

From: [Lawyer, Dennis](#)
To: [Simpson, Paul D. \(CDC/OCOO/OSSAM\) \(pds1@cdc.gov\)](mailto:pds1@cdc.gov)
Subject: U.S. Department of Health and Human Services, Request for Additional Information Concerning Application for a License Renewal, Control 585009
Date: Wednesday, November 26, 2014 9:31:00 AM

Dear Mr. Paul Simpson,

This is in reference to your application dated November 21, 2014, requesting for renewal to Nuclear Regulatory Commission License No. 10-06772-02, Docket No. 03013108. In order to continue our review, we need the following additional information:

1. As stated in the electronic mail dated October 24, 2014, question 2, according to NUREG-1556, Volume 5, "Consolidated Guidance About Material Licenses, Program-Specific Guidance About Self-Shielded Irradiator Licenses," Section 8.5.1, applicants are to provide the manufacturer's name and model number for each sealed source and device requested. Your response dated November 21, 2014, did not appear to have the device manufacturer and model number as registered in the sealed source and device registry. Please provide this information.
2. As stated in electronic mail dated October 24, 2014, question 8, according to NUREG-1556, Volume 5, section 8.10.6, Operating and Emergency Procedures, an applicant should make certain statements about their operating and emergency procedures. You made the first statement but did not appear to state, "Operating and emergency procedures will be developed, implemented, maintained, and distributed and will meet the Criteria in the section entitled 'Radiation Safety Program -Operating and Emergency Procedures' in NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated June 1998." You however did submit alternate procedures. Your application did not appear to contain operating procedures of your irradiator. The emergency procedures did not appear to include performing surveys as an action required by the emergency procedures. You may wish to review Appendix O of NUREG-1556, Volume 5, when developing the procedure or make the above statement.
3. Your response to the electronic mail dated October 24, 2014, question 9 appears to have changed section 9.c on page 9. It states that you will use personnel licensed to perform leak test services or use a leak test kit. However in your Leak Test procedure on page 25, it appears that the only option is for you to analyze the leak test. If you wish to perform your own leak tests, please include the statement, "As an alternative, we will implement the model leak test program published in Appendix P to NUREG - 1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Information about Self-Shielded Irradiators,' dated October 1998." Please amend sections as necessary so they are in agreement.
4. The copy of the Statement of Intent dated November 18, 2014, contained the incorrect license number. When the original is submitted, please ensure that the license number is corrected and that the supporting documentation that shows the Chief Operating Officer is authorized to sign the Statement of Intent is enclosed.

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

the Region 1 Office (Address below) and refer to Mail Control No. 585009. If you have technical questions regarding this letter, please call me at (610) 337-5366.

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). We request a reply from you within 30 calendar days from the date of this e-mail to ensure timeliness of your renewal.

Region 1 Office Mailing Address: Licensing Assistance Team, US Nuclear Regulatory Commission Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406-2713.

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