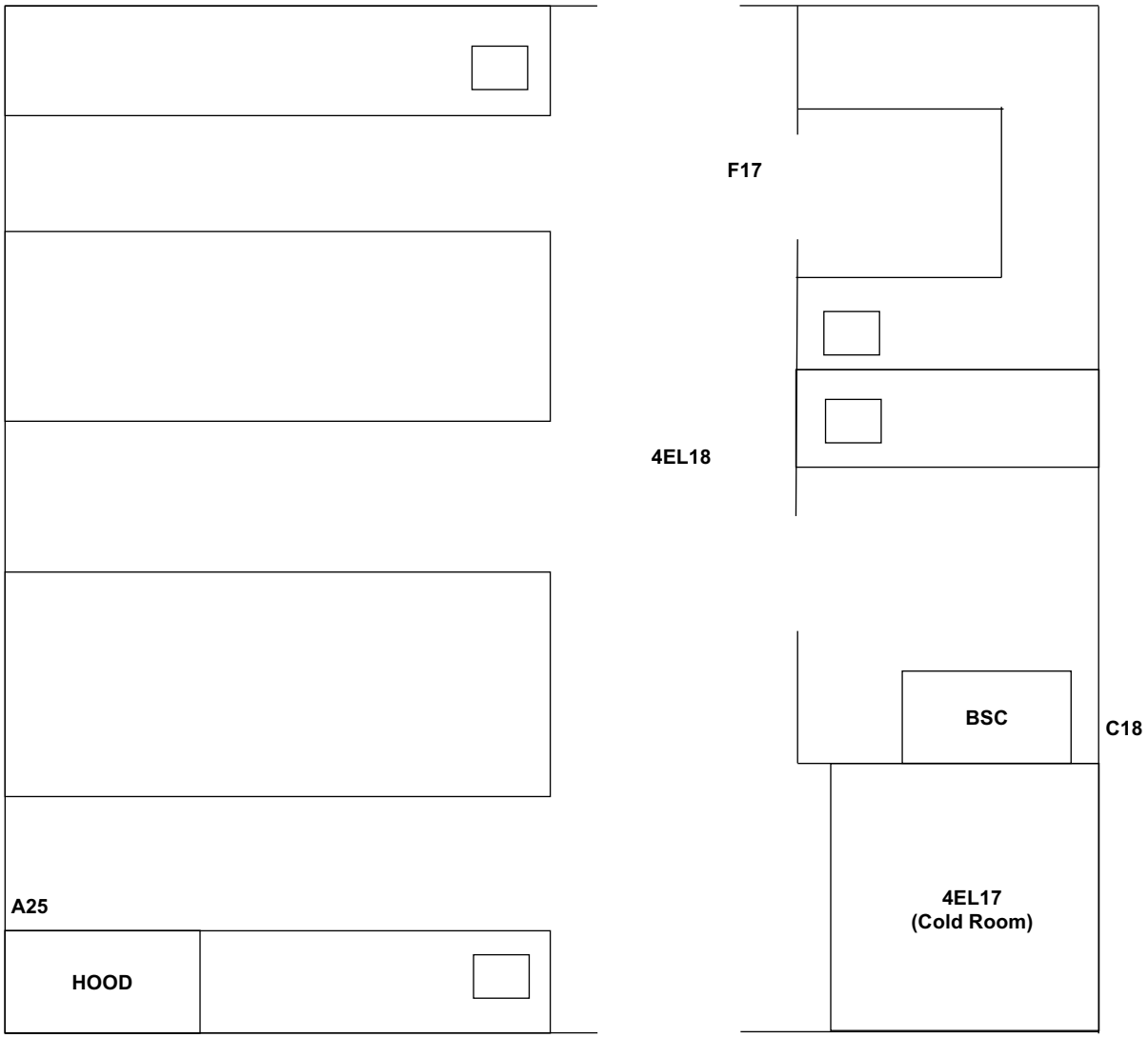
Final Status Points (Static result (cpm)):

3EL014: B6 (603)
3EL014: F13 (695)

MONITORING AND SURVEY FORM

Surveyor:	Date:
Watts, C.	9/21/18
Client:	**Location:**
FDA Wiley Building	4EL18 Suite

Area Diagram:



Comments:
Drawing not to scale.
"E" = Ceiling, "F" = Floor
Approximate size 1,225 ft^2

Meter information

L2221 (#147494)
43-37 (#216994)
DOC: 4/12/18

Note(s):

Final Status Points (Static result (cpm)):

4EL018: A25 (604)
4EL018: C18 (648)
4EL018: F17 (714)

Attachment Three

Final Status Survey
Static Measurements

ATTACHMENT THREE

Final Status Survey

Static Measurement Results
14C DCGL = 3.7E6 DPM/100cm^2

Scaler/Ratemeter: L2221 #147494
Detector: 43-37 (#216994)

Survey Date: 9/21/18
Detector Size: 584 cm^2

Room	Grid	Matrix	Matrix Background	Static Result 1-Minute (GCPM)	Net CPM	DPM/100cm^2	Uncertainty*	Result
1D008	A11	Drywall	612	610	-2	-4	48.45	< DCGL
1D011	D7	Drywall	612	672	60	114	50.85	< DCGL
1D011	F10	Floor	686	688	2	4	51.45	< DCGL
1D012	F29	Floor	686	675	-11	-21	50.97	< DCGL
1D012	F39	Metal	571	577	6	11	47.12	< DCGL
1D012	D10	Drywall	612	621	9	17	48.88	< DCGL
BEL04	A10	Drywall	612	669	57	108	50.74	< DCGL
BEL04	F13	Floor	686	703	17	32	52.01	< DCGL
BEL04	C8	Drywall	612	641	29	55	49.66	< DCGL
BEL19	F14	Floor	686	729	43	82	52.96	< DCGL
BEL19	D7	Metal	571	568	-3	-6	46.75	< DCGL
BEL18	F10	Floor	686	636	-50	-95	49.47	< DCGL
3EL14	B6	Drywall	612	603	-9	-17	48.17	< DCGL
3EL14	F13	Floor	686	695	9	17	51.71	< DCGL
4EL18	A25	Drywall	612	604	-8	-15	48.21	< DCGL
4EL18	C18	Drywall	612	648	36	68	49.93	< DCGL
4EL18	F17	Floor	686	714	28	53	52.42	< DCGL

* Uncertainty calculated at the 95% Confidence Level

Attachment Four

Final Status Survey
Wipe Results

ATTACHMENT FOUR

FDA Wiley Bldg Final Status Survey
Data Reduction Spreadsheet
(Survey Unit One)

Liquid Scintillation Counter Results
Beckman LS 6500 (S/N 7067149)
Run ID #CW180921

Sample ID	Sample Location	Background (cpm)	CPM	Efficiency (3H)	Time (m)	MDA	DPM/100cm^2	Uncertainty (95%CL)
1	1D008 (A11)	23	0.00	0.6055	4	19.7	0.00	5.46
2	1D011 (D7)	23	0.25	0.6059	4	19.6	0.41	5.47
3	1D011 (F10)	23	0.00	0.6053	4	19.7	0.00	5.46
4	1D012 (F29)	23	0.00	0.5828	4	20.4	0.00	5.67
5	1D012 (F39)	23	0.00	0.598	4	19.9	0.00	5.53
6	1D012 (D10)	23	0.00	0.5952	4	20.0	0.00	5.56
7	BEL04 (A10)	23	0.00	0.6022	4	19.8	0.00	5.49
8	BEL04 (F13)	23	0.00	0.5912	4	20.1	0.00	5.59
9	BEL04 (C8)	23	0.00	0.5921	4	20.1	0.00	5.58
10	BEL19 (F14)	23	0.00	0.6039	4	19.7	0.00	5.48
11	BEL19 (D7)	23	0.00	0.598	4	19.9	0.00	5.53
12	BEL18 (F10)	23	0.25	0.5896	4	20.2	0.42	5.62
13	3EL14 (B6)	23	0.00	0.6044	4	19.7	0.00	5.47
14	3EL14 (F13)	23	0.00	0.5945	4	20.0	0.00	5.56
15	4EL18 (A25)	23	0.00	0.6057	4	19.6	0.00	5.46
16	4EL18 (C18)	23	0.75	0.6038	4	19.7	1.24	5.52
17	4EL18 (F17)	23	0.00	0.5915	4	20.1	0.00	5.59

Attachment Five

Instrument Quality Assurance

ATTACHMENT FIVE

Instrument Quality Assurance

Final Status Surveys

Scaler/Ratemeter	**Model:**	L-2221	**Serial #:**	147494	**Calibration Date:**	4/12/18	
Gas proportional	**Model:**	43-37	**Serial #:**	216994	**Mode:**	BETA	

Date	Technician / Reviewer	BKGD (CPM)		Acceptable Range (CPM)		Source ID	Isotope	Source Reading (CPM)		Acceptable Range (CPM)		RESULT
		x	_ x	+20% -20%	+3σ -3σ			x	_ x	+10% -10%	+3σ -3σ	
21-Sep	CW	749	765	918	897	1215-36-1	14C	12777	12839	14123	13142	**PASS**
	CW			612	633					11555	12536	
21-Sep	CW	797	765	918	897	1215-36-1	14C	12904	12839	14123	13142	**PASS**
	CW			612	633					11555	12536	

Minimum Detectable Concentrations (MDCs)
(NUREG 1507 Table 3.1, Strom & Stansbury, 1992)

Direct Monitoring

L2221 (SN 147494)
Probe: 43-37 (216994) E_{tot} = ^{14}C 2π Efficiency (36%) x Surface efficiency (25%)

MDC Static
Reports MDC in dpm/100cm^2

		ENTER:		
B_R	background, ambient (cpm)	B_R	750	
t_b	background count time (minutes)	t_b	10	
t_s	sample count time (minutes)	t_s	1	
E_{tot}	total detector efficiency for radionuclide of interest	E_{tot}	0.09	
A	detector probe area (cm^2)	A	584	

t_s / t_b	0.1
	1.1
B_R*t_s*calc	825
sqrt	28.7228
* 3.29	94.4981
plus 3	97.4981
ts*Etot*A/100	0.5256

MDC STATIC **185** dpm/100cm^2
Result < 50% DQO

MDC Scan
Reports MDC in dpm/100cm^2

		ENTER:		
d'	desired performance variable (1.38)	b_i	12.50	cps
b_i	background count during the residence interval	E_{tot}	0.09	
i	residence interval (seconds)	A	584	
p	surveyor efficiency (0.5)			
E_{tot}	total detector efficiency for radionuclide of interest			
A	detector probe area (cm^2)			

43-37
i 1 seconds at one probe width per second

60 / i	60.00
cps	12.50
sqrt	3.54
	212.13
* 1.38	292.74
sqrt(0.5)	0.71
* Etot	0.06
* 5.82	0.37

MDC SCAN **790** dpm/100cm^2

L2221 (SN 147494)
Probe: 43-68 (149769) E_{tot} = ^{14}C 2π Efficiency (35%) x Surface efficiency (25%)

MDC Static
Reports MDC in dpm/100cm^2

		ENTER:		
B_R	background, ambient (cpm)	B_R	185	
t_b	background count time (minutes)	t_b	10	
t_s	sample count time (minutes)	t_s	1	
E_{tot}	total detector efficiency for radionuclide of interest	E_{tot}	0.0875	
A	detector probe area (cm^2)	A	126	

t_s / t_b	0.1
	1.1
B_R*t_s*calc	203.5
sqrt	14.2653426
* 3.29	46.9329772
plus 3	49.9329772
ts*Etot*A/100	0.11025

MDC STATIC **453** dpm/100cm^2
Result < 50% DQO

MDC Scan
Reports MDC in dpm/100cm^2

		ENTER:		
d'	desired performance variable (1.38)	b_i	3.08	cps
b_i	background count during the residence interval	E_{tot}	0.0875	
i	residence interval (seconds)	A	126	
p	surveyor efficiency (0.5)			
E_{tot}	total setector efficiency for radionuclide of interest			
A	detector probe area (cm^2)			

43-68
i 1 seconds at one probe width per second

60 / i	60
cps	3.08333333
sqrt	1.75594229
	105.356538
* 1.38	145.392022
sqrt(0.5)	0.70710678
* Etot	0.06187184
* 1.26	0.07795852

MDC SCAN **1865** dpm/100cm^2

Minimum Detectable Concentrations (MDCs)

Wipe Samples
Beckman LS 6500, S/N 7067149

GROSS BETA

		ENTER:		
B_R	background (cpm)	B_R	28	
t_b	background count time (minutes)	t_b	4	
t_s	sample count time (minutes)	t_s	4	
E_{tot}	total setector efficiency for radionuclide of interest	E_{tot}	0.53	Full open window using ^{3}H efficiency

t_s / t_b	1
	2
B_R*t_s*calc	224
sqrt	14.9666
* 3.29	49.2402
plus 3	52.2402
ts*Etot	2.12

GROSS BETA
MDC **25** dpm/100cm^2
Result < 50% DQO

Clym Environmental Services, LLC
1539 Tilco Dr., Suite 123
Frederick, MD 21704
Office: 888-289-2324
Fax: 301-694-6797
contact@clymenvironmental.com

Customer:	**Instrument:** Ludlum
Clym Environmental Services, LLC	**Model:** 2221
Address:	**Serial Nr:** 147494
1539 Tilco Dr	
Suite 123	**Detector(s):** Ludlum
Frederick, MD 2170	**Model:** 43-37
	Serial Nr: PR216994

Functional Tests Pre-Calibration (Yes / No)

Inspection Item	Accept	Reject	Comment
Cable	Y		
Battery Level	Y		
Mechanical Zero	Y		
Connections	Y		
Test of Moving Parts	Y		
Light Sensitivity	Y		
Operating Voltage		N	1100v alpha, 1700v alpha/beta
Check Source Reading	Y		
Other: Threshold		N	4mv

Instrument Calibration Information

Instrument Scale	Calibration Value (cpm)	Ratemeter Response (cpm) Initial	Ratemeter Response (cpm) Existing	Delta %	Correction Factor
x 1	100	100	100	0.00	1.00
x 1	400	400	400	0.00	
x 10	1,000	1,000	1000	0.00	1.00
x 10	4,000	4,000	4000	0.00	
x 100	10,000	10,000	10000	0.00	1.00
x 100	40,000	40,000	40000	0.00	
x 1k	100,000	100,000	100000	0.00	1.00
x 1k	400,000	400,000	400000	0.00	

Detector Efficiency Information

Source Nuclide	Serial Nr.	Emission rate 2pi	Detector Model / Serial Nr.		Eff
14C	1577-27-2	68,520	43-37	PR216994	36
32Si	1577-27-1	59,460	43-37	PR216994	66

Comments:

Eff 2pi: 239Pu 0.47 Eff total (4pi): Unat 0.31 (alpha + beta) and 0.05 (alpha)

Calibrated By: WM Reviewed By: FW

Date: 12-Apr-18 Date: 14-Apr-18

Attachment Six

Waste Shipment Manifest

ENERGYSOLUTIONS
We're part of the solution

Monday, November 19, 2018

Charles Watts
CLYM Environmental Services/Frederick, MD
1539 Tilco Drive Suite 123
Frederick, MD 21704

Dear Mr. Watts:

The attached signed shipping manifest copies are your notice of receipt of the radioactive waste materials shipment specified on the manifest number below.

Manifest Number	Date Received
2432-FDA-181114-2	11/19/2018

Thank you for your business.

Sincerely,

Tammy J. Hall

Shipping and Receiving

cc: Manifest File
Shipping and Receiving file

ENERGYSOLUTIONS
We're part of the solution

Manifest Discrepancies

None

020600
194087

FORM 540 — Duratek, Inc. - Commercial Processing

UNIFORM LOW-LEVEL RADIOACTIVE WASTE MANIFEST
SHIPPING PAPER

1 EMERGENCY TELEPHONE NUMBER (Include Area Code): 800-424-9300

ORGANIZATION: CHEMTREC

2. IS THIS AN "EXCLUSIVE USE" SHIPMENT? ☐ YES ☑ NO

3. TOTAL NUMBER OF PACKAGES IDENTIFIED ON THIS MANIFEST ⟹ 2

4. DOES EPA REGULATED WASTE REQUIRING A MANIFEST ACCOMPANY THIS SHIPMENT? ☐ YES ☑ NO
If "Yes," provide Manifest Number ⟹

EPA MANIFEST NUMBER

5. SHIPPER – NAME AND FACILITY
Clym Env Svcs for Food & Drug Administration
Wiley Building
5001 Campus Drive
College Park, MD 20740

SHIPPER I.D. NUMBER: T-MD095-L18
☑ COLLECTOR ☐ PROCESSOR ☐ GENERATOR TYPE (Specify)

USER PERMIT NUMBER: NA
SHIPMENT NUMBER:

CONTACT: Martin Wright
TELEPHONE NUMBER (Include Area Code): 301-436-2104

6. CARRIER – Name and Address
Tri State Motor Transit, Co.
PO Box 113
Joplin, MO 64802
Truck #:
Trailer #:

EPA I.D. NUMBER: MOD095038988

SHIPPING DATE: 11/14/2018

CONTACT: Twyla McDermott
TELEPHONE (Include Area Code): 865-882-7077

SIGNATURE – Authorized carrier acknowledging waste receipt
DATE: 11-14-18

7. FORM 540 AND 540A — PAGE 1 OF 1 PAGE(S)
FORM 541 AND 541A — 1 PAGE(S)
FORM 542 AND 542A — None PAGE(S)
ADDITIONAL INFORMATION — None PAGE(S)

8. MANIFEST NUMBER (Use this number on all continuation pages): FDA 181114-2

9. CONSIGNEE - Name and Facility
Duratek, Inc. - Commercial Processing
Bear Creek Operations
1560 Bear Creek Road
Oak Ridge, TN 37830

CONTACT: Shipping and Receiving
TELEPHONE (Include Area Code): 865-481-0222

SIGNATURE – Authorized consignee acknowledging waste receipt
DATE: 11.19.18

10. CERTIFICATION
This is to certify that the herein-named materials are properly classified, described, packaged, marked, and labeled and are in proper condition for transportation according to the applicable regulations of the Department of Transportation. This also certifies that the materials are classified, packaged, marked, and labeled and are in proper condition for transportation and disposal as described in accordance with the requirements of 10 CFR Parts 20 and 61, or equivalent state regulations.

AUTHORIZED SIGNATURE: [signature] TITLE: ESO DATE: 11/14/18

11. U.S. DEPARTMENT OF TRANSPORTATION DESCRIPTION (including proper shipping name, hazard class, UN ID number, and any additional information)	12. DOT LABEL "RADIOACTIVE"	13. TRANSPORT INDEX	14. PHYSICAL AND CHEMICAL FORM	15. INDIVIDUAL RADIONUCLIDES	16. TOTAL PACKAGE ACTIVITY MBq	mCi	17. LSA/SCO CLASS	18. TOTAL WEIGHT OR VOLUME (Use appropriate units)	19. IDENTIFICATION NUMBER OF PACKAGE
UN2910, Radioactive material, excepted package-limited quantity of material, 7 Dry active waste for compaction	NA	NA	Solid Salts, proteins on glass, metal, plastic	H-3 U-Nat	1.9425E+00	5.2500E-02	NA	100 LBS; 7.5 FT3	FDA-1801-DAW
UN2910, Radioactive material, excepted package-limited quantity of material, 7 Dry active waste for compaction	NA	NA	Solid Salts, proteins on glass, metal, plastic	H-3	3.7000E-01	1.0000E-02	NA	60 LBS; 7.5 FT3	FDA-1802-DAW

FOR CONSIGNEE USE ONLY

TENNESSEE "LICENSE FOR DELIVERY" NO _____

SOUTH CAROLINA TRANSPORT PERMIT NO _____

US ECOLOGY GENERATOR NO _____

US ECOLOGY PERMIT NO _____

20. GENERATOR CERTIFICATION STATEMENT

A) Radioactive Materials. Certification is hereby made to Duratek, Inc. that this shipment of low-level radioactive material/waste has been prepared in accordance with radioactive waste management program which has been approved by the Nuclear Regulatory Commission or an Agreement State regulatory agency and with the current revision of the Duratek Material Acceptance Criteria.

B) Hazardous Materials. Generator hereby certifies that this material does not contain a hazardous waste as defined in 40 CFR 261.

C) Data. Generator hereby represents and warrants that all data set forth in this (UNIFORM LOW-LEVEL RADIOACTIVE WASTE MANIFEST) are true and correct in all respects and in accordance with all applicable governmental laws, rules, regulations and Duratek, Inc. State of Tennessee Radioactive Material Licenses.

MARTIN GOUGH — Print Name; [signature] — Signature; 11/14/18 — Date

FORM 540 (10-96)