



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION I  
2100 RENAISSANCE BLVD.  
KING OF PRUSSIA, PA 19406-2713

July 12, 2017

Brian L. Baker, Center Director  
Department of Health and Human Services  
Food and Drug Administration  
Winchester Engineering & Analytical Center  
109 Holton Street  
Winchester, MA 01890

SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG  
ADMINISTRATION, WINCHESTER ENGINEERING & ANALYTICAL CENTER,  
REQUEST FOR ADDITIONAL INFORMATION, MAIL CONTROL NO. 591020

Dear Mr. Baker:

This is in reference to your letter dated May 9, 2017, with the attached Decommissioning Funding Plan (DFP) provided in support of the requirement to update your financial assurance for License No. 20-08361-01. We completed the review of the DFP and have no additional questions about the DFP.

Please provide a new financial assurance instrument in the amount of the cost estimate for the DFP. Be sure to provide all required documents in support of the instrument. Detailed information may be found in NUREG-1757, "Consolidated NMSS Decommissioning Guidance," Volume 3, "Financial Assurance, Recordkeeping, and Timeliness," Revision 1 (NUREG-1757, Vol. 3, Rev. 1). If you provide a Statement of Intent, as in the past, the required documentation includes:

1. The statement of intent (originally signed duplicate);
2. Documentation verifying that the signatory is authorized to represent the licensee in providing the statement of intent;
3. A description of the means that will be used to adjust the site-specific cost estimate over the life of the facility;
4. A certification that financial assurance has been provided (see NUREG-1757, Vol. 3, Rev. 1, Appendix A.2.4 "Model Certification of Financial Assurance").

We will continue our review upon receipt of this information. Please reply to my attention at:

Betsy Ullrich, Senior Health Physicist  
Mail Control No. 591020  
USNRC, Region I  
Division of Nuclear Materials Safety  
2100 Renaissance Boulevard  
King of Prussia, PA 19406

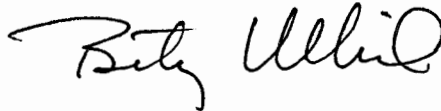
An electronic version of the NRC's regulations is available on the NRC Web Site at: [www.nrc.gov](http://www.nrc.gov). Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at (610) 337-5040 or via electronic mail at [Elizabeth.Ullrich@nrc.gov](mailto:Elizabeth.Ullrich@nrc.gov).

Thank you for your cooperation.

Sincerely,



Betsy Ullrich, Senior Health Physicist  
Commercial, Industrial, R&D  
and Academic Branch  
Division of Nuclear Materials Safety  
Region I

License No. 20-08361-01  
Docket No. 030-04675  
Mail Control No. 591020

cc: Edmond Baratta, Radiation Safety Officer

An electronic version of the NRC's regulations is available on the NRC Web Site at: [www.nrc.gov](http://www.nrc.gov). Additional information regarding use of radioactive materials may be obtained on the NRC Web Site at: <http://www.nrc.gov/materials/miau/mat-toolkits.html>. This site also provides the link to the toolbox for updated information on the revised regulations for naturally-occurring and accelerator-produced radioactive materials (NARM).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS). ADAMS is accessible from the NRC Web Site at: <http://www.nrc.gov/reading-rm/adams.html>. Please be aware that you may request that certain portions of your submittal to NRC be withheld from public disclosure as proprietary information. To do this, you must execute an affidavit as specified in 10 CFR 2.390. You must list all portions that you wish to be held proprietary, along with your reasoning as to why that is appropriate. While it is allowable, please refrain from submitting proprietary information in support of a license unless necessary. Keep in mind that all NRC licenses are considered to be in the public domain, and therefore may be viewed by any member of the public who requests to see them.

If you have any questions regarding this request for additional information, please contact me at (610) 337-5040 or via electronic mail at [Elizabeth.Ullrich@nrc.gov](mailto:Elizabeth.Ullrich@nrc.gov).

Thank you for your cooperation.

Sincerely,

Betsy Ullrich, Senior Health Physicist  
Commercial, Industrial, R&D  
and Academic Branch  
Division of Nuclear Materials Safety  
Region I

License No. 20-08361-01  
Docket No. 030-04675  
Mail Control No. 591020

cc: Edmond Baratta, Radiation Safety Officer

DOCUMENT NAME: **G:\WBL Documents\WBL License RAIL20-08361-01.591020.docx**  
[LAT to enter ADAMS Accession No.]

**SUNSI Review Complete: Betsy Ullrich**

After declaring this document "An Official Agency Record" it will be released to the Public.  
To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	RI:DNMS EUllrich	N					
NAME							
DATE	7/12/17						

OFFICIAL RECORD COPY