



UNITED STATES  
**NUCLEAR REGULATORY COMMISSION**  
REGION I  
475 ALLENDALE ROAD  
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 2, 2008

Docket Nos.	030-01786	License Nos.	19-00296-10
	030-08478		19-00296-17
	030-17872		19-00296-20
Control Nos.	138097		
	141494		
	141495		

Alfred C. Johnson, Ph.D.  
Director, Office of Research Services  
National Institutes of Health  
Department of Health and Human Services  
21 Wilson Drive MSC 6780  
Bethesda, MD 20892-6780

**SUBJECT:** NATIONAL INSTITUTES OF HEALTH, REQUEST FOR ADDITIONAL INFORMATION CONCERNING FINANCIAL ASSURANCE DOCUMENTS, CONTROL NOS. 138097, 141494 AND 141495

Dear Dr. Johnson:

This is in reference to your letter dated November 27, 2007, providing additional information for your financial assurance for decommissioning for Nuclear Regulatory Commission License No. 19-00296-10. Based on your additional information, financial assurance actions have been opened for License Nos. 19-00296-17 and 19-00296-20. In order to continue our review, we need the following additional information:

1. In your response to Item 1 of our letter dated October 29, 2007, you stated that the NRC asserted that the NIH Chief Financial Officer does not have sufficient authority to sign the Statement of Intent. However, the NRC does not know if the individual who signed the Statement of Intent has sufficient authority, because, as stated in our letter dated October 29, 2007, the Functional Statement (Title 42, Chapter 6A, Subchapter III, Part A, Section 282 "Director of National Institutes of Health") that you submitted with the financial assurance does not address the position of Deputy Director or Chief Financial Officer. This Functional Statement addresses only the position of Director, acting for the Secretary.

In accordance with in NUREG-1757, Vol. 3, Appendix A.16.3, please provide documentation that the person signing the Statement of Intent dated December 15, 2005, is authorized to represent the licensee in this transaction. If the authorization originates in a statute authorizing the head of an agency to request such funds, the documentation should be included that describes the delegation of such authority to the person signing the financial assurance. If an updated or revised Statement of Intent is required and a different individual signs the revised Statement of Intent, you should provide the appropriate documentation for the individual signing the revised Statement of Intent.

2. In your response to Item 4 regarding financial assurance for sealed sources, you stated that only one irradiator, listed on License No. 19-00296-17, meets the criteria to provide financial assurance. Given the sum of fractions you submitted in your response, you are correct that a decommissioning funding plan is not required, but the \$113,000 amount is required by 10 CFR 30.35(d). In addition, please note that, in accordance with 10 CFR 30.35(d), financial assurance is based on your possession limits, not on the actual amount possessed or initially loaded into a sealed source, and that the limit applies to the total for all sealed sources authorized under a license, not for a single source.
  - a. License No. 19-00296-17 currently contains Condition No. 13, which prohibits you from possessing licensed materials in quantities which require the provision of financial assurance. We will amend the license to remove this condition, based on the information you provided that one irradiator alone exceeds the quantity for which financial assurance is required to be provided.
  - b. License No. 19-00296-20 currently contains the same prohibition in Condition No. 13. However, the total amount of cobalt-60 authorized on the license (2,000 curies + 9,000 curies + "any single source...") exceeds the 10,000 curie limit, above which the regulations require that financial assurance be provided. Based on the total amount of material authorized to be possessed, financial assurance in the amount of \$113,000 is also required for this license and Condition No. 13 should be removed.
  - c. We are no longer using the condition "No single source to exceed the maximum activity specified in the certificate of registration issued by the U. S. Nuclear Regulatory Commission or an Agreement State" but must list maximum possession limits for each sealed source authorized on your license. Because we will be amending both License Nos. 19-00296-17 and 19-00296-20 to reflect the correct requirements for financial assurance, we request at this time that you provide the maximum quantity per source/model and the total maximum quantity (number of sources) for each item to be authorized on the licenses.
  - d. When you submit your Certification Statement for your financial assurance in accordance 10 CFR 30.35(e), it needs to list all the licenses, and the types and quantities of materials for which financial assurance is provided. A single Certification Statement may be used for all three licenses, or you may provide a separate Statement of Intent and Certification Statement for each license. A model "Certification of Financial Assurance" Statement is shown in NUREG-1757, Volume 3, Appendix A.2.4.
3. The following items all refer to the "Decommissioning Funding Plan Estimate" dated November 2005, enclosed with your November 27, 2007 letter.
  - a. The first page of assumptions appears to be based on recent experiences with decommissioning of NIH laboratory facilities. Specify the facilities, and the year(s) in which the decommissioning activities were performed, that are used as the basis of the assumptions. Under Table A.3.9, it states that level of effort is

based on Building 36 decommissioning, but there is no description of Building 36 or justification why that building is a good comparison for the other facilities.

- b. Confirm if these experiences include laboratories in which alpha-emitters may have been used, such as uranyl acetate for electron microscopy stains, or other research with alpha-emitting radionuclides. Such facilities usually require more sensitive surveys than laboratories in which beta- or gamma-emitting radionuclides were used. Revise the costs to account for surveys of alpha-emitters, if applicable.
  - c. Explain why, for some buildings, hoods are listed as potentially contaminated equipment but no ductwork is listed. According to the assumptions, each contaminated hood is assumed to have 50 linear feet of ductwork associated with it. Revised tables and costs should be submitted, if applicable.
  - d. Explain why facilities and equipment such as cold rooms (or other temperature controlled rooms), animal facilities, shelves, cabinets, refrigerators, freezers, centrifuges, incubators, vacuum pumps, drain lines (pipes), and other such items typically found in research laboratories are not included in the decommissioning assumptions or estimates. Such facilities and equipment typically require surveys to determine if they may be released for unrestricted use, or disposal as radioactive waste. Revised tables and costs should be submitted, if applicable.
  - e. During the decommissioning of the wastewater treatment facility at Fort Detrick, under the jurisdiction of another licensee, a considerable amount of contaminated sewage sludge was required to be disposed of. However, your decommissioning cost estimate does not appear to include any costs for disposal of sludge. Explain why, and submit revised tables and costs, if applicable.
4. Based on the issues identified above, you may wait to provide a revised Statement of Intent and Certification Statement until the amount of the financial assurance to be provided, and the materials to be listed on the Certification Statement, are accepted by the NRC.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Regulations, Guidance, and Communications**. 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 7:00 a.m. to 8:00 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 Nos. 138097, 141494 and 141495. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

A. Johnson  
National Institutes of Health

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Sincerely,

***Original signed by Elizabeth Ullrich***

Betsy Ullrich  
Senior Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

cc:  
Robert A. Zoon, Radiation Safety Officer

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**SUNSI Review Complete: EUIrich**

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