DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administ ation
College Park, MD 20740

FE5 2009

Mr. Thomas K. Thompson, Senior Health Physicist
U.S. Nuclear Regulatory Commission, Region I
Division of Nuclear Materials Safety
Commercial and R&D Branch
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

MS16
P-7

NRC License No. 19-30771-01
Docket No. 03036120
Control No. 141772

RE: Mail Control No. 141772, Request for additional information concerning financial assurance documents.

This letter is to provide additional information regarding the Nuclear Regulatory Commission (NRC) Type B Broad Scope License 19-30771-01 financial assurance documents on file in your office. Therefore, the Center for Food Safety and Applied Nutrition (CFSAN) is expecting that the current license activities will continue during your review of the updated certification of financial assurance document and decommissioning funding plan as required in NUREG 1757, Vol 3, Appendix A.

Pursuant to 10 CFR 30 the FDA Decommissioning Financial Assurance Statement of Intent and FDA Staff Manual Guide 1410.21, General Redelegations of Authority from the Commissioner to other Officers of the Food and Drug Administration, effective May 17,2007, will be provided under separate correspondence.

Questions regarding this response or if additional information is needed during CFSAN's financial assurance document review, please contact the undersigned at 301-436-2114 or Ms. Constance Sims Rosser, Radiation Safety Officer at 301-436-2105.

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Sincerely,

Thomas D. Williams, M.B.A.
Executive Officer for
Center for Food Safety
and Applied Nutrition

Enclosures

141772

Checklist 1 Master Checklist for Decommissioning Financial Assurance

Name of Licensee/Applicant DHHS/FDA/CFSAN

Mailing Address 5100 Paint Branch Parkway College Park, MD 20740

Facility Address Harvey W Wiley Building College Park, MD
Murkirk Road Complex, Laurel, MD + Temporary jobsites

License Number(s) 19-30771-01

Date of Submission January 2009

Applicable Parts of 10 CFR (check all that apply): ☒ Part 30 ☐ Part 40 ☐ Part 70 ☐ Part 72

Type of Submission:

- ☐ Certification of Financial Assurance → attach Checklist 2
- ☒ Decommissioning Funding Plan → attach Checklist 3
- ☐ Decommissioning Plan → attach Checklist 18

Type of Mechanism:

☐ Prepayment

- ☐ Trust → attach Checklist 4–A
- ☐ Escrow Account → attach Checklist 5–A
- ☐ Government Fund → attach Checklist 6
- ☐ Certificate of Deposit → attach Checklist 7–A
- ☐ Deposit of Government Securities → attach Checklist 8

☐ Surety, Insurance, or Other Guarantee Method

- ☐ Surety Bond → attach Checklist 9–A
- ☐ Letter of Credit → attach Checklist 10–A
- ☐ Line of Credit → attach Checklist 11–A
- ☐ Insurance → attach Checklist 12–A
- ☐ Parent Company Guarantee → attach Checklist 13–A
- ☐ Self-Guarantee → attach Checklist 14–A

☐ External Sinking Fund → attach Checklist 15

☒ Statement of Intent → attach Checklist 16–A

☐ Special Arrangement with a Government Entity → attach Checklist 18–B

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Adminis ration
College Park. MD 2074)

FEB 4 2009

CERTIFICATION OF FINANCIAL ASSURANCE

Principal: Department of Health and Human Services, Food and Drug Administration
Center for Food Safety and Applied Nutrition
Harvey W. Wiley Building, HFS-650
5100 Paint Branch Parkway
College Park, Maryland 20740

NRC License No. 19-30771-01, Docket No. 03036120, Control No. 141772

Facility Addresses: Harvey W. Wiley Building, 5100 Paint Branch Parkway, College Park, Maryland 20740; Muirkirk Road Complex Facilities, Laurel, Maryland 20708 and any Temporary Job Sites anywhere in the United States where the U.S. NRC maintains jurisdiction for regulating the use of licensed material, including areas of exclusive Federal jurisdiction within Agreement States.

Issued to: U.S. Nuclear Regulatory Commission

I certify that Center for Food Safety and Applied Nutrition is licensed to possess the following types of sealed sources or plated foils and unsealed byproduct material with a half-life greater than 120 days licensed under 10 CFR Part 30 in the following amounts:

Type of Material
Any chemical or physical form, as specified in Section 33.100, Schedule A, of 10 CFR **33** quantities by isotope.

Amount of Material
If only one radionuclide is possessed the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column 1. If two or more radionuclides are possessed, the possession limit is determined as follows: For each radionuclide, determine the ratio of the quantity possessed to the applicable quantity specified in 10 CFR 33.100, Schedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the licensed shall not exceed unity.

I also certify that financial assurance in the amount of $3,205,000 has been obtained for the purpose of decommissioning as prescribed by 10 CFR Part 30.

Thomas D. Williams, M.B.A.
Executive Officer for
Center for Food Safety
and Applied Nutrition

Enclosures

[Code of Federal Regulations]
[Title 10. Volume 1]
[Revised as of January 1. 2003]
From the U.S. Government Printing Office via GPO Access
[CITE: 10CFR33.100]

[Page 546-5471

TITLE 10--ENERGY

CHAPTER I--NUCLEAR REGULATORY COMMISSION

PART 33--SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL..
Table of Contents

Sec. 33.100 Schedule A.

Byproduct material	Col. I curies	Col. II curies
Antimony-122	1	0.01
Antimony-124	1	.01
Antimony-125	1	.01
Arsenic-73	10	.1
Arsenic-74	1	.01
Arsenic-76	1	.01
Arsenic-77	10	.1
Barium-131	10	.1
Barium-140	1	.01
Bismuth-210	.1	.001
Bromine-82	10	.1
Cadmium-109	1	.01
Cadmium-115m	1	.01
Cadmium-115	10	.1
Calcium-45	1	.01
Calcium-47	10	.1
Carbon-14	100	1.
Cerium-141	10	.1
Cerium-143	10	.1
Cerium-144	.1	.001
Cesium-131	100	1.
Cesium-134m	100	1.
Cesium-134	.1	.001
Cesium-135	1	.01
Cesium-136	10	.1
Cesium-137	.1	.001
Chlorine-36	1	.01
Chlorine-38	100	1.
Chromium-51	100	1.
Cobalt-58m	100	1.
Cobalt-58	1	.01
Cobalt-60	.1	.001
Copper-64	10	.1
Dysprosium-165	100	1.
Dysprosium-166	10	.1
Erbium-169	10	.1
Erbium-171	10	.1
Europium-152 9.2 h	10	.1

NRC License No 19-30771-01

Europium-152 13 y	.1	.001
Europium-154	.1	.001
Europium-155	1	.01
Fluorine-18	100	1.
Gadolinium-153	1	.01
Gadolinium-159	10	.1
Gallium-72	10	.1
Germanium-71	100	1
Gold-198	10	.1
Gold-199	10	.1
Hafnium-181	1	.01
Holmium-166	10	.1
Hydrogen-3	100	1
Indium-113m	100	1
Indium-114m	1	.01
Indium-115m	100	1
Indium-115	1	.01
Iodine-125	.1	.001
Iodine-126	.1	.001
Iodine-129	.1	.01
Iodine-131	.1	.001
Iodine-132	10	.1
Iodine-133	1	.01
Iodine-134	10	.1
Iodine-135	1	.01
Iridium-192	1	.01
Iridium-194	10	.1
Iron-55	10	.1
Iron-59	1	.01
Krypton-85	100	1
Krypton-87	10	.1
Lanthanum-140	1	.01
Lutetium-177	10	.1
Manganese-52	1	.01
Manganese-54	1	.01
Manganese-56	10	.1
Mercury-197m	10	.1
Mercury-197	10	.1
Mercury-203	1	.01
Molybdenum-99	10	.1
Neodymium-147	10	.1

[[Page 547]]

Neodymium-149	10	.1
Nickel-59	10	.1
Nickel-63	1	.01
Nickel-65	10	.1
Niobium-93m	1	.01
Niobium-95	1	.01
Niobium-97	100	1.
Osmium-185	1	.01
Osmium-191m	100	1.
Osmium-191	10	.1
Osmium-193	10	.1
Palladium-103	10	.1
Palladium-109	10	.1
Phosphorus-32	1	.01
Platinum-191	10	.1

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Platinum-193m	100	1.
Platinum-193	10	.1
Platinum-197m	100	1
Platinum-197	10	.1
Polonium-210	.01	.0001
Potassium-42	1	.01
Praseodymium-142	10	.1
Praseodymium-143	10	.1
Promethium-147	1	.01
Promethium-149	10	.1
Rhenium-186	10	.1
Rhenium-188	10	.1
Rhodium-103m	1,000	10.
Rhodium-105	10	.1
Rubidium-86	1	.01
Rubidium-87	1	.01
Ruthenium-97	100	1.
Ruthenium-103	1	.01
Ruthenium-105	10	.1
Ruthenium-106	.1	.001
Samarium-151	1	.01
Samarium-153	10	.1
Scandium-46	1	.01
Scandium-47	10	.1
Scandium-48	1	.01
Selenium-75	1	.01
Silicon-31	10	.1
Silver-105	1	.01
Silver-110m	.1	.001
Silver-111	10	.1
Sodium-24	1	.01
Strontium-85m	1,000	10.
Strontium-85	1	.01
Strontium-89	1	.01
Strontium-90	.01	.0001
Strontium-91	10	.1
Strontium-92	10	.1
Sulphur-35	10	.1
Tantalum-182	1	.01
Technetium-96	10	.1
Technetium-97m	10	.1
Technetium-97	10	.1
Technetium-99m	100	1.
Technetium-99	1	.01
Tellurium-125m	1	.01
Tellurium-127m	1	.01
Tellurium-127	10	.1
Tellurium-129m	1	.01
Tellurium-129	100	1
Tellurium-131m	10	.1
Tellurium-132	1	.01
Terbium-160	1	.01
Thallium-200	10	.1
Thallium-201	10	.1
Thallium-202	10	.1
Thallium-204	1	.01
Thulium-170	1	.01
Thulium-171	1	.01
Tin-113	1	.01
Tin-125	1	.01

NRC License No. 19-30771-01

Tungsten-181	1	.01
Tungsten-185	1	.01
Tungsten-187	10	.1
Vanadium-48	1	.01
Xenon-13lm	1.000	10.
Xenon-133	100	1.
Xenon-135	100	1.
Ytterbium-175	10	.1
Yttrium-90	1	.01
Yttrium-91	1	.01
Yttrium-92	10	.1
Yttrium-93	1	.01
Zinc-65	1	.01
Zinc-69m	10	.1
Zinc-69	100	1.
Zirconium-93	1	.01
Zirconium-95	1	.01
Zirconium-97	1	.01
Any byproduct material other than alpha emitting byproduct material not listed above	.1	.001

(Set. 201. Pub. L. 93-438; 88 Stat. 1242 (42 U.S.C. 5841))

[33 FR 14579, Sept. 28. 1968]

A.3 Decommissioning Funding Plans

A decommissioning funding plan (DFP) is a financial assurance demonstration that is based on a *site-specific cost estimate* for decommissioning the facility. The amount of the facility-specific cost estimate becomes the minimum required level of financial assurance coverage. Any licensee may use a DFP, but certain licensees *must* use a DFP, as discussed in Section A.1. Licensees who use DFPs must undertake the following actions, as summarized in Checklist 3.

- Prepare a site-specific decommissioning cost estimate (see Section A.3.1).
- Determine the means that will be used to adjust the cost estimate and associated funding levels periodically over the life of the facility (see Section A.3.2).
- Submit the required documentation (see Section A.3.3).

Checklist 3 Decommissioning Funding Plans

License Number(s): 19-30771-01

Applicable Parts of 10 CFR (check all that apply): ☒ Part *30* ☐ Part 40 ☐ Part 70

☒ Prepare a detailed, site-specific cost estimate (see Section A.3.1).

☒ Determine the means that will be used to adjust the site-specific cost estimate and associated funding levels periodically over the life of the facility (see Section A.3.2).

☒ Include the necessary documentation (see Section A.3.3).

☒ Include a detailed, site-specific cost estimate that includes the following:

- ☒ Description of the means that will be used to adjust the site-specific cost estimate and associated funding level.
- ☒ A certification that financial assurance for decommissioning has been provided in the amount of the decommissioning cost estimate.

☒ Include a financial instrument and supporting documentation.

A.3.1 Preparing the Site-Specific Cost Estimate

In evaluating decommissioning cost estimates, NRC considers the following factors:

- the completeness of the estimate (i.e., scope),
- the level of detail presented, and
- the reasonableness of the estimate (i.e., the accuracy and magnitude of estimated costs).

DECOMMISSIONING FUNDING PLAN

For:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition

Nuclear Regulatory Commission
Radioactive Materials License 19-30771-01

January 2009

Prepared by:

Clym Environmental Services, LLC
5104 Pegasus Court
Frederick, MD 21704

Charles Watts, Project Manager

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1.0 BACKGROUND

The Center for Food Safety and Applied Nutrition, known as CFSAN, is one of six product-oriented centers, in addition to a nationwide field force, that carry out the mission of the Food and Drug Administration (FDA). FDA is a scientific regulatory agency responsible for the safety of the nation's domestically produced and imported foods, cosmetics, drugs, biologics, medical devices, and radiological products. It is one of the oldest federal agencies whose primary function is consumer protection. The agency touches and directly influences the lives of everyone in the United States. FDA is recognized internationally as the leading food and drug regulatory agency in the world. Many foreign nations seek and receive FDA's help in improving and monitoring the safety of their products. FDA is part of the Executive Branch of the United States Government within the Department of Health and Human Services (DHHS) and the Public Health Service (PHS).

The stated mission of the Center is, "CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled." In support of the research that underpins this mission, CFSAN holds a Type B Broadscope Radioactive Materials License from the United States Nuclear Regulatory Commission (NRC). This License allows for the manipulation and storage of sealed and unsealed sources of radioactivity. Regulations governing such usage of radioactive material call for licensees to set aside funding for future decommissioning of impacted facilities and to assure proper license termination. The required funding level is determined by either an amount prescribed in NRC regulations or by the submittal of a Decommissioning Funding Plan (DFP) that includes a detailed discussion of a cost estimate to be used as the funding level. Requirements for funding levels are provided in NRC regulations found in Title 10 of the Code of Federal Regulations, Part 30 (10 CFR 30). Further guidance for decommissioning funding is found in NUREG 1757, Volume 3 (Final Report) dated September 2003 and entitled "NMSS Decommissioning Guidance, Financial Assurance, Recordkeeping, and Timeliness."

FDA has tasked Clym Environmental Services, LLC (Clym) with the creation of this Decommissioning Funding Plan through a subcontract with Clean Venture, Inc. (CVI). This plan serves to replace the current Decommissioning Funding Plan for CFSAN radioactive materials license #19-30771-01 (Docket #030-36120) including five (5) amendments and expiring September 30, 2015. This license includes some research activities involving radioactive materials that are conducted by another branch of the FDA, the Center for Veterinary Medicine (CVM).

CVM states its mission as follows, "The Center for Veterinary Medicine is a consumer protection organization. We foster public and animal health by approving safe and

effective products for animals and by enforcing other applicable provisions of the Federal Food, Drug, and Cosmetic Act and other authorities." Though CVM follows its own mission, it has committed to adhering to the requirements of the CFSAN radioactive materials license and each of the commitments made by CFSAN in assuring the safe and compliant use of radioactive materials in its important research. (Throughout this plan, when CFSAN is referenced it is intended to include CVM so far as the CVM commitment to this license are applicable).

The use of radioactive materials by CFSAN as evidenced by historical records associated with the current NRC license, reveal that radioactive materials have been used by the Center for many decades. The research associated with licensed use of radioactivity has included a number of facilities over time. As the FDA has evolved, new sites have been constructed and older sites have undergone renovation or have been vacated. Throughout this process, the footprint of radioactive material use has been monitored and controlled by both the licensing authority as well as the CFSAN Radiation Safety Office.

This document identifies the current authorized places of radioactive materials usage, taking into account former facilities that have been decommissioned. With this scope of modern radioactive material work identified, the Decommissioning Funding Estimate for the release of facilities restricted by the CFSAN radioactive materials license controls will be detailed. Additionally, the financial mechanism chosen to meet the funding level will be described.

2.0 REGULATORY REFERENCES AND DISCUSSION OF APPLICABILITY

The Nuclear Regulatory Commission (NRC) states in Title 10 of the Code of Federal Regulations, Part 30.35 (10 CFR 30.35(a)(1)) that, "Each applicant for a specific license authorizing the possession and use of unsealed byproduct material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in appendix B to part 30 shall submit a decommissioning funding plan as described in paragraph (e) of this section. The decommissioning funding plan must also be submitted when a combination of isotopes is involved if R divided by 10^5 is greater than 1 (unity rule), where R is defined here as the sum of the ratios of the quantity of each isotope to the applicable value in appendix B to part 30."

The CFSAN radioactive materials license is identified as a "Type B specific license of broad scope." 10 CFR 33.11(b) defines this license type as, "...a specific license authorizing receipt, acquisition, ownership, possession, use, and transfer of any chemical or physical form of byproduct material specified in § 33.100, Schedule **A,** of this part for purposes authorized by the Act. The possession limit for a Type B broad license, if only one radionuclide is possessed thereunder, is the quantity specified for that radionuclide in § 33.100, Schedule A, Column I. If two or more radionuclides are possessed thereunder, the possession limit for each is determined as follows: For each radionuclide, determine

the ratio of the quantity possessed to the applicable quantity specified in § 33.100, Scliedule A, Column I, for that radionuclide. The sum of the ratios for all radionuclides possessed under the license shall not exceed unity."

A Type B specific license of broad scope therefore allows for the possibility of many isotopes to be held in inventory at one time, as long as this concept of "unity" is maintained. The concept of "unity" is applied to both license possession limits as well as requirements for decommissioning funding plans. The difference between the two comparisons is the value specified in the regulations (e.g. Appendix B vs. 33.100 Schedule A, Column 1). The following tables illustrate this exercise. In each table a "sample CFSAN inventory" is used. This inventory is based on isotopes that have been possessed by CFSAN in the past and is not intended as a present inventory.

Table 1.0 offers an example of isotopes that might be possessed by CFSAN under the authority of a Type B specific license of broad scope.

Table 1.0 Sample Inventory Within **Unity**

Isotope	Schedule A. Column 1 Value (uCi)	Sample CFSAN Inventory (uCi)	Ratio
Hydrogen-3	100,000,000	150,000	0.002
Carbon-14	100,000,000	50,000	0.001
Sulfur-35	10,000,000	70,000	0.007
Phosphorus-32	1,000,000	70,000	0.070
Calcium-45	1,000,000	25,000	0.025
Phosphorus-33	100,000	25,000	0.250
Krypton-85	100,000,000	25,000	0 00025
Iodine-129	100,000	25,000	0.250
Flourine-18	100,000,000	25,000	0.00025
		UNITY **(R)** =	**0.88050**

Table 2.0 makes the two considerations required for decommissioning funding plans in the columns labeled "$R/10^5$" and "T ½ > 120 Days." The same sample CFSAN inventory is used in this example. The column headed "$R/10^5$ (T ½ >120d only)" gives the result by isotope and calculates "R" as the final result.

Table 2.0 Sample Inventory Exceeding Unity and Requiring a DFP

Isotope	Sample CFSAN Inventory (uCi)	10 CFR 30 App B Value (uCi)	R / 10^5	R / 10^4	R / 10^3	T ½ > 120 Days?	R / 10^5 (T ½ > 120d only)
H-3	150.000	1,000	0.01	0.1	1	Yes	0.01
C-14	50,000	100	0.0015	0.015	0 15	Yes	0.0015
S-35	70,000	100	0.007	0 07	7	No	0
P-32	70,000	10	0.07	0.7	7	No	0
Ca-45	25,000	10	0.025	0.25	2.5	Yes	0.025
P-33	25.000	0.10	2.5	25	250	No	0
Kr-85	25.000	100	0.0025	0.025	0.25	Yes	0.0025
I-129	25,000	0.10	2.5	25	250	Yes	2.5
Cr-51	25,000	1,000	0.00025	0.0025	0.025	No	0
Cl-36	25,000	10	0.025	0.25	2.5	Yes	0.025
I-125	25,000	1	0.25	2.5	25	No	0
Fl-18	25,000	1,000	0.00025	0.0025	0.025	No	0
						R =	2.559

As this simple analysis shows, " R clearly exceeds 1, confirming that FDA/CFSAN has possession limits requiring the submittal of a decommissioning funding plan.

10 CFR 30.35 offers different vehicles for meeting the funding level identified in a DFP for financial assurance. For governmental entities, such as the FDA/CFSAN, 10 CFR 30.35(f)(4) allows, "In the case of Federal, State, or local government licensees, a statement of intent containing a cost estimate for decommissioning...and indicating that funds for decommissioning will be obtained when necessary."

3.0 SCOPE

The main intent of this effort is to review data from site operations, sample analyses, past licenses and permits, and incidents and related clean-up activities in order to qualify the affected areas that will require decommissioning surveys and potential remedial actions. Once identified, all areas will be assigned an estimated level of effort to complete survey and remediation. This assessment is not intended as a comprehensive site characterization, but rather a means of defining the probable areas of survey and remediation required for termination of CFSAN's radioactive materials license.

It should be noted that this assessment focuses on areas of potential concern that can be identified using the following methods:

3.1 Records Review

A records review is relied upon to: qualify the extent of historical licensed usage, identify areas of known or potential contamination, and gauge the effectiveness of

radiological controls. During this project the following documents were targeted for review:

- Radioactive materials licenses (current and expired)
- Authorized user permits
- Incidents, accidents and spills
- Exposure records
- Correspondence with licensing authority
- Correspondence to and from Radiation Safety Officer
- Radiation Safety Committee meeting minutes and notes
- Records of survey
- Records of Decontamination and Decommissioning
- Records of waste disposal
- Records of inventory

Other records were reviewed as deemed necessary. Records relating to a potential long-term impact to the site (e.g. sanitary sewer disposal, ground or area contamination, etc.) were of principal concern.

3.2 Licensed Area Inspection and Personnel Interview

Areas that were identified during records review as those of known present, previous or potential radioactive materials use or storage were designated for inspection. During the inspection, areirs were observed for any structural changes (e.g. renovation) and the Radiation Safety Officer was interviewed to gain a better understanding of radioactive materials protocols.

4.0 NARRATIVE

Regulatory guidance was selected to provide an outline for completing this project (NUREG 1757, Volume 3 (Final Report) dated September 2003 and entitled "NMSS Decommissioning Guidance, Financial Assurance, Recordkeeping, and Timeliness"). In this document a strategy for preparing a comprehensive Decommissioning Funding Plan, inclusive of a site-specific cost estimate, is described. The following actions are defined as individual steps in completing this process:

- ✓ Prepare a detailed, site-specific cost estimate;
- ✓ Determine the means that will be used to adjust the site-specific cost estimate and associated funding levels periodically over the life of the license;
- ✓ Include a financial instrument and supporting documentation.

Within each of these components further guidance is offered. Complete decommissioning cost estimates are to consist of three basic parts: 1) a facility description, 2) the estimated decomn~issioningcosts (inclusive of labor and non-labor costs as well as a contingency factor, and 3) key assumptions. A suggested format using sample tables to define cost items and assumptions is provided. It should be noted here that the CFSAN license covers four "facilities" and therefore the estimate will reference these current licensed areas of use: 1) Harvey W. Wiley Building (College Park, MD), 2) Module One (MOD-1, Laurel, MD), 3) Beltsville Research Facility (BRF, Laurel, MD) and 4) Module-2 / A & H-Buildings (MOD-2, Laurel, MD). The MOD-2 facility is where the CVM conducts its work with radioactivity under the CFSAN license. It is noted that "temporary job sites' throughout the United States are also included as authorized places of use. These temporary job sites are not considered herein as they will be decommissioned, as needed, on a case by case basis and the funding associated with this work will be procured as a part of principal project operations.

Guidance for determining the means of adjusting the cost estimate over time provides that, "Licensees who use DFPs must specify the means (i.e. the method and frequency) by which they will periodically adjust their cost estimates and associated funding levels over the life of their facilities. In general, cost estimates should be updated with the current prices of goods and services at least every five (5) years or when the amounts and types of material at the facility change. Adjustments should be made to account for inflation, for other changes in the prices of goods and changes in expected decomn~issioningprocedures."

Lastly, NRC requires that licensees submitting DFPs provide with their submittal the following:

- ✓ A site-specific cost estimate;
- ✓ A description of the means that will be used to adjust the site-specific cost estimate and associated funding levels periodically over the life of the license;
- J A certification of financial assurance by the licensee that financial assurance for decommissioning has been provided in the amount of the decommissioning cost estimate, and
- J An originally signed duplicate of the financial instruments that .provide financial assurance for decomn~issioning.

With the objectives set, the data collection process was initiated and a summary of findings of note follows.

4.1 Brief History of Radioactive Material Use

CFSAN has employed radioactive materials under varying iterations of this radioactive materials license since the 1960s. Research protocols have included both *in vitro* and *in vivo* procedures of microcurie and millicurie quantities of radioactive materials. Both volatile and nonvolatile forms of various nuclides have been manipulated.

Formerly, a principal site of radioactive materials use and storage was Federal Office Building **8** (FB-8) located in Washington, DC. FDA moved all operations from **FB-8** starting in **2002** and the facility was designated for comprehensive decommissioning. During this decommissioning effort a great deal was learned regarding the types and extent of contamination resulting from years of CFSAN research protocols as well as the complexities of surveying research facilities supporting CFSAN operations, decontaminating different surfaces within these areas and disposing of associated radioactive wastes. For these reasons, the lessons learned during the **FB-8** decommissioning will serve as a reference for future efforts.

4.2 Incidents of Note

Presently all areas using or storing radioactive materials are modern and have been renovated or constructed within the last twenty years. All of these facilities have been included in the CFSAN Radiation Protection Program and have undergone frequent surveys, audits and inspections. The only exception to this finding is a stand-alone cold room with the Beltsville Research Facility (BRF). This cold room is known to have interior radioactive contamination and has been designated for remedial actions. This unit is further described in Section 5.0 under BRF.

4.3 Recent Use of Radioactive Materials

Radioactive materials use and receipt logs show the decline of radioactive material usage at the FDA over the past twenty years. In addition there has been a significant decline in the number of isotopes employed, especially the number of long-lived isotopes. Unsealed source:; of radioactivity are used in conducting *in vitro* and *in vivo* experimentations. Long-lived isotopes that are manipulated in unsealed form primarily consist of ^{3}H and ^{14}C. Sealed sources of radioactivity are used in various research applications and are leak tested regularly.

It was found during recent remedial efforts that naturally occurring compounds (e.g. uranyl acetate, etc.) are used in some protocols. These materials are

procured under a general license, but will be accounted for in decommissioning survey design.

4.4 Anticipated Use of Radioactive Materials

For the foreseeable future the FDA anticipates radioactive material usage to remain static in terms of both radioisotopes and associated activities. With the flexibility allowed by a broadscope license, FDA may employ other radioisotopes in the future.

5.0 FACILITY DESCRIPTION

CFSAN and CVM occupy four facilities that are authorized for radioactive materials usage and storage: Harvey W. Wiley Building (Wiley Building), Module One (MOD-I), Module-2 (MOD-2) Buildings A and H, and the Beltsville Research Facility (BRF). These facilities are furthered detailed herein:

Harvey W. Wiley Building (Wiley Building)

The Wiley Building is located at 5100 Paint Branch Parkway in College Park, Maryland. This state of the art facility encompasses approximately 410,000 ft^2 of research and administrative space. CFSAN, as a part of a facility consolidation effort, began occupying the facility in 2001. It is estimated that the Wiley Building houses over 38,000 ft^2 of laboratory space.

This facility has been as an authorized place of radioactive materials use since March 2005. The principal long-lived isotopes in use at the facility include carbon-14, hydrogen-3, natural uranium and nickel-63 (in sealed form only). Presently, only ten (10) labs are actively employing radioactive materials, however the license allows for use and storage of radioactive materials throughout the facility.

Presently impacted areas include: BEL019; 1D012; 1D009; 1D011; 3EL014; 4EL013; 4EL015; 4EL016; 4EL017; and 4EL018. Records reveal that radioactive material usage at the facility is actively managed and that a robust survey and monitoring program is in place. These surveys will be used to support site characterization and to develop decommissioning sampling plans.

There are no records of significant spills or releases of radioactive materials at this site.

Module One (MOD-1)

The Module One facility is a 230,000 ft^2 research facility that was constructed in 1990. The facility address is 8301 Muirkirk Road, Laurel, MD. This site is known as the Muirkirk Road Complex (MRC). This facility was designed with modern radioactive materials controls, such as chemical fume hoods with filtration systems and a dedicated waste management facility. There is approximately 36,000 ft^2 of research lab space in the facility.

The principal long-lived isotopes in use at the facility include carbon-14, hydrogen-3, natural uranium and nickel-63 (in sealed form only). Records reveal that the following labs are actively employing (or have formerly employed) radioactive materials, however the license allows for use and storage of radioactive materials throughout the facility.

Impacted Areas include: G103; G313; G402; G414; 1107; 1309; 1317; 1402; 1404; 1810; 2303; 2305; 2313; 2315; 2319; 2321; 2412; 2416; 2418; 3313; 3327; 3329; 3404; 3406; 3408; 3410; 3416; 3811; 3813; Waste Room; Janitor's Closet; and Waste Processing Facility. All of these areas will be designated for survey.

Records reveal that radioactive material usage at the facility is actively managed and that a robust survey and monitoring program is in place. These surveys will be used to support site characterization and to develop decommissioning sampling plans.

There are no records of significant spills or releases of radioactive materials at this site.

Module Two (MOD-2) Building A and Building H

The Module Two, Building A facility is a 82,100 ft^2 research facility that was constructed in 1996. The H-Building is an approximate 13,500 ft^2 research facility also completed in 1996. Both buildings are located on the Muirkirk Road Complex. These modern facilities include approximately 41,000 ft^2 of research. The CVM occupies both of these facilities.

The principal long-lived isotopes in use include carbon-14 and hydrogen-3. Records reveal that the following labs are actively employing (or have formerly employed) radioactive materials, however the license 'allows for use and storage of radioactive materials throughout the facility.

Impacted Areas include: Building A (G-408, 1303, 1306, 1518 and 1520); Building H (H-10 and H-11). There are effluent collection tanks associated with

both buildings. Building A, Room 1303 is supported by two (2) 7,000-gallon collection tanks (located in Room G-408). Room 1306 contains the Bag-in/Bag-out filter system for Room 1303. The H-Building is supported by two (2) 10,000-gallon wastewater tanks. All of these tanks will be designated for survey.

Records reveal that radioactive material usage at the facility is actively managed and that a robust survey and monitoring program is in place. These surveys will be used to support site characterization and to develop decommissioning sampling plans. In addition radioactive materials use and storage areas have remained static since the facility began operation.

There are no records of significant spills or releases of radioactive materials at this site.

Beltsville Research Facility (BRF)

Also located on the MRC, the BRF is a single story building that houses approximately 4,500 ft^2 of research laboratories. In addition there is a covered loading dock/storage area, a support building and an area where kennels that housed research animals used to stand. The principal long-lived isotopes in use include carbon-14 and hydrogen-3. Records reveal that the labs listed below are actively employing (or have formerly employed) radioactive materials. Historically, other areas in the building were authorized for radioactive materials use or storage, including the loading dock. The facility has undergone a significant renovation and these areas were extensively surveyed. It should be noted that after this renovation the numbering convention for rooms in the building was changed.

Present impacted areas include: 1402 (Cold Room/Freezer); 1405; 1406; 1407; 1409 and 1414. All of these areas and the loading dock will be designated for survey. In addition the Waste Processing Facility for the MRC is located behind BRF. This facility has been designated for survey and is classified as impacted.

Records reveal that recent radioactive material usage at the facility has been actively managed and that a robust survey and monitoring program is in place. These surveys will be used to support site characterization and to develop decommissioning sampling plans. Records of former site operations (dating to the 1960s) are less complete. It is reported that radioactive liquid waste was disposed via two (2) different septic systems and the drainfield(s) were designated for survey in a previous decommissioning funding plan. A Phase II environmental assessment, inclusive of radioactive sampling, was conducted in October 1993 by Greenhome & O'Mara, Inc. of Greenbelt, MD. This report does not reveal any significant radiological findings. However, it reports that thirteen

(13) soil and water samples were collected that were in association with the abandoned septic system. These results will be included in the site characterization, however it is anticipated that additional sampling will be needed in support of final status surveys and in keeping with previous decommissioning plan commitments.

There are no records of significant spills of radioactive materials at this site. However there is known fixed contamination within the single, stand alone Cold Box / Freezer unit. This unit is currently designated for survey and removal and therefore is not included in the cost estimate.

6.0 ASSUMPTIONS

Based on the data gathered from the records review, a listing of areas of potential radioactive materials use and/or storage was compiled (see Section 5). This listing includes areas associated with radiation safety records and is believed to be comprehensive. Given the differences in regulatory requirements, survey technique and instrument sensitivity, it is assumed that areas of fonner use or storage may exhibit levels of radioactivity greater than present day release criteria. For this reason these areas were included in this assessment as they may require additional survey and/or remedial effort upon license termination.

The primary cause for widespread radioactive contamination (> lm^2) in any facility is the result of poor or inadequate radiological controls. FDA has no such documentation of large spills or widespread contamination that have not been adequately decontaminated. The risk of contamination is diminished over time as many of the short-lived nuclides that FDA is licensed to possess would have undergone decay. It is for this reason that this assessment focuses on "high-risk", "high-use" areas. Within each accessible area an effort was made to identify approximate physical dimensions associated with high-risk surfaces (floors, benches, lower walls) and an inventory of high-risk systems (chemical fume hoods, sinks and floor drains). In addition, survey data was reviewed for usage or storage area to gauge the presence of removable or non-penetrating sources of radioactivity in high-risk areas.

The CFSAN radioactive materials license allows for radioactive materials use throughout the research areas in each facility detailed herein. Therefore this estimate considers all available lab space as potentially impacted areas. The cost estimate makes certain assumptions about the future footprint of radioactive materials usage based on current conditions and past trends. During the decommissioning of Federal Office Building 8, the results of decades of research involving unsealed and sealed sources of both specifically and generally licensed radioactivity were studied. These lessons have been applied in designing this cost estimate as that decommissioning project provided a unique opportunity to establish metrics for the characterization, survey, sampling,

decontamination and waste packaging operations required of a major CFSAN research facility.

In order to build the cost estimate, key assumptions have been made. These assumptions are necessary to arrive at a realistic, yet conservative, figure for financial assurance. The limitations associated with this estimate must also include a consideration of the following assumptions.

First, basic universal assumptions include:

- All applicable records have been made available for review;
- Reviewed survey data is also representative of conditions in inaccessible areas;
- All types, quantities and uses (past, present and anticipated) of radioactive material have been adequately defined.

In addition, secondary assumptions have been made in order to arrive at the funding estimate. These assumptions have been used to qualify the expected level of effort for labor costs and the potential amounts and types of radioactive waste generated during decommissioning activities.

1) All areas of present or former radioactive material use and/or storage that have not been specifically released from radiological controls by the NRC will be considered "impacted" (or having the potential for radioactive contamination).

2) Initial, or "scoping" surveys, will be conducted such that a percentage of high-risk surfaces and systems will be assayed dependent on area classification.

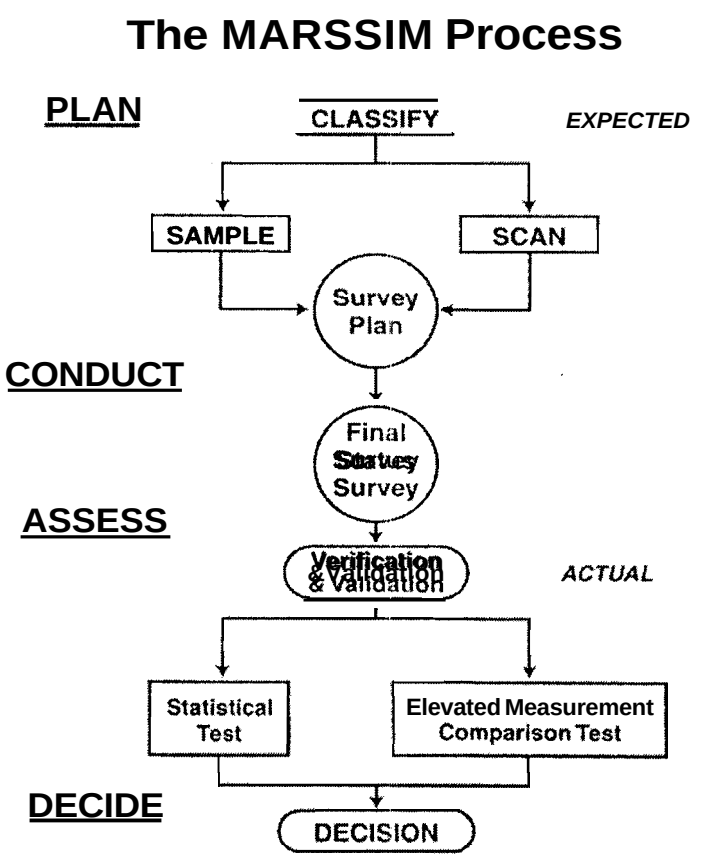
3) Based on operational history, there will be minimal radioactive contamination (as a percentage of high-risk surface areas or systems) and much of this contamination can be successfully decontaminated on site (and will not require significant volumetric sampling).

CFSAN has adopted the guidance found in the Multi-Agency Radiation Site Survey Investigation Manual (MARSSIM) for decommissioning its facilities for release from radiological controls. This survey strategy is the basis for the following cost estimate. The MARSSIM framework is used to detennine if the mean of collected survey data meets Derived Concentration Guideline Levels (DCGLs) and therefore is focused on the Final Status Survey (FSS). The guidance provided in the MARSSIM on the historical

site assessment, the scoping surveys, the characterization surveys, and the remedial action support surveys are intended to address the need for appropriate data in designing the Final Status Survey.

The MARSSIM process can be simply divided into four main phases of data collection and review: Planning, Conducting, Assessing and Decision Making. Figure 1.0 depicts the basic MARSSIM outline.

Figure 1.0 Basic MARSSIM Outline



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 CFSAN/CVM research, 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 the scoping and characterization surveys and;
- Provide initial classification of the site, or survey units within the site, as impacted or non-impacted.

It should be noted that the initial classification is the catalyst for future phases and is critical to the ultimate success of the Final Status Survey. 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.

Once the initial classification is completed, a "scoping survey" sampling plan is conceived and implemented to further classify each impacted area. A defense is also prepared to support the classification of all non-impacted areas. After scoping, characterization surveys are conducted. This leads to remedial operations and ultimately final status surveys.

Specifically, the following project schedule is anticipated throughout this estimate:

Phase One: ***Preparation & Planning***

Historical Site Assessment
Work Plan(s) Development
Site Health and Safety Plan
Staff Orientation and Training
Supply and Equiprnent Detail

Phase Two: ***Scoping and Characterization***
Scoping Surveys
Characterization Surveys

Phase Three: ***Remedial Actions***
Decontamination Efforts
Waste Packaging
Waste Shipment

Phase Four: ***Final Status***
Decommissioning Plan
Sampling Plan
Final Status Surveys
Draft Report Preparation

The NRC guidance found in NUREG 1757, Volume 3 (Final Report) dated September 2003 and entitled "NMSS Decommissioning Guidance, Financial Assurance, Recordkeeping, and Timeliness," recommends the use of tables to organize the decommissioning funding components. These reference tables have been used in this estimate and the original table designations have been maintained for ease of comparison (see attached).

The following tables are applicable to CFSAN's radioactive materials license:

1) Number and Dimensions of Facility Components **(A.3.5)**

This table (see attached) considers the survey components within impacted areas. An effort has been made to arrive at an approximate surface area for each component. This data has been compiled from various sources provided by CFSAN. Components are assumed to include: chemical fume hoods, benches (including casework), sinks (including drain lines), floors, lower walls, and ductwork. Special components include the wastewater tanks at MOD-2.

2) Planning and Preparation **(A.3.6)**

This table considers the components of the first stages of decommissioning and returns results in required workdays, by labor category designation, for each activity. The decommissioning staff is assumed to consist of: (1) Supervisor, (1) Health Physicist, (8) Health Physics Technicians and (1) Clerical/Administrative Support staff. This table includes all preparatory activities such as the development of work and health and safety plans, initial site assessment and sampling plans, as well as scoping and characterization surveys. Labor estimates are derived from previous decommissioning experiences. It is anticipated that this

entire decommissioning process will require approximately 275 workdays (including non-billable time such as two week review periods between each phase of operations).

3) **Decontamination** or Dismantling of Radioactive Components **(A.3.7)**

This table returns the number of required workdays by labor category for the survey, decontamination, dismantling, and waste management of expected components. A number of assumptions have been made in order to determine the expected level of effort. These assumptions include:

a) 25% of all chemical fume hoods will be impacted, of these hoods 50% will be contaminated;
b) For each contaminated chemical fume hood, 25% will require dismantling and disposal, 75% will be decontaminated and resurveyed;
c) For each contaminated hood there will be 10 linear feet of contaminated ducting;
d) 10% of all sinks will be impacted, of these sinks 25% will be contaminated;
e) For each contaminated sink, 25% will require dismantling and disposal, 75% will be decontaminated and resurveyed;
f) For each contaminated sink there will be 10 linear feet of contaminated drain line;
g) 10% of all lower walls, floors and benches will be impacted, of this surface area 25% will be contaminated;
h) For contaminated wall, floor or bench surface areas, 10% will require dismantling and disposal; 90% will be decontaminated and resurveyed;
i) The radioactive waste dump sink and associated drain line from the Waste Processing Facility will be impacted and disposed;
j) Workdays will be eight **(8)** hours each and will not fall on a weekend or Government recognized holiday;
k) Supervisor and Health Physicist hours are calculated as a percentage of HP technician time (10% and 25% respectively);
l) Survey, dismantling, decontamination and waste packaging labor hours are based on averages documented during the decommissioning of **FB-8.**

4) Final Status Surveys **(A.3.9)**

This table details the activities conducted during final status surveys and returns the number of required workdays by labor category. **A** ratio of expected effort by facility as compared to realized labor hours during the FB-8 decommissioning project is applied. This ratio takes into account the expected footprint of impacted spaces and any complex component that may require additional effort. Due to

their size and expected concentration of use, the MOD-1 and Wiley Buildings are expected to require the most effort. MOD-2 with its expected smaller footprint of radioactive materials use will require less effort, but it is recognized that the survey and potential decontamination of the effluent wastewater tanks may complicate this effort. Finally, given the significant survey and renovation operations that have taken place at the BRF, this facility is anticipated to require the least effort.

5) Total Workdays by Labor Category (A.3.11)

This summary table totals the required effort by labor category for tables A.3.6, A.3.7 and A.3.9. The result is the total number of workdays by labor designation.

6) Worker Unit Cost Schedule (A.3.12)

This table identifies the labor rate for each category. These rates were derived using the current rate schedule in CFSAN's contract with Clean Venture, Inc. for Comprehensive Waste Management Services. These rates were validated during the competitive bidding process and will be updated as new contracts or other decommissioning outsourcing options are chosen. Labor rates are inclusive of general and administrative expense, labor burden and fringe costs. This table assumes that there are 260 working days in one (1) year and that there are eight (8) working hours in one workday.

7) Total Cost by Major Decommissioning Task (A.3.13)

This summary table considers the cost of each major decommissioning task for each labor category.

8) Packaging, Shipping and Disposal of Radioactive Wastes Excluding Labor Costs (A.3.14)

This table projects the costs associated with waste packaging and disposal resulting from decommissioning operations. CFSAN plans to employ large volume containers for dry, solid waste packaging. These "B-25" containers were successfully used during FB-8 operations. B-25 containers hold approximately 3 cubic meters of waste and the average weight of a filled B-25 is 3,000 pounds. Container delivery costs assume one (1) delivery of containers.

Waste generation rates are based on averages identified during FB-8 remedial operations and include: contaminated hoods will result in 1.5 m^3 of solid waste each; all contaminated sinks and drain lines will result in 3 m^3 of solid waste; and each 350 ft^2 of contaminated floors, walls and benches will result in 3 m^3 of solid

waste. Liquid scintillation vial (LSV) waste will be generated in support of scoping surveys, characterization surveys, decontamination and dismantling operations, equipment release, personal surveys and final status surveys. It is estimated that BRF will require five (5) 55-gallon drums of LSV waste and each of the other three (3) facilities, MOD-1, MOD-2 and Wiley will require generate ten (10) 55-gallon drums each.

Waste transport and disposal rates are based on the current line item prices in CFSAN's contract with Clean Venture.,Inc.

9) Equipment / Supply Costs Excluding Containers **(A.3.15)**

This table identifies expected supporting equipment and supply costs. A unit cost, based on current market rates provided by CFSAN contractors, is provided for each item. It is assumed that all of these items will be required for decontamination operations. Further, it is assumed that the liquid scintillation counters and radiation detection instrumentation will be required for both decontamination and final status operations. The number of workdays for each item is based on the activity for which it is used and the corresponding effort identified in previous tables.

10) Laboratory Costs **(A.3.16)**

This table identifies expected laboratory costs. The cost for analyzing wipe samples collected during decontamination and final status surveys is included in the survey pricing. This table only identifies the samples to be collected in order to document that the drainfield(s) at BRF are suitable for release from radiological controls. It is assumed that fifty (50) samples will be collected in support of this survey and that these samples will undergo radiochemical processing for analysis of long-lived nuclides used at the facility (carbon-14, hydrogen-3 and nickel-63).

11) Miscellaneous Costs (A.3.17)

Typically, a policy guaranteeing funds for decommissioning is required. The policy can be open-ended or for a specified term, at the conclusion of which it must be renewed. The level of insurance must be at least equal to the licensee's prescribed amount of estimated decommissioning cost. Licensees may eliminate the insurance requirement by having an escrow account or a bond guaranteed by a large financial institution. For an institution that is part of the federal government, such as CFSAN, there should be no need for insurance, escrow or bond.

The only cost identified in this table will be per diem costs for subcontracted health physics technicians. This rate is estimated to be $155.25/person/workday.

12) Total Decommissioning Costs (A.3.18)

This final summary table considers the total estimated cost for decommissioning by task or component. Further this table calculates the required twenty-five percent (25%) contingency fee for unexpected costs. The total estimated cost for the decommissioning of facilities authorized to use radioactive materials under NRC license number 19-30771-01 is **$3,204,852.21.** A simple estimate of the cost per building is included that is based on the expected level of effort.

Decommissioning costs will be thoroughly reconsidered and adjusted accordingly with each license renewal application.

7.0 LIMITATIONS OF ESTIMATE

This estimate is limited by the assumptions previously defined herein. Moreover this estimate provides a snapshot in time of the form a decommissioning effort at CFSAN facilities may take. Therefore this estimate is time sensitive and should be evaluated for completeness and coherence as CFSAN's use of radioactive materials evolves. Given the potential pricing changes associated with cost of living allowances, the volatility of the radioactive waste disposal industry, regulatory requirements for site closure and license termination, among others, this estimate should be periodically reviewed and updated or validated, as necessary.

Furthermore this estimate should be viewed as a guide in preparing for decommissioning with the clear understanding that actual costs will certainly differ from projected costs. The ultimate limitation to this effort is that this estimate is consistently conservative and based on anticipated license termination activities to be undertaken today. With these restrictions for future events in mind, this estimate provides a solid funding plan for the comprehensive survey and release of all CFSAN facilities from current radiological controls.

8.0 DECOMMISSIONING FUNDING COMMITMENT

A commitment to decommissioning funding, in the amount defined herein, in accordance with 10 CFR 30.35(f)(4) will be provided under separate correspondence. Decommissioning cosls will be thoroughly reconsidered and adjusted accordingly with each license renewal application or as deemed necessary by CFSAN.

9.0 REFERENCES

(1) "MARSSIM FRAMEWORK", KEN DUVALL, US DOE/OEPA LETTER OF UNDERSTANDING, (JULY 1999).

(2) MULTI-AGENCY RADIATION SURVEY AND SITE INVESTIGATION MANUAL (MARSSIM), NUREG-1575/EPA 402-4-97-016, REV.1, (AUGUST 2000).

(3) NUREG 1757, VOLUME 3 (FINAL REPORT) ENTITLED "NMSS DECOMMISSIONING GUIDANCE, FINANCIAL ASSURANCE, RECORDKEEPING, AND TIMELINESS," (SEPTEMBER 2003).

(4) CFSAN RADIOACTIVE MATERIALS LICENSE FILES, AS PROVIDED BY C. S. ROSSER

(5) "DECOMMISSIONING FUNDING PLAN FOR FOOD AND DRUG ADMINISTRATION FACILITIES," Prepared by The Kevrick Company, Inc. 8401 Colesville Road, Suite 610, Silver Spring, MD 20910 (October 1992).

(6) ENVIRONMENTAL PROTECTION AGENCY REPORT: GUIDANCE FOR THE DATA QUALITY OBJECTIVES PROCESS. EPA/600/R-96/055, EPAQA/G-4 (SEPTEMBER 1994).

(7) NMSS DECOMMISSIONING PROGRAM: STANDARD REVIEW PLAN 14.0 FACILITY RADIATION SURVEYS, US NUCLEAR REGULATORY COMMISSION, (SEPTEMBER 2000).

(8) MULTI-AGENCY RADIATION LABORATORY PROTOCOLS (MARLAP) MANUAL (FINAL).

10.0 ACRONYMS

B-25	a $3m^3$ bulk waste container
BRF	Beltsville Research Facility
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
Clym	Clym Environmental Services, LLC
CVI	Clean Venture, Inc.
CVM	Center for Veterinary Medicine
DCGL	Derived Concentration Guideline Level
DFP	Decommissioning Funding Plan
DHHS	Department of Health and Human Services
FB-8	Federal Office Building 8
FDA	Food and Drug Administration
FSS	Final Status Survey
H-Building	Building H, Module Two of the Muirkirk Road Complex
HP	Health Physicist
HSA	Historical Site Assessment
LSV	Liquid scintillation vial(s)
MRC	Muirkirk Road Complex
NRC	Nuclear Regulatory Commission
MARSSIM	Multi-Agency Radiation Survey and Site Investigation Manual
NMSS	Office of Nuclear Material Safety and Safeguards

MOD-1	Module One building of the Muirkirk Road Complex
MOD-2	Module Two buildings of the Muirkirk Road Complex
PHS	Public Health Service
Wiley	Harvey W. Wiley Building

11.0 Attachments

One:	Reference Table A.3.5
Two:	Reference Table A.3.6
Three:	Reference Table **A.3.7**
Four:	Reference Table A.3.9
Five:	Reference Table A.3.11
Six:	Reference Table A.3.12
Seven:	Reference Table A.3.13
Eight:	Reference Table A.3.14
Nine:	Reference Table **A.3.15**
Ten:	Reference Table **A.3.16**
Eleven:	Reference Table A.3.17
Twelve:	Reference Table A.3.18

Food & Drug Administration
Center for Food Safety and Applied Nutrition
Decommissioning Funding Plan
Radioactive Materials License #19-30771-01

ATTACHMENT ONE

REFERENCE TABLE **A.3.5**

FDA/CFSAN
Decommissioning Funding Plan
Reference Table A.3.5

Number and Dimensions of Facility Components (Total)

Component	Number of Components	Dimensions of Components	Totals
Chemical fume hoods (ft^2)	150	180	27,000
Lab benches (ft^2)	N/A	25953	25,953
Sinks (ft^2)	368	6	2,208
Floors (ft^2)	N/A	120113	120,113
Walls (ft^2)	N/A	120113	120,113
Ductwork (ft^2)	137	80	10,960
Other (see below)	1	2000	1,536

FDA/CFSAN
Decommissioning Funding Plan
Reference Table A.3.5

Number and Dimensions of Facility Components (Wiley)

Component	Number of Components	Dimensions of Components	Total Dimensions
Chemical fume hoods	*82*	180	14,760
Lab benches	N/A	12630	12,630
Sinks	205	6	1,230
Floors	N/A	38713	38,713
Walls	N/A	38713	38,713
Ductwork	82	80	6,560
Other	0	0	

FDA/CFSAN
Decommissioning Funding Plan
Reference Table A.3.5

Number and Dimensions of Facility Components (BRF)

Component	Number of Components	Dimensions of Components	Total Dimensions
Chemical fume hoods	8	180	1,440
Lab benches	N/A	1470	1,470
Sinks	22	6	132
Floors	N/A	4528	4,528
Walls	N/A	4528	4,528
Ductwork	8	80	640
Other	0	0	-

FDA/CFSAN
Decommissioning Funding Plan
Reference Table A.3.5

Number and Dimensions of Facility Components (MOD-1)

Component	Number of Components	Dimensions of Components	Total Dimensions
Chemical fume hoods	45	180	8,100
Lab benches	N/A	10488	10,488
Sinks	115	6	690
Floors	N/A	35977	35,977
Walls	N/A	35977	35,977
Ductwork	45	80	3,600
Other	0	0	-

FDA/CFSAN
Decommissioning Funding Plan
Reference Table* A.*3.5

Number and Dimensions of Facility Components (MOD-2, H-Bldg)

Component	Number of Components	Dimensions of Components	Total Dimensions
Chemical fume hoods	15	180	2,700
Lab benches	N/A	1365	1,365
Sinks	26	6	156
Floors	N/A	40895	40,895
Walls	N/A	40895	40,895
Ductwork	15	80	1,200
Other (Tanks, ft^2)	1	2000	2,000

Food & Drug Administration
Center for Food Safety and Applied Nutrition
Decommissioning Funding Plan
Radioactive Materials License #19-30771-01

ATTACHMENT TWO

REFERENCE TABLE **A.3.6**

FDA/CFSAN
Decommissioning Funding Plan
Reference *Table A.3.6*

Planning and Preparation (Workdays)

Assumes a staff of (1) Supervisor; (1) Health Physicist; (8) Techs and (1) Clerical

Activity	Labor Category			
	Supervisor	Health Physicist	HP Technician	Clerical
Preparation of Documentation for Regulatory Agencies	4	0	0	4
Submittal of Decommissioning Plan to NRC (when required by reaulation)	40	11	11	8
Development of Work Plans	40	16	11	11
Procurement of Special Equipment	5	5	5	5
Staff Training	12	14	48	8
Characterization of Radiological Condition of the Facilities (including sampling, soil and groundwater analysis, if applicable, etc.)	90	185	1000	23
TOTALS	191	231	1075	59

FDA/CFSAN
Decommissioning Funding Plan
***Reference Table* A. 3.6**

Wiley Building

Activity	*Labor Category*			
	Supervisor	Health Physicist	HP Technician	
Preparation of Documentation for Regulatory Agencies	1	0	0	1
Submittal of Decommissioning Plan to NRC (when required by regulation)	10	2	2	2
Development of Work Plans	10	2	2	2
Procurement of Special Equipment	2	2	2	0
Staff Training	3	3	8	1
Characterization of Radiological Condition of the Facilities (including sampling, soil and groundwater analysis, if applicable, etc.)	30	60	320	5

FDA/CFSAN
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***Reference Table* A.3.6**

BRF

Activity	*Labor Category*			
	Supervisor	Health Physicist	HP Technician	Clerical
Preparation of Documentation for Regulatory Agencies	1	0	0	1
Submittal of Decommissioning Plan to NRC (when required by regulation) .	10	2	2	2
Development of Work Plans	10	2	2	2
Procurement of Special Equipment	2	2	2	0
Staff Training	3	3	8	1
Characterization of Radiological Condition of the Facilities (including sampling, soil and groundwater analysis, if applicable, etc.)	10	20	120	5

FDA/CFSAN
Decommissioning Funding Plan
Reference *Table A.3.6*

MOD-1

Activity	*Labor Category*			
	Supervisor	Health Physicist	HP Technician	Clerical
Preparation of Documentation for **Regulatory Agencies**	1	0	0	1
Submittal of Decommissioning Plan to NRC (when required by regulation)	10	*2*	*2*	*2*
Development of Work Plans	10	*2*	*2*	*2*
Procurement of Special Equipment	2	*2*	*2*	0
Staff Training	3	3	8	1
Characterization of Radiological Condition of the Facilities (including sampling, soil and groundwater analysis, if applicable, etc.)	30	60	320	*5*

FDA/CFSAN
Decommissioning Funding Plan
Reference Table A.3.6

MOD-2 / A & H Bldg

Activity	*Labor Category*			
	Supervisc	Health Physicist	HP Technician	Clerical
Preparation of Documentation for Regulatory Agencies	1	0	0	1
Submittal of Decommissioning Plan to NRC (when required by regulation)	10	5	5	2
Development of Work Plans	10	10	5	5
Procurement of Special Equipment	2	2	2	0
Staff Training	3	5	24	5
Characterization of Radiological condition of the Facilities (including sampling, soil and groundwater analysis, if applicable, etc.)	20	45	240	8

ATTACHMENT THREE

REFERENCE TABLE A.3.7

FDA/CFSAN
Decommissioning Funding Plan
Reference Table A.3.7

Decontamination or Dismantling of Radioactive Facility Components (Workdays)

Component	Decontamination Method(s)	Quantity	Labor Category		
			Supervisor	Health Physicist	HP Technician
Chemical fume hoods	Decay-in-storage; Pack/Dispose; Size/Resurvey; Clean/Resurvey	19	8.4	21.1	84.4
Lab benches	Decay-in-storage; Pack/Dispose; Size/Resurvey; Clean/Resurvey	649	2.52	6.3	25.2
Sinks	Decay-in-storage; Pack/Dispose; Size/Resurvey; Clean/Resurvey	19	10.08	25.2	100.8
Floors	Decay-in-storage; Pack/Dispose; Size/Resurvey; Clean/Resurvey	3003	2.52	6.3	25.2
Walls	Decay-in-storage; Pack/Dispose; Size/Resurvey; Clean/Resurvey	3003	2.52	6.3	25.2
Ducting	Decay-in-storage; Pack/Dispose; Size/Resurvey; Clean/Resurvey	187.5	included with hoods	included with hoods	included with hoods
H Bldg Tanks	Pack/Dispose; Size/Resurvey; Clean/Resurvey	2000	5	5	8
Rad Waste Sink and Drainlines	Pack/Dispose	1	5	5	30
		Total Workdays:	[illegible]	[illegible]	[illegible]

FDA/CFSAN
Decommissioning Funding Plan
Reference Table A.3.7

Assumptions for building table:

1) There are no glove boxes, activated materials, hot cells or storage tanks.
2) 25% of chemical fume hoods will be impacted; 50% of impacted hoods will be contaminated.
3) For contaminated chemical fume hoods, 25% will require disposal; 75% will be decontaminated and resurveyed
4) For each contaminated hood there will be 10 feet of contaminated ducting
5) Work days consist of 8 hours
6) Radioactive waste disposal sinks and associated drainlines will be packaged for offsite disposal
7) 10% of sinks will be impacted; 25% of impacted sinks will be contaminated
8) For contaminated sinks, 25% will require disposal; 75% will be decontaminated and resurveyed
9) 10% of lower walls, floors and benches will be impacted; 25% of impacted surfaces will be contaminated
10) For contaminated benches, walls and sinks, 10% will require disposal, 90% will be decontaminated and resurveyed
11) Extensive monitoring and swipe sample collection (wlth off-site analysis) will be a part of all decontamination efforts
12) Labor based on tech hours in worksheet (HP at 25%, Super at 10%)

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ATTACHMENT FOUR

REFERENCE TABLE A.3.9

FDA/CFSAN
Decommissioning Funding Plan
Reference Table* A.*3.9

Final Radiation Surveys (Workdays)

Labor ***averages*** for ***Decommissioning*** of FB-8

Activity	Ratio	Labor Cateogory			
		Supervisor	Health Physicist	HP Tech	Clerical
HSA, Work Plans, etc.	1	30	0	0	3
Field Work	1	130	260	1040	10
Meetings, etc.	1	14	14	0	0
Survey reports	1	30	6	0	6
Administrative	1	0	0	0	0
TOTAL		204	280	1040	19

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Reference Table A.3.9

Workdays by Building

Building	Ratio	*Labor Cateogory*			
		Supervisor	Health Physicist	HP Tech	Clerical
Wiley	0.4	81.6	112	416	7.6
MOD-1	0.4	81.6	112	416	7.6
MOD-2 / H-Bldg	0.3	61.2	84	312	5.7
BRF	0.1	20.4	28	104	1.9
TOTALS		244.8	336	1248	22.8

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ATTACHMENT FIVE

REFERENCE TABLE **A.**3.11

FDA/CFSAN
Decommissioning Funding Plan
***Reference Table* A.3.11**

Total Workdays by Labor Category

Task	*Labor Category*			
	Supervisor	Health Physicist	HP Technician	Clerical
Planning and Preparation (Totals from Table A.3.6)	191	231	1075	59
Decontamination and/or Dismantling of Radioactive Facility Components (Totals from A.3.7)	36	75	299	0
Final Radiation Survey (Totals from A.3.9)	245	336	1248	23
TOTALS	**472**	**642**	**2622**	**82**

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ATTACHMENT SIX

REFERENCE TABLE **A.3.12**

FDA/CFSAN
Decommissioning Funding Plan
Reference *Table A.3.12*

Worker Unit Cost Schedule

Labor Cost Component	*Labor Category* Supervisor	Health Physicist	HP Tech	Clerical
Salary and Fringes	$ -	$ -	$ -	$ -
Overhead Rate	$ -	$ -	$ -	$ -
Total Cost per Year	$ 269,942.40	$ 194,958.40	$ 101,774.40	$ 101,774.40
Total Daily Cost	$ 1,038.24	$ 749.84	$ 391.44	$ 391.44

Assumptions:
260 working days per year, 8 hours worked per day.

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ATTACHMENT SEVEN

REFERENCE TABLE **A.3.13**

FDA/CFSAN
Decommissioning Funding Plan
Reference Table* A.*3.13

Total Cost by Major Decommissioning Task

Task	*Cost by Labor Category*				Total Labor Cost
	Supervisor	Health Physicist	HP Technician	Clerical	
Planning and Preparation	$ 198,303.84	$ 173,213.04	$ 420,798.00	$ 23,094.96	$ 815,409.84
Decontamination and/or Dismantling of Radioactive Facility Components	$ 37,457.10	$ 56,383.28	$ 116,952.49	$ -	$ 210,792.87
Final Radiation Survey	$ 254,161.15	$ 251,946.24	$ 488,517.12	$ 8,924.83	$ 1,003,549.34
TOTALS	$ 489,922.10	$ 481,542.56	$1,026,267.61	$ 32,019.79	$ 2,029,752.06

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ATTACHMENT EIGHT

REFERENCE TABLE **A.3.14**

FDA/CFSAN
Decommissioning Funding Plan
Reference *Table A.3.14*

Packaging, Shipping and Disposal of Radioactive Wastes (Excluding Labor Costs)

(a) Packing Material Costs: All waste is assumed to be solid radioactive waste to be packaged in "B25" containers B25 containers hold approximately 3 m^3 of solid waste..

Waste Type	Volume (m^3)	Number of Containers	Type of Container	Unit Cost	Total Packaging Costs
Floors; Lab benches; Shelves; Lower walls, etc.	5	2.0	8-25	$ 450.00	$ 900.00
Chemical fume hoods, ducting, etc.	7.0	3.0	*8-25*	$ 450.00	$ 1,350.00
Sinks, drains, etc.	1.0	1.0	*8-25*	$ 450.00	$ 450.00
TOTALS	13	*6*			$ *2,700.00*

(b) and (c) Shipping and Disposal Costs (combined): Rates utilized are reasonable waste transport and disposal rates based on current contracts held by CFSAN. The average weight of a filled 525 box is 3,000 lbs.

Waste Type	Disposal Volume	Container Information	Weight (lbs)	Unit Cost	Total Shipping / Disposal Costs
Bulk dry active (m^3)	13	B-25	3000	$ 9.48	$ 361,632.50
Liquid scintillation vials (Exempt) (ft^3)	262.5	55 gallon drum	250	$ 782.80	$ 27,398.00
				TOTAL	**$ 389,030.50**

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ATTACHMENT NINE

REFERENCE **TABLE A.3.15**

FDA/CFSAN
Decommissioning Funding Plan
Reference *Table A.3.15*

Equipment / Supply Costs (Excluding Containers)

Equipment / Supplies	Quantity	Unit Cost	(Total Equipment / Supply Costs
Sizing tools	38	$46 / day	$ 1,748.00
Liquid scintillation counter(s)	**76**	$63.30 / day	$ 4,810.80
HEPA vacuums	152	$10 / day	$ 1,520.00
Radiation detection instrumentation (team)	76	$361.92 / day	$ 27,505.92
Vehicle	**152**	$50 / day	$ 7,600.00
Personal protective equipment	342	$45/person/day	$ 15,390.00
		TOTAL	$ 58,574.72

It is assumed that all items shown in this table will be required for decontamination activities. The liquid scintillation counter and radiation detection instrumentation will be required for both decontamination activities and final status surveys.

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ATTACHMENT TEN

REFERENCE TABLE **A.3.16**

FDA/CFSAN
Decommissioning Funding Plan
***Reference Table* A.3.16**

Laboratory Costs

Activity / Item	Total Cost
Sample containers	$ 750.00
Sample transport	$ 1,375.00
Testing / analysis	$ 34,814.00
TOTALS	$ 36,939.00

***Assumes 50** total **samples, basic radiochemistry** (3H, 14C, 63Ni)*

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ATTACHMENT ELEVEN

REFERENCE TABLE A.3.17

FDA/CFSAN
Decommissioning Funding Plan
Reference Table A.3.17

Miscellaneous Costs

Activity / Item	Total Cost
License fees	$ -
Insurance*	$ -
Taxes	$ -
Per Diem ($/person day)	$ 46,885.50
TOTALS	$ 46,885.50

*Typically, a policy guaranteeing funds for decommissioning is required. The policy can be open-ended or for a specified term, at the conclusion of which it must be renewed. The level of insurance must be at least equal to the licensee's prescribed amount of estimated decommissioning cost. Licensees may eliminate the insurance requirement by having an escrow account or a bond guaranteed by a large financial institution. For an institution that is part of the federal government, there should be no need for insurance, escrow or bond.

License, insurance and taxes are factored into contract rates
Per Diem assumes an 8 person team, at $155.25/person/day

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ATTACHMENT TWELVE

REFERENCE TABLE A.3.18

FDA/CFSAN
Decommissioning Funding Plan
Reference *Table A.3.18*

Total Decommissioning Costs

Task / Component		Cost	Percentage of Cost
Planning and Preparation (A.3.13)	$	815,409.84	**31.80%**
Decontamination and/or Dismantling of Radioactive Facility Components (A.3.13)	$	210,792.87	**8.22%**
Final Radiation Survey (A.3.13)	$	1,003,549.34	**39.14%**
Packing Material Costs (A.3.14a)	$	2,700.00	**0.11%**
Shipping and Waste Disposal Costs (A.3.14b/c)	$	389,030.50	**15.17%**
Equipment / Supply Costs (A.3.15)	$	58,574.72	**2.28%**
Laboratory Costs (A.3.16)	$	36,939.00	**1.44%**
Miscellaneous Costs (A.3.17)	$	46,885.50	**1.83%**
SUBTOTAL	$	2,563,881.77	
25% Contingency	$	640,970.44	
TOTAL	**$**	**3,204,852.21**	

Estimated Cost by Building

Building	Cost	Ratio
Wiley	$ 961,455.66	0.3
MOD-1	$ 961,455.66	0.3
MOD-2 / H-Bldg	$ 801,213.05	0.25
BRF	$ 480,727.83	0.15