



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

July 19, 2007

Docket No. 03004675  
Control No. 140668

License No. 20-08361-01

John Marzilli  
Director  
Department of Health and Human Services  
Food and Drug Administration  
Winchester Engineering and Analytical Center  
109 Holton Street  
Winchester, MA 01890-1197

SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR  
ADDITIONAL INFORMATION CONCERNING APPLICATION FOR  
AMENDMENT TO LICENSE, CONTROL NO. 140668

Dear Mr. Marzilli:

This is in reference to your letter dated June 12, 2007 requesting to amend Nuclear Regulatory Commission License No. 20-08361-01. In order to continue our review, we need the following additional information:

1. The possession limits for Radium-226 you requested require that you submit a Decommissioning Funding Plan (DFP), in addition the financial assurance you currently have in place, in accordance with financial assurance requirements of 10 CFR 30.35. This plan must include an actual estimate of the costs for decommissioning your facility and a mechanism to fund the Plan. Submit the required financial assurance or modify your licensing request such that the additional financial assurance is not required. You may wish to refer to Volume 3 of NUREG-1757, "Consolidated NMSS Decommissioning Guidance" for assistance in formulating your response.
2. The possession limits for Thorium-229 you requested require that you submit a Decommissioning Funding Plan (DFP), in addition the financial assurance you currently have in place, in accordance with financial assurance requirements of 10 CFR 40.36. This plan must include an actual estimate of the costs for decommissioning your facility and a mechanism to fund the Plan. Submit the required financial assurance or modify your licensing request such that the additional financial assurance is not required. You may wish to refer to Volume 3 of NUREG-1757, "Consolidated NMSS Decommissioning Guidance" for assistance in formulating your response.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://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 1-888-293-6498. The GPO is open from 7:00 a.m. to 8:00 p.m. EST, Monday through Friday (except Federal holidays).

J. Marzilli  
Department of Health and Human Services

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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. 140668. If you have any technical questions regarding this deficiency letter, please contact Farrah Gaskins at (610) 337-5143.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

***Original signed by Elizabeth Ullrich***

Elizabeth Ullrich  
Senior Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

cc:  
James J. Cherniak, Radiation Safety Officer

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**SUNSI Review Complete: FGaskins**

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DATE	7/19/2007		7/19/2007					

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