



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

September 25, 2020

Brian L. Baker, P.E., Director
U.S. Department of Health and Human Services
U.S. Food and Drug Administration;
Winchester Engineering & Analytical Center (WEAC)
109 Holton Street
Winchester, Massachusetts 01890-1197

SUBJECT: US DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR
ADDITIONAL INFORMATION, MAIL CONTROL NO. 621400

Dear Mr. Baker:

This is in reference to your letter dated July 6, 2020, regarding NRC License No. 20-08361-01. We reviewed the Decommissioning Funding Plan dated May 2020, Certification of Financial Assurance dated July 6, 2020, and Statement of Intent dated June 1, 2020. In addition, we compared the Decommissioning Funding Plan dated May 2020 with the Decommissioning Funding Plan dated May 2017. To conduct our review, we used Section 4 and Appendix A of NUREG-1757, "Consolidated Decommissioning Guidance: Financial Assurance, Recordkeeping, and Timeliness, Vol. 3, Rev. 1", dated February 2012 (NUREG-1757, Vol. 3) (<https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v3/>).

In order to continue our review, we need the following additional information:

Please submit an amended Decommissioning Funding Plan to reflect the following:

- 1 In Section 4 of your Decommissioning Funding Plan dated May 2020 (DFP2020), we noted that several cost estimating tables contained the identical cost estimate information that had been submitted in your Decommissioning Funding Plan dated May 2017 (DFP2017). Specifically, tables A.3.12., "Worker Unit Cost Schedule"; A.3.14., "Packaging, Shipping, and Disposal of Radioactive Wastes"; A.3.15., "Equipment/Supply Costs"; and A.3.16., "Laboratory Costs" need your attention and re-evaluation. Please refer to the guidance in Section 4 and Appendix A.3.1.2 of NUREG-1757, Vol. 3, Rev. 1 to determine your response.
 - a. Indicate if third party labor costs were included in the DFP2020 cost estimating tables. Indicate if you compared the most recent U.S. Bureau of Labor Statistics (U.S. BLS) tables for your area for 2017 and 2019. If not, please review the U.S. BLS tables and submit the most recent labor costs. Please note, that you may not use your own labor costs.

- b. Indicate if you contacted the waste disposal service for an update on costs to confirm if the costs for waste containers, services and disposal have changed since 2017. If not, please contact the waste disposal service to determine if any changes have occurred and provide the updated information in your response.
- 2 In table A.3.14.a. "Packaging, Shipping, and Disposal of Radioactive Wastes- Packing Material Costs" in DFP2020, we noted the following:
 - a. The Waste Type estimate denoted as "Low-Level Waste in bulk containers" (listed in DFP2017) had been deleted from the DFP2020 table. If this deletion was unintentional, then include your estimate for this category into the DFP2020. If this deletion was intended, please succinctly explain the reason for the deletion.
 - b. The Waste Type estimate denoted as "Special Nuclear Materials" listed in DFP2020 indicates a value in the "Disposal Volume" column, however the units for the value had been omitted. Please indicate the proper units for the value.
- 3 In table A.3.14.b. "Packaging, Shipping, and Disposal of Radioactive Wastes - Shipping Costs" in DFP2020, we noted that the Waste Type estimate denoted as "Low-Level Waste in bulk containers" (listed in DFP2017) had been deleted from the DFP2020 table. If this deletion was unintentional, then include the estimate for this category to the DFP2020 table. If this deletion was intended, please succinctly explain the reason for the deletion.
- 4 In table A.3.14.c. "Packaging, Shipping, and Disposal of Radioactive Wastes - Waste Disposal Costs" in DFP2020, we noted the following:
 - a. The Waste Type estimate denoted as "Solid Low-Level Bulk Radiological Waste (LLRW)" listed in DFP2020 is identical to the estimate denoted as "Solid Low-Level Bulk Radiological Waste from WEAC operations" listed in DFP2017. Please see Item 1. of this letter to provide your response.
 - b. The Waste Type estimate denoted as "Low-Level Waste in bulk containers" (listed in DFP2017) was deleted from the DFP2020 table. If this deletion was unintentional, then include the estimate for this category into the DFP2020. If this deletion was intended, succinctly explain the reason for the deletion.
 - c. The Waste Type estimate denoted as "Solid Standards" listed in DFP2020 appears to have been calculated using the "Unit Cost" and the "Surcharge Cost" values from the "Low-Level Waste in bulk containers" listed in DFP2017. Please recalculate the "Solid Standards" using the appropriate "Unit Cost" and the "Surcharge Cost" values. Also, please include the dollar sign (\$) for the surcharge value.

- d. The "Total Disposal Cost" calculated in DFP2020 is identical to the "Total Disposal Cost" calculated in DFP2017. Based on the above indicated discrepancies, please recalculate the "Total Disposal Cost" and incorporate the new total into the overall DFP total.
- e. The Waste Type estimate denoted as "Special Nuclear Materials" listed in DFP2020 indicates a value in the "Disposal Volume" column, however the units for this value had been omitted. Please indicate the proper units for the value.

Once we have approved your amended Decommissioning Funding Plan in its entirety, we will request that you submit an amended Certification of Financial Assurance and Statement of Intent. Please do not submit the above documents with your reply to this Request for Additional Information.

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

Laurie Kauffman
Mail Control No. 621400
R1DNMSMAIL.RESOURCE@nrc.gov
or
USNRC, Region I
Division of Nuclear Materials Safety
2100 Renaissance Boulevard
King of Prussia, PA 19406

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

An electronic version of the NRC's regulations is available on the NRC Web Site at: 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 Laurie Kauffman at 610-337-5323 or via electronic mail at Laurie.Kauffman@nrc.gov.

Thank you for your cooperation.

Sincerely,

Steven Courtemanche, 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. 621400

cc: Elon Malkin, Radiation Safety Officer

US DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR ADDITIONAL
INFORMATION, MAIL CONTROL NO. 621400 DATED SEPTEMBER 25, 2020

DOCUMENT NAME: G:\DNMS\WBL Documents\WBL License RAI\L20-08361-01.621400.FA_RAI.docx

SUNSI Review Complete: Laurie Kauffman

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/end "E" = Copy w/ attach/end "N" = No copy

OFFICE	RI:DNMS	N	RI:DNMS	N				
NAME	LKauffman (lak)		SCourtemanche (src)					
DATE	09/24/2020		09/25/2020					

OFFICIAL RECORD COPY