



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

October 29, 2007

Docket No. 030-01786  
Control No. 138097

License No. 19-00296-10

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 NO. 138097**

Dear Dr. Johnson:

This is in reference to the letter dated December 19, 2005 providing revised financial assurance for decommissioning for Nuclear Regulatory Commission License No. 19-00296-10. The following paragraphs discuss the current requirement for financial assurance, and the current status of your financial assurance, and conflicting or insufficient information provided:

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(d) must submit certification for financial assurance and a decommissioning funding plan (DFP) in any new or renewal application submitted after July 27, 1990. This plan must include an actual estimate of the costs for decommissioning your facility and a mechanism to fund the plan. 10 CFR 30.35(e) requires that the cost estimate be adjusted at least every 3 years.

Your current financial assurance is provided by

- (1.) the Statement of Intent for \$110,626,000.00, signed by Harold Varmus, M.D., dated February 3, 1997. This amount of financial assurance is based on the cost estimate provided by Mr. Robert Zoon in a letter dated February 25, 1997.
- (2.) the Certification of Financial Assurance for \$1,125,000.00, signed by Dr. Michael M. Gottesman dated February 14, 2003. There was no basis provided for this amount of financial assurance. (Although it is the same amount as a default amount applicable to certain licensees, the quantities of material possessed under your license are greater than those that can use the default amounts; in addition, this default amount did not become required until October 3, 2003.)

In a letter dated February 15, 2005, to Mr. Zoon, the NRC reminded you of the new regulations that were effective October 3, 2003. For your license, that change in the regulations required

that the DFP be reviewed and a new cost estimate be provided every 3 years, with implementation of this regulation to be completed by December 4, 2006.

In a letter dated September 8, 2005, to Mr. Zoon, Sandra Gabriel of this office requested a new Certification of Financial Assurance be submitted, because of the discrepancy between the amount of financial assurance provided by the February 3, 1997 Statement of Intent and the amount listed in the February 14, 2003, Certification of Financial Assurance. Ms. Gabriel also requested that the DFP be revised to account for the cost of decommissioning the facilities you wish to add in Frederick County, Maryland.

The information provided with your letter dated December 19, 2005, was intended to respond to Ms. Gabriel's request. In order to continue our review, we need the following additional information:

1. The new Statement of Intent, (signed by Colleen Barros, and undated) and the new Certification of Financial Assurance (signed by Colleen Barros and dated December 15, 2005) provide for financial assurance in the amount of \$5,653,000.00

- a. 10 CFR 30.35 requires that licensees submit the DFP to the NRC. 10 CFR 30.35(e) requires that the DFP contain a cost estimate. Although the letter referred to development of a revised "Decommissioning Funding Cost Estimate for License No. 19-00296-10", this was not included. In addition, a DFP was not included.

Current guidance for the development of an DFP, including the cost estimate, may be found in NUREG-1757, "Consolidated NMSS Decommissioning Guidance", Volume 3, "Financial Assurance, Recordkeeping, and Timeliness", Part II, "Financial Assurance Overview" (NUREG-1757, Vol. 3). Based on the amount of the cost estimate, and acceptance of the decommissioning funding plan, you may be required to adjust the amount of the financial assurance provided for the license.

Please provide the DFP and the cost estimate that results from the DFP, using the above guidance.

- b. The current accepted Statement of Intent is for the amount of \$110,626,000.00. We cannot accept the proposed lesser amount of \$5,653,000.00 considering that this is intended to also cover the new facilities proposed for use at Fort Detrick in Frederick County, Maryland. (Note that, when the facilities at Fort Detrick were decommissioned by the previous licensee, the process took more than 5 years.) In order to accept the new amount, the DFP and cost estimate should contain sufficient detail to explain the change in the amount to approximately half the amount that was accepted in 1997.

Provide sufficient detail in the above DFP and cost estimate to justify the new, lower amount, or provide financial assurance in a new amount that is based on the 1997 cost estimate, plus the revised DFP which includes the additional cost estimate for activities at Fort Detrick. Please note that, if a new DFP and revised

cost estimate is submitted, you should wait until they are determined to be acceptable before providing a Statement of Intent and Certification of Financial Assurance in the new amount.

- c. The Statement of Intent and the Certification of Financial Assurance was signed by the Deputy Director for Management and Chief Financial Officer. However, the Functional Statement submitted with the financial assurance does not address the position of Deputy Director. Provide documentation that the person signing the Statement of Intent 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. Additional guidance may be found in NUREG-1757, Vol. 3, Appendix A.16.3.
2. Confirm that the DFP was (or will be) based on past activities performed under the license since it was issued, not just on activities that are currently performed.
  3. Confirm that the following activities will be performed prior to the release of facilities for unrestricted use and/or termination of the licenses, and submit a revised DFP and cost estimate to include these activities if they are not already included:
    - a. For all laboratories in which licensed materials are currently or were previously used since licensed operations began, including those laboratories which may have been released in accordance with the conditions of the license,
      - i. survey records will be reviewed to determine if the surveys previously performed meet the NRC's license termination criteria at the time the NRC releases a facility (an entire building) for unrestricted use and/or the license is terminated.
      - ii. if survey records are no longer available for those laboratories, they will be re-surveyed to determine if they meet NRC's license termination criteria at the time of license termination.
    - b. Decommissioning surveys of a facility will be performed in accordance with NUREG-1757 procedures (or superceding guidance, if applicable), including
      - i. a historical site assessment to determine the types, quantities, forms, and uses of licensed materials in the facility;
      - ii. a site characterization survey, if necessary, to determine the type and extent of radiological contamination in order to classify areas appropriately;
      - iii. decontamination and remediation of contaminated areas, if any; and

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- iv. a final status survey that demonstrates the facility meets NRC's license termination criteria for the radionuclide(s) used in the facility.
4. At this time, your Statement of Intent and Certification of Financial Assurance is applicable only to License No. 19-00296-10. If you want other NIH licenses to be covered by the same Statement of Intent and Certification of Financial Assurance, then those licenses must be referenced in the documents, and the DFP and cost estimate be revised to include the additional licensed activities.

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; 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 No. 138097. If you have any technical questions regarding this deficiency letter, please call me at .

Sincerely,

***Original signed by Elizabeth Ullrich***  
Betsy Ullrich  
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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