



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

April 11, 2014

Docket No. 03008631  
Control No. 583472

License No. 32-14048-04

Todd W. Baker  
Acting Director, Safety, Health and Environmental Management  
U.S. Environmental Protection Agency  
109 T.W. Alexander Drive  
Mail code D343-02  
Research Triangle Park, NC 27711

**SUBJECT: U.S. ENVIRONMENTAL PROTECTION AGENCY, REQUEST FOR  
ADDITIONAL INFORMATION CONCERNING APPLICATION FOR RENEWAL  
OF LICENSE, CONTROL NO. 583472**

Dear Mr. Baker:

This is in reference to your application dated February 28, 2014, requesting to renew Nuclear Regulatory Commission License No. 32-14048-04. In order to continue our review, we need the following additional information:

1. The application did not list the manufacturer and model numbers of the sealed sources you wish to be licensed to possess. 10 CFR 30.32(g)(1) requires, except as provided in paragraphs (g)(2), (3), and (4) of 10 CFR 30.32, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either: (i) Identify the source or device by manufacturer and model number as registered with the Commission under 10 CFR 32.210 of this chapter, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or (ii) Contain the information identified in 10 CFR 32.210(c) of this chapter. Please provide the manufacturer and model numbers of sealed sources you wish to be licensed or information as allowed by 10 CFR 30.32(g). If the information cannot be provided, you may license the source in the form of "any" but may impact your financial assurance.
2. In item 6 of your application, you did not provide the purposes for which licensed material will be used. Please describe in general terms the purposes for which the licensed material will be used.
3. With regard to your Radiation Safety Committee (RSC):
  - a. You specified a minimum of four members for a quorum. Your application did not specify if any specific members must be a part of the quorum. The minimum members considered acceptable for a quorum by NRC staff are: Chairperson,

Radiation Safety Officer (RSO), management representative, and committee member(s) representing the department/area from which radiation safety issues/request, to be discussed at a given meeting originated, and any other committee member whose field of expertise is necessary to assure all safety aspects of the issue/request have been addressed. Please note that it is generally not acceptable to have an alternate attend in place of the Chairperson or RSO.

- b. Your application did not describe the criteria used for selecting members other than they are selected from various departments. Please describe the criteria used for selecting members within a department.
4. You requested for additional flexibility to make some program changes and revise procedures previously approved by the NRC without amendment. Your request is in accordance with NUREG-1556, Volume 11, "Consolidation Guidance About Material Licenses, Program-Specific Guidance About Licenses of Broad Scope," except that 1) the duties of the RSC must include the implementation of program and procedural changes and 2) a description of the process for procedure program review and approval, including documentation of the specific change. At a minimum, documentation shall state the reason for the change and summarize the radiation safety matters that were considered prior to approval of the change. Please state that duties of the RSC include the implementation of program and procedural changes. Please provide a description of the process for procedure program review and approval by the RSC, including documentation of the specific change.
5. With regard to your training, it appears that some training attributes may be missing from your program. Suggested topics of your training program are presented in NUREG-1556, Volume 7, "Consolidation Guidance About Material Licenses, Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope," Appendix J. Please confirm that your training program for radiation workers includes a discussion of authorized users and supervised users, applicable regulations, license conditions, and permits, appropriate radiation safety procedures, the obligation to report unsafe conditions, and workers right to occupational dose records for laboratory workers handling open compounds of radioactive materials.
6. If licensed materials are to be used in animals, please submit:
  - a. a description of the training that will be provided to individuals caring for animals containing licensed materials, and
  - b. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages.

Appendix H of NUREG-1556, Volume 7 addresses considerations for laboratory animal uses and may be helpful to you in developing a response.
7. In the "Instruments" section of item 10 of your application, you state that instrument calibrations may be performed with the assistance by the National Institute of

Environmental Health Sciences (NIEHS). Please describe who performs the calibration and who's equipment is used in the calibration. Please submit how many instruments per year are being performed. If EPA personnel perform the calibration, then please submit the training and procedures used.

8. In the "Transfer of Radioactive Material" section of item 10 of your application states that the Radiation Safety Officer designates sealed source custodians and provides oversight of their usage. For specifically licensed sealed sources, please describe how your application demonstrates that a review, approval, and recording by the radiation safety committee of safety evaluation of proposed uses prior to use of the byproduct material as stated in 10 CFR 33.13(3)(iii) is performed. Also describe how you will meet License Condition No. 11.A. for these sealed source custodians.
9. In "Disposal by Incineration" section of Item 10 of your application describes incinerator operations.
  - a. Please provide the carbon chemical form of the exhaust on the incinerator so that the daily activity limit and effluent concentration in air limits of 10 CFR 20, Appendix B, Table II, Column 1 can be confirmed.
  - b. You listed tritium and carbon-14 as the principal isotopes being incinerated. Please confirm that these are the only isotopes being incinerated or list all other isotopes that are being incinerated.
  - c. NUREG-1556, Volume 11, Appendix states for applicants to describe the recordkeeping procedures for the waste incineration program. Records must be adequate to document all receipts, incinerations, environmental releases of effluents, and any disposals of ash generated in the incineration process. These records must be maintained in the same units as applicable regulations. Please describe the records being maintained for incinerator operations.
10. Your application describe that you share facilities with NIEHS. For areas of use, please describe methods or procedures on the control of material and agreement about the responsibility of decommissioning of the shared facilities.

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://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).

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 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.

T. Baker

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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. 583472. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

***Original signed by Dennis R. Lawyer***

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

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**SUNSI Review Complete: DLawyer**

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