



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740-38

SEP 24 2008

P-7  
MS-16

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

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 financial assurance documents.

CFSAN has reviewed our NRC License Amendment No. 5 in its entirety. During this review, an error was identified in Condition 10 of the amendment. Condition 10 indicates that the Harvey W. Wiley Building is a facility located in Laurel, Maryland. This facility is located in College Park, Maryland. CFSAN is requesting that Condition 10 be amended to read: "Licensed material may be used or stored only at the licensee's facilities located at 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."

CFSAN has reviewed and evaluated Condition 12 and the proposed license amendment options. Our decision is to maintain the current possession limits and prepare a decommissioning funding plan (DFP). After reviewing the DFP requirements set forth in NUREG 1757, Volume 3, Appendix A, we anticipate submitting the DFP to your office in December 2008.

A Certificate Statement is attached to ensure compliance with the deficiency noted during the financial assurance document audit. This Certificate Statement will be updated and resubmitted with the DFP as required in NUREG 1757, Vol 3, Appendix A.

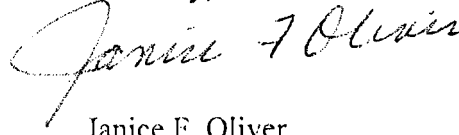
141772  
NMSS/RGNI MATERIALS-002

Page 2 --Mr. Thomas K. Thompson

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 301-436-2429 or Ms. Constance Sims Rosser, Radiation Safety Officer at 301-436-2105.

Sincerely,



Janice F. Oliver  
Deputy Director  
for Operations  
Center for Food Safety  
and Applied Nutrition

Enclosures

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Prepared By

D/B: crosser/HFS-657/5/12/2008

E/B: crosser/HFS-657/7/1/2008

E/B: crosser/HFS-657/7/9/2008

E/B: crosser/HFS-657/8/6/2008

E/B: crosser/HFS-657/8/18/2008

E/B:crosser/HFS-657/8/20/2008



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

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SEP 24 2008

## 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-001  
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

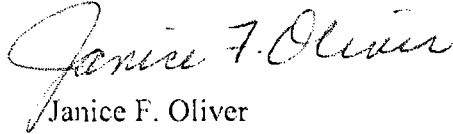
Any chemical or physical form, as specified in Section 33.100, Schedule A, of 10 CFR 33 quantities by isotope.

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 1, for that radionuclide. The sum of the ratios for all radionuclides possessed under the licensed shall not exceed unity.

Page 2 -- Certification of Financial Assurance

I also certify that financial assurance in the amount of \$1,125,000 has been obtained for the purpose of decommissioning as prescribed by 10 CFR Part 30.



Janice F. Oliver  
Deputy Director  
for Operations  
Center for Food Safety  
and Applied Nutrition

Enclosures

Page 2 – Certification of Financial Assurance

Prepared By

D/B: crosser/HFS-657/5/12/2008

E/B: crosser/HFS-657/7/1/2008

E/B: crosser/HFS-657/7/9/2008

[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 546-547]

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

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

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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



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

## Section 10CFR33.100

Tungsten-181.....	1	.01
Tungsten-185.....	1	.01
Tungsten-187.....	10	.1
Vanadium-48.....	1	.01
Xenon-131m.....	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

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

[33 FR 14579, Sept. 28, 1968]

APPENDIX A

**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  
Murrink Road Complex, Laurel, MD + Temporary job sites

License Number(s) 19-30771-01

Date of Submission September 24 2008

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

APPENDIX A

financial assurance coverage. Licensees may wish to use a DFP if, for example, they wish to obtain the optimal amount of financial assurance, or because use of prescribed amounts may overstate a facility's decommissioning costs. Guidance on preparing DFPs is presented in Section A.3 of this appendix.

Licensees may be eligible to use a particular prescribed amount depending on the type of license and the types and quantities of materials authorized under the particular license, as summarized below.<sup>6</sup> Note that the relevant quantities and types of materials are those authorized under a particular license, even if a licensee does not currently or usually possess or use these same quantities and types of materials. The following discussion of applicable prescribed amounts is organized into three parts corresponding to the three general license types:

- Part 30--Byproduct Material
- Part 40--Source Material
- Part 70--Special Nuclear Material

Only radionuclides with a half life of greater than 120 days are included in the determination of financial assurance requirements.

<b>Checklist 2 Certifications of Financial Assurance</b>	
License Number(s): <u>19-30771-01</u>	
Applicable Parts of 10 CFR (check all that apply):	<input checked="" type="checkbox"/> Part 30 <input type="checkbox"/> Part 40 <input type="checkbox"/> Part 70
<input checked="" type="checkbox"/> Determine the appropriate prescribed amount(s) (see Section A.2.1)	
<input checked="" type="checkbox"/> Amount required under Part 30 for sealed sources:	<u>\$ 150,000</u>
<input checked="" type="checkbox"/> Amount required under Part 30 for unsealed sources:	<u>\$ 975,000</u>
<input type="checkbox"/> Amount required under Part 40:	_____
<input type="checkbox"/> Amount required under Part 70:	_____
<input type="checkbox"/> Total of all prescribed amounts for all licenses:	<u>\$ 1,125,000</u>
<input checked="" type="checkbox"/> Prepare certification statement (see Section A.2.2)	
<input checked="" type="checkbox"/> Include the necessary documentation (see Section A.2.3):	
<input checked="" type="checkbox"/> Certification statement (see Section A.2.4)	
<input checked="" type="checkbox"/> Financial instrument and supporting documentation	

## APPENDIX A

**A.2.1.1 Part 30 Prescribed Amounts**

Part 30 prescribes three levels of financial assurance. **Check 10 CFR 30.35(d) to determine current specification for prescribed amount.** The following apply to the use of prescribed amounts by Part 30 licensees.

- **The lowest level prescribed amount of \$75,000 applies** to Part 30 licensees who are authorized to possess or use sealed sources or plated foils with a half-life greater than 120 days
  - in amounts greater than  $10^{10}$  times the applicable quantities of Appendix B to 10 CFR Part 30 (reproduced as Attachment A.2 to this appendix) or
  - for a *combination* of isotopes, if R divided by  $10^{10}$  is greater than 1 (when R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix B to 10 CFR Part 30).
- **The middle level prescribed amount of \$150,000 applies** to Part 30 licensees who are authorized to possess or use unsealed byproduct material with a half-life greater than 120 days
  - in amounts greater than  $10^3$  but less than or equal to  $10^4$  times the applicable quantities of Appendix B to 10 CFR Part 30 or
  - for a *combination* of isotopes, if R divided by  $10^3$  is greater than 1 but if R divided by  $10^4$  is less than or equal to 1 (when R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix B to 10 CFR Part 30).
- **The highest level prescribed amount of \$750,000 applies** to Part 30 licensees who are authorized to possess or use unsealed byproduct material with a half-life greater than 120 days in amounts exceeding the limit applicable to the \$150,000 prescribed amount, as stated above, but
  - in amounts greater than  $10^4$  but less than or equal to  $10^5$  times the applicable quantities of Appendix B to 10 CFR Part 30 or
  - for a *combination* of isotopes, if R divided by  $10^4$  is greater than 1 but if R divided by  $10^5$  is less than or equal to 1 (when R is defined as the sum of the ratios of the quantity of each isotope to the applicable value in Appendix B to 10 CFR Part 30).
- **A prescribed amount may not be used** for a Part 30 license authorizing the possession or use of byproduct material in amounts exceeding the limit applicable to the highest level prescribed amount (\$750,000), as stated above. These licensees must prepare DFPs, as discussed in Section A.3.
- **No financial assurance is required** for a Part 30 licensee who is authorized to possess or use (1) unsealed byproduct material with a half-life greater than 120 days in amounts less than or equal to  $10^3$  times the applicable quantities of Appendix B to 10 CFR Part 30 (reproduced as Attachment 2 to this appendix) or, for a combination of isotopes, if R divided by  $10^3$  is less