

From: [Lawyer, Dennis](#)
To: [Brian Livingston \(brian.livingston@usuhs.edu\)](mailto:brian.livingston@usuhs.edu)
Subject: University of Uniformed Services, Request for Additional Information Concerning Application for a License Renewal, Control 585397
Date: Tuesday, January 13, 2015 9:00:00 AM

Dear Brian Livingston,

This is in reference to your application dated November 20, 2014, requesting for renewal to Nuclear Regulatory Commission License No. 19-083302, Docket No. 03004545. In order to continue our review, we need the following additional information:

1. 10 CFR 30.35 requires that licensees authorized to possess and use unsealed licensed material with a half-life greater than 120 days in quantities greater than those described in 10 CFR 30.35(a) must submit decommissioning funding plan (DFP) in any new or renewal application. It is noted that you have submitted a DFP, and it is being reviewed by the NRC staff under Control 582847. Please confirm that the financial assurance being reviewed with Control 582847 serves as the submission for the renewal.
2. Your application has restrictions on the material amount for items 6.A. through 6.D.; 6.G.; and 6.H. to be less than that amount which would require a decommissioning funding plan. As you have submitted a decommissioning funding plan and it does not rely upon this restriction for the calculation basis, it is unclear why this is being requested. Please confirm to remove this restriction as a DFP is being performed. This should be reflected in the Certification of Financial Assurance.
3. In your application, you have requested the removal of item 6.N. and 6.O. from your current license. In order to remove the material, you need to show that the material did not contaminate your facility and that it has been transferred to an authorized person. For item 6.O., please submit the latest leak test of the material prior to transferring the material. For item 6.N., please submit surveys which show that the material did not result in contamination of the facility above Subpart E of 10 CFR 20 values. Additionally, please send the information demonstrating that the material was properly transferred to an authorized recipient.
4. Section 6 of your application gives a specific series of self-shielded irradiator. The series of irradiator is not registered in the Sealed Source and Device registry using that series designation. Please submit the specific manufacturer and model numbers of the irradiators in your possession under this license.
5. NUREG-1556, Volume 5, "Consolidated Guidance About Materials, Licenses Program-Specific Guidance About Self-Shielded Irradiator Licenses," Section 8.6, states, If the self-shielded irradiator will be used for the purposes listed on the SSD Registration Certificate, state the following: "The self-shielded irradiator(s) will be used for the purposes described in their respective SSD Registration Certificates." If the self-shielded irradiator will be used for purposes other than those listed on the SSD Registration Certificate, specify these purposes and submit safety analyses (and procedures, if needed) to support safe use. Please provide the appropriate response for your two self-shielded irradiators.

6. In your application, you state that you will be using check sources at temporary job locations for training purposes. As this is a new request, please describe what type of training is being performed, the purpose for training, and what type of workers are being trained.
7. 10 CFR 33.13c(3) requires administrative procedures to assure control and use of byproduct material, completion of safety evaluation of proposed uses which take into consideration factors like adequacy of facilities, and the Radiation Safety Committee (RSC) will review, approve and record the authorization. In the Radiation Safety Officer's (RSO) responsibilities, you authorize the RSO to make increased authorization up to 10 times the amount of the currently approved radionuclides. Please explain how the RSO may make this decision when this does not appear to be factored into the consideration of the RSC when issuing the authorization for a set amount of radionuclides and facility in the original decision?
8. Your application states that the Radionuclide and X-Ray Safety Subcommittee (RXSS) approves new radiation users, and new uses of radiation. The application did not appear to state the criteria for new users or new uses that the RXSS used for approved nor the number of members on the committee. NUREG-1556, Volume 11, Section 8.7.2 states to submit the criteria used by the RSC for approving new users and new uses. Please submit the criteria used for approving new uses and new users. You may wish to review the "response from applicant" portion of Section 8.9 of NUREG-1556, Volume 11 before responding.
9. Your current license has the condition for greater flexibility. NRC will provide even greater flexibility to Type A Broad Scope licensees to make program changes and changes to procedures specifically identified in documents which were previously approved by the Commission and incorporated into the license, without prior Commission approval. If you would like to continue this authorization for this flexibility, please provide the following statements.
 - a. Changes to your program and procedures will be limited to the following areas: training; audit program; radiation monitoring instruments; material receipt and accountability; safe use of radionuclides and emergency procedures; and radiation surveys. In addition, state that you will apply for, and receive an amendment to your license prior to implementing any other programmatic or procedural changes.
 - b. The proposed revision will be documented, reviewed, and approved by the your Radiation Safety Committee in accordance with established procedures prior to implementation.
 - c. The revised program will be in accordance with regulatory requirements, will not change the license conditions, and will not decrease the effectiveness of the Radiation Safety Program.
 - d. Your staff will be trained in the revised procedures prior to implementation.

- e. Your audit program will evaluate the effectiveness of the change and its implementation.
10. NUREG-1556, Volume 11, Section 8.7.2 states to provide the criteria used for selecting members of the RSC. Please provide the criteria used for selecting members to your RSC and the subcommittee, RXSS. Additionally include the basis for the number of personnel serving on the RXSS.
 11. A delegation of authority for the RSO as required by NUREG-1556, Volume 11, Section 8.7.3 did not appear to be provided. Please provide a copy of senior management's written statement of delegation of authority to the Radiation Safety Officer. This statement should include the requisite authority to communicate with and direct your personnel regarding NRC regulations and license provisions and to enforce these requirements including the ability to terminate any unsafe operation involving the use of licensed material. Appendix J of NUREG-1556, Volume 11 contains a model delegation of authority and may be helpful to you in developing your response.
 12. Your application does not appear to adequately describe the training topics covered for different groups of workers. As stated in NUREG-1556, Volume 11, Section 8.8, please submit a description of the radiation safety program developed for each group of workers including the topics covered. It is noted that the licensee has workers operating self-shielded irradiators, animal handling, as well as other activities. For self-shielded irradiator users, you can state: "Before using licensed material, authorized users will receive the training described in Appendix G in NUREG-1556, Vol. 5, 'Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Self-Shielded Irradiator Licenses,' dated June 1998." The description for the low level cobalt facility was sufficient and does not need to be repeated.
 13. Section 8.9 of NUREG-1556, Volume 11, states to describe special considerations to that your RSC will use in authorizing byproduct material use and to specify their locations. Animal handling and housing facilities is one of these type facilities with special considerations. Appendix H of NUREG-1556, Volume 7, "Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," provides guidance on the information that should be addressed concerning the use of radioactive materials in animals. Please provide a description of the animal handling and housing facilities and specific location using Appendix H as guidance.
 14. In Section 8.9 of NUREG-1556, Volume 5, please provide the statement: "We will ensure that each area where a self-shielded irradiator is located corresponds to the 'Conditions of Normal Use' and 'Limitations and/or Other Considerations of Use' on the applicable irradiator's Sealed Source and Device Registration Certificate; the floor beneath the self-shielded irradiator is adequate to support the weight of the irradiator; each self-shielded irradiator is secured to prevent unauthorized access or removal; and each area where a self-shielded irradiator is located is equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas) or the location of the area and other controls ensure a low-level radiation risk attributable to fires." Or, you may submit alternative information; be sure to include

justification for placing an irradiator in an area that does not correspond to the “Conditions of Normal Use” and the “Limitations and/or Other Considerations of Use.”

15. Section 8.10.8 of NUREG-1556, Volume 5, discusses maintenance of self-shielded irradiators. It states for the applicant for routine maintenance to submit either of the following: 1) A statement that: “We will implement and maintain procedures for routine maintenance of our self-shielded irradiators according to each manufacturer’s (or distributor’s) written recommendations and instructions.” or 2) Provide Alternative procedures for NRC’s review. It also states for non-routine Maintenance: Submit either of the following: 1) A statement that: “We will have the self-shielded irradiator manufacturer (or distributor) other person authorized by NRC or an Agreement State perform non-routine maintenance;” or 2) the information listed in Appendix I supporting a request for authorization to perform this work.
16. Your application in section 10.6, “Safe Use of Radionuclides and Emergency Procedures,” and 10.7, “Surveys” stated that you would adopt procedures from NUREG-1556, Volume 11, Revision 1. This revision is currently in draft and may be changed prior to issuance. Please state that you will implement the complementary appendix in the NUREG-1556, Volume 11 that is currently issued.
17. Section 8.11 of NUREG-1556, Volume 11 states to provide procedures for waste collection, storage, and the disposal of any of the authorized methods described in the NUREG-1556, Volume 11. Please submit the procedures for decay in storage and sewer disposal and other methods you utilize in Section 8.11.

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. 585381. 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). 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.

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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