



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

April 19, 2016

Brian L. Baker
Center Director, WEAC
Department of Health and Human Services
Public Health Service, FDA
Winchester Engineering and Analytical Center (WEAC)
109 Holton Street
Winchester, MA 01890-1197

SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR
ADDITIONAL INFORMATION CONCERNING FINANCIAL ASSURANCE
DOCUMENTS, CONTROL NO. 591020

Dear Mr. Baker:

We reviewed your latest financial assurance (FA) instrument and Decommissioning Funding Plan (DFP) dated June 2016 (ML16159A341). We identified a number of items in the DFP that affect the cost estimate, as described below. Please address each item and resubmit a revised DFP and new cost estimate. After we have reviewed the revised DFP and cost estimate, we will request a new Statement of Intent (SI) and a new Certification of Financial Assurance (CFA). Please do NOT submit a new SI or CFA until we have reviewed your new cost estimate and DFP.

1. Review and update Section 2 of your DFP to include specific quantities and types of materials authorized by your license as well as radionuclides used in the past that are known, or suspected, to have caused contamination above the limits specified in Subpart E, "Radiological Criteria for License Termination," of 10 CFR Part 20.
2. The residual contamination limits for alpha emitters specified in your Tables 4a and 4b may not be sufficient to meet the radiological criteria for unrestricted use for the release of buildings as required by 10 CFR 20.1402, Subpart E. For example, the screening value that NRC determined will meet the Subpart E criteria for thorium-232 plus progeny is 6 disintegrations per minute per 100 square centimeters area (6 dpm/100 cm²), total residual contamination, of which not more than 10% may be removable. This is less than the 22 dpm/100 cm² on your Table 4a for removable contamination. Other alpha emitters also have lower release limits than specified in your cost estimate tables. Neither of the tables addressed total contamination (fixed plus removable). In addition, the values noted in Table 4b are applicable to release of equipment only, not for building surfaces.

There are several acceptable methods to determine unrestricted release criteria for buildings and other locations.

- One method is to use screening values for each radionuclide. Screening values found in NUREG-1757, "Consolidated Decommissioning Guidance",

Volume 1, "Decommissioning Process for Materials Licensees," Appendix B, "Screening Values." Screening values can also be found in NUREG/CR-5512 Volume 3, "Residual Radioactive Contamination from Decommissioning," Table 5.19, using the concentration (dpm/100 cm²) equivalent to 25 millirem per year (mrem/y) for $P_{crit} = 0.90$ (This can be found using Accession No. ML010940257 in the NRC document system ADAMS).

- A second method is to develop site-specific Derived Concentration Guideline Levels (DCGL) using NRC's current version of the DandD code. Such site-specific DCGL values may be less restrictive than the NRC default screening values. These DCGL values do not need to be submitted for the DFP, but will require review and approval prior to use during actual decommissioning.
- A third method is to develop site-specific DCGL values using RESRAD. Such site-specific DCGL values may be less restrictive than the NRC default screening values. Although these do not need to be submitted with the DFP, DCGL values developed with RESRAD will require review and approval prior to use in actual decommissioning. Because RESRAD has many more site-specific parameters than DandD, this review is more complex and will require submission of input parameters, output results, and sensitivity analysis.

Please revise your criteria for alpha emitters and adjust your DFP and cost estimate, if necessary, to account for more stringent release limits for alpha emitters and/or the time and effort required to develop site-specific DCGL values.

3. The tables in A.3.14 seem inconsistent. Our understanding is that the tables should be consistent in addressing the packing material costs (Table A.3.14(a)), shipping costs (Table A.3.14(b)), and disposal costs (Table A.3.14(c)) for the wastes you have identified. For example, liquids that may require disposal as radioactive waste would have costs associated with the drum or other containers used to hold the liquids or solidify the waste, absorbent filler, or other packaging materials required; a shipping cost for those packaged containers of liquid waste; and cost for the disposal of those containers in an authorized radioactive waste disposal site.

Please revise Section A.3.14 cost estimates for disposal of waste. Based on your submission, your waste types may include solids, standards, mixed wastes, SNM, bulk debris and/or low-level radioactive waste and your packaging may include barrels, drums, and bulk containers of some type. Shipping costs and disposal costs should include all your waste types and packaging types.

4. Please review and correct the following math errors in the DFP:
 - a. Table A.3.6: The total work days in the Health Physicist (HP) and Health Physicist Technician (HPT) columns are incorrect, and should be 193 and 67, respectively. These errors are carried forward to Table A.3.11.
 - b. Table A.3.11:
 - (1) Correct the errors in the numbers in row 1 (Planning and Preparation) due to incorrectly carrying forward the totals from Table A.3.6. Specifically in row 1,

the "Labor Category H" column should be 193 and the "Labor Category T" column should be 67. These errors are carried forward to Table A.3.13.

- (2) Correct the errors in row 3 (Restoration of Contaminated Areas on Facility Grounds) due to incorrectly carrying forward the values from Table A.3.8. Specifically in row 3, the "Labor Category F" column should be 0, the "Labor Category H" column should be 120, the "Labor Category Column T" should be 120, and the "Labor Category L" column should be 180. These errors are carried forward to Table A.3.13.
- c. Table A.3.13 should be revised to correct errors carried forward from Tables A.3.6, A.3.8, and A.3.11.
- d. Table A.3.18: This table will need to be updated to account for the changes required in Table A.3.14 described in Item 3 above, and to correct the previous math errors carried forward.

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

Betsy Ullrich, Senior Health Physicist
Mail Control No. 591011
USNRC, Region I
Division of Nuclear Materials Safety
2100 Renaissance Boulevard
King of Prussia, PA 19406

In order to continue review of your application, we request that you submit your response to this letter within 60 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 me at 610-337-5040 or James Cassata at 610-337-5303 or via electronic mail at elizabeth.ullrich@nrc.gov or james.cassata@nrc.gov.

B. Baker

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Thank you for your cooperation.

Sincerely,

/RA/

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 J. Baratta, Radiation Safety Officer

B. Baker

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Sincerely,

/RA/

Betsy Ullrich, Senior Health Physicist
Commercial, Industrial, R&D
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Division of Nuclear Materials Safety
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Docket No. 030-04675
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cc: Edmond J. Baratta, Radiation Safety Officer

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SUNSI Review Complete: JCassata

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