



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

October 25, 2013

Docket No. 03004675
Control No. 582296

License No. 20-08361-01

Patrick Regan, Ph.D.
Acting Center Director, WEAC
Department of Health and Human Services
Public Health Service, FDA
Winchester Engineering and Analytical Center
109 Holton Street
Winchester, MA 01890-1197

SUBJECT: DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUEST FOR
ADDITIONAL INFORMATION CONCERNING FINANCIAL ASSURANCE
DOCUMENTS, CONTROL NO. 582296

Dear Dr. Regan:

This is in reference to your letter dated September 9, 2013, providing financial assurance for decommissioning for Nuclear Regulatory Commission License No. 20-08361-01. In order to continue our review, we need the following additional information:

1. According to 10 CFR 30.35(e)(2), in part, at the time of license renewal and at intervals not to exceed 3 years, the decommissioning funding plan must be resubmitted with adjustments as necessary to account for changes in costs and the extent of contamination. You have provided an updated cost estimate but not the other components of a decommissioning funding plan. The components missing are as stated:
 - a. in 10 CFR 30.35(e)(1)(i)(C), the volume of onsite subsurface material containing residual radioactivity that will require remediation to meet the criteria for license termination.;
 - b. in 10 CFR 30.35(e)(1)(ii), identification of and justification for using the key assumptions contained in the decommissioning cost estimate; and
 - c. in 10 CFR 30.35(e)(1)(iii) a description of the methods of assuring funds for decommissioning from paragraph (f) of this section, including means for adjusting cost estimates and associated funding levels periodically over the life of the facility.
2. Section A.3.4 of your cost estimate gave a description of how license materials are used. Your response did not include all of your unsealed byproduct and special nuclear materials. Please provide a description for all of your materials.

3. Section A.3.14(a) lists your packing material costs and section A.3.14(c) lists your amount of waste material. The quantity of material for packing and waste was inconsistent. Please determine an amount and correct or explain why the amounts should be different.
4. The Certification of Financial Assurance received in your letter dated September 9, 2013, contained errors. Please correct the following errors and resubmit:
 - a. The broad scope allowance was stated as atomic number 3 through 83 instead of 1 through 83 as listed on the license.
 - b. Radium 228 was not listed.
 - c. The quantity of material for radium 226 was listed as 1.1 millicuries instead of 1.0 millicuries.
 - d. Americium-241 (any isotope) should be listed as Americium (any isotope).

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. 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 8:00 a.m. to 5:30 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. 582296. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Edmond J. Baratta, Radiation Safety Officer

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SUNSI Review Complete: DLawyer

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