

From: [Lawyer, Dennis](mailto:Lawyer.Dennis)
To: edmond.baratta@fda.hhs.gov
Subject: Department of Health and Human Services, Request for Additional Information Concerning Application for a License Amendment, Control 581333
Date: Monday, August 26, 2013 12:27:00 PM

Dear Mr. Baratta

This is in reference to your letter dated July 9, 2013, requesting for amendment to Nuclear Regulatory Commission License No. 20-08361-01, Docket No. 030-04675. In which you requested an increase in licensed material authorization. You have submitted an updated cost estimate dated August 9, 2013 to support your amendment request dated July 9, 2013. 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. as stated in 10 CFR 30.35(e)(1)(ii), identification of and justification for using the key assumptions contained in the decommissioning cost estimate;
 - c. (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; and
 - d. (iv) a certification by the licensee that financial assurance for decommissioning has been provided in the amount of the cost estimate for decommissioning. Please see guidance in NUREG-1757, Volume 3, Revision 1, "Consolidated Decommissioning Guidance, Financial Assurance, Recordkeeping, and Timeliness," Section A.2 for guidance associated with the Certification of Financial Assurance. This certification needs to include the requested materials which require financial assurance.
2. Section A.3.4 of your cost estimate gave a description of how license materials are used. Your response was only for materials A through C and special nuclear materials. Please provide a description for all of your materials.
3. Section A.3.14(a) lists your packing material costs. You specified one barrel for 5 cubic meters. However in section A.3.14(c), you specified 16 cubic meters of waste. This would appear that you would need to appropriate more packing material than described.
4. There was not a purpose of the requested radium-226 source listed. Please provide what you would like the authorized use to be for the radium-226 source.

We will continue our review upon receipt of this information. Please reply to my attention at the Region 1 Office and refer to Mail Control No. 581333. If you have technical

questions regarding this letter, please call me at (610) 337-5366.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Please note that you may not reply to this letter by return e-mail. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your application.

Dennis Lawyer
Health Physicist
U.S. Nuclear Regulatory Commission
Division of Nuclear Material Safety
610-337-5366
610-337-5269 (F)