



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

February 4, 2014

Docket No. 03036434
Control No. 582589

License No. 20-30847-01

COL Deborah L. Whitmer
Commander
Department of the Army
U. S. Army Research Institute of Environmental Medicine
Kansas Street, Building 42
Natick, MA 01760-5007

SUBJECT: DEPARTMENT OF THE ARMY, REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR RENEWAL TO LICENSE, CONTROL NO.
582589

Dear COL Whitmer:

This is in reference to your application dated October 31, 2013, requesting to renew Nuclear Regulatory Commission License No. 20-30847-01. The NRC has published guidance for licensee's and applicants which may be useful to you. The guidance appropriate to your license is the "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Gas Chromatographs and X-Ray Fluorescence Analyzers" (NUREG-1556, Volume 7). In order to continue our review, we need the following additional information:

1. Your application provided the element name and mass number and maximum requested possession limit for the material requested; however, in accordance with NUREG-1556 Volume 7, Section 8.5.1, the following information regarding the materials is requested: 1) for unsealed materials provide the chemical and/or physical form; and 2) For potentially volatile materials (e.g., I-125, H-3) specify whether the material will be free (volatile) or bound (non-volatile).
2. Your application requests that Mr. Michael Blaha be named on your license as an alternate Radiation Safety Officer (RSO). The NRC does not recognize alternate or assistant RSOs. The individual listed on an NRC license as the RSO is the individual responsible for overseeing the implementation of the radiation safety program. However, the RSO may delegate certain tasks to other qualified individuals. The RSO must confirm that those delegated tasks were performed as required and in compliance with NRC regulations and your NRC license. No response is required regarding this item.
3. Your license requires financial assurance in accordance with 10 CFR 30.35. Please review your current "Certification of Financial Assurance" dated January 10, 2007; and your "Statement of Intent" dated January 10, 2007, and respond with your commitment that the current documents listed above are active and correct. Alternately, you may submit new financial assurance documents to replace those listed above.

4. In Item No. 6 of your application, you state that the purposes for which licensed material will be used includes the internal or external administration of byproduct material into animal models. Appendix H of NUREG-1556, Volume 7, provides suggested guidance for implementing procedures and training for individuals regarding the use of animals in studies. You do not need to respond to this item; however, this will be reviewed during NRC inspections.
5. Item No. 8 of your application describes the "Training for Individuals Working in or Frequenting Restricted Areas." In accordance with NUREG-1556, Volume 7, Appendix C Item 8, please submit a description of the radiation safety training program including, in part, the groups of workers, including ancillary personnel (e.g. janitorial staff, security officers, etc.), the method of assessment of training, and a statement that authorized users will be trained *prior* to handling radioactive materials. Additionally, your application did not provide information regarding the training of individuals you do not expect to receive greater than 100 millirem in a year. Please provide information regarding that training as well. Appendix J of NUREG-1556, Volume 7, provides suggested guidance for developing training for individuals.
6. In accordance with NUREG-1556 Volume 7, the following information is requested under Item 9 of your application:
 - a. A description of the area(s) assigned for the receipt, storage, preparation and measurement of radioactive materials,
 - b. A diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety.
 - c. Where volatile radioactive materials may become airborne, provide diagrams containing schematic descriptions of the ventilation systems, with pertinent airflow rates, pressures, filtration equipment, and monitoring systems.
 - d. If it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted.
 - e. If radioactive materials will be used with animals, include a description of the animal handling housing facilities. (See NUREG-1556 Volume 7, Section 9, and Appendix H).

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. 582589. For expedience, you may submit a signed, scanned copy of your response to my e-mail address at Dennis.Lawyer@nrc.gov. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture

D. Whitmer

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Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,

***Original signed by Scott Wilson
for Dennis R. Lawyer***

Dennis R. Lawyer
Health Physicist
Commercial, Industrial, R&D, and Academic Branch
Division of Nuclear Materials Safety

cc:
Jeffrey Oliver, Radiation Safety Officer

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