



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 19, 2008

Docket No. 03036120
Control No. 141772

License No. 19-30771-01

Janice F. Oliver
Deputy Director
Department of Health & Human Services
Food and Drug Administration
Harvey W. Wiley Building, HFS-001
5100 Paint Branch Parkway
College Park, MD 20740

SUBJECT: DEPARTMENT OF HEALTH & HUMAN SERVICES, REQUEST FOR
ADDITIONAL INFORMATION CONCERNING FINANCIAL ASSURANCE
DOCUMENTS, CONTROL NO. 141772

Dear Ms. Oliver:

This is in reference to a recent audit NRC conducted on your financial assurance for decommissioning for Nuclear Regulatory Commission License No. 19-30771-01. We have noted some corrections and additional information that is needed on your financial assurance documents for your license as follows:

1. Condition 12 of your NRC license, as now written, would require that a decommissioning funding plan (DFP) be provided. It appears that your possession limits may not need to be in those quantities indicated in the present condition 12 and you could eliminate the need for a DFP. Please review the following license condition and indicate if this would cover your possession needs. If so you could request that the license be amended to this condition. If not please submit a DFP.

(Replacement Condition 12.)

- A. If only one radionuclide is possessed, the possession limit is the quantity specified for that radionuclide in 10 CFR 33.100, Schedule A, Column I. 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 license shall not exceed unity.
- B. Notwithstanding Paragraph A of this Condition and 10 CFR 33.100, Schedule A, Column I,
 - (i) the applicable quantities for the following radionuclides are reduced to:

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Department of Health & Human Services

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Carbon 14	10 curies
Krypton 85	10 curies
Iodine 129	10 millicuries

Any byproduct material other than alpha emitting byproduct material not listed in 10 CFR 33.100, Schedule A	10 millicuries
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(ii) the following nuclides are added:

Any byproduct material with atomic number 84 through 98	1 millicurie
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2. Please provide a Certification Statement. Examples of Certification Statements may be found in NUREG-1757, Vol. 3, Appendix F, page F20.
3. If you plan to use a prescribed amount of F.A. as permitted by 10 CFR 30.35 (b) then your Statement of Intent should be for \$1,125,000 not \$ 1,200,000 as currently indicated.
4. Please indicate each location of use of byproduct material on your Statement of Intent rather than just referring to the facilities authorized under the Department of Health and Human Services.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 141772. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5303.

Sincerely,

Original signed by Thomas K. Thompson

Thomas K. Thompson
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

J. Oliver
Department of Health & Human Services

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cc:
Constance S. Rosser, Radiation Safety Officer

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SUNSI Review Complete: TThompson

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