



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PENNSYLVANIA 19406-2713

June 27, 2012

Docket No. 03004544
Control No. 577649

License No. 19-07538-01

Steven K. Pollack, Ph.D.
Director
Department of Health & Human Services
Food and Drug Administration
CDRH/DIAM/OSEL WO62, Room 4126
10903 New Hampshire Avenue
Silver Springs, MD 20993

SUBJECT: DEPARTMENT OF HEALTH & HUMAN SERVICES, REQUEST FOR
ADDITIONAL INFORMATION CONCERNING APPLICATION FOR
AMENDMENT TO LICENSE, CONTROL NO. 577649

Dear Dr. Pollack:

This is in reference to your letter dated May 23, 2012, requesting to amend Nuclear Regulatory Commission License No. 19-07538-01. In order to continue our review, we need the following additional information:

1. The review of your application determined that it was signed by the Radiation Safety Officer. A person of management authority other than the Radiation Safety Officer should sign the application as the Certifying Official. Please confirm, by your signature, that you are in agreement with the contents of the application dated May 23, 2012, to terminate your license.
2. You provided liquid scintillation counter results entitled "FDA/CDRH Leak Test Results." Please confirm that a leak test was performed of all sealed sources that were present and previously used at your location. Please state the energy sensitivity of the liquid scintillation counter for the respective isotopes using your counting protocol, eg. Am-241, Pu-239, Co-57, Cd-109, etc.
3. You provided information about the disposal of three Americium-241 sources and one Plutonium-239 source. The FDA/CDRH Leak Test Results Record provides information about a number of other sealed sources for which there is no record of their being transferred to or disposed of as waste to an authorized recipient. Please provide a record of the transfer or disposal of those sealed sources in the record but not accounted for in the record provided with your May 23, 2012, application.
4. On the "FDA/CDRH Leak Test Results" Record, the results of an evaluation of items 10 – 17 were contained in a facsimile received November 24, 2010. Dade Moeller & Associates determined the radionuclide and the amount of contamination on the items and indicated that the company was willing to assist you in the disposal of the items.

Please provide confirmation in the form of a transfer record that a waste disposal firm accepted the items or that you disposed of the items directly to a radioactive materials landfill.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. 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 8:00 a.m. to 5:30 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. 577649. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5075.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Steve Courtemanche

Steven Courtemanche
Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
Mary D. Walker, Radiation Safety Officer

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SUNSI Review Complete: SCourtemanche

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