From: Miller, John
To: saterj@mail.nih.gov
Subject: Request for additional information - Renewal Application -
Date: Monday, June 29, 2015 9:09:00 AM

Leidos Biomedical Reseach, Inc.
License No. 19-21091-01
Docket No. 030-19755
Control No. 586980

Mr. Sater

In order to continue the review of your renewal application for your NRC license to use radioactive materials, we need additional information. If you have any questions, please contact me (610-337-5089).

1. In Block 2. of the NRC Form 313, you have provide "Jerry T. Moore" as the licensee name. The NRC does not issue licenses to the Radiation Safety Officer. Please confirm that it is acceptable to issue the renewal license with the following name and address:

   "Leidos Biomedical Research, Inc.
   NCI Campus at Frederick
   P.O. Box B
   Frederick, Maryland 21702".

2. Please describe the criteria that will be used by the RSC and the RSO for approving new authorized users **and** new uses of radioactive material.

3. Item 10. On page of your application states the current audit program is "in line" with NUREG-1556 guidance and audits are performed on a routine basis. Please describe your audit program and the audit mechanism implemented by the RSO/Consultant to determine user compliance with NRC regulations. Please specify how frequently audits of work areas will be performed. Appendix M of NUREG-1556 Vol. 11 provides guidance for establishing an effective audit program.

4. Appendix R of NUREG-1556 Vol. 11 recommends that a lab coat or other protective clothing and disposable gloves be worn at all times when handling licensed material. On page 16 of your application you indicate that when personnel are manipulating radioactive material, proper personnel protective equipment (PPE) will be worn. Please confirm that proper PPE includes as a minimum a lab coat or other protective clothing and disposable gloves or provide justification for not including these items as appropriate PPE.

5. In your application you indicate that you will be analyzing your own leak test samples. Please provide the following;

a. A description of the instrumentation that will be used for analyzing each radionuclide.
b. The method used to determine the efficiency-of-counting for each instrument for the radionuclides that will be assayed and show the calculation of the efficiency-of-counting.

c. The actual calculation of the minimal detectable activity for each radionuclide to demonstrate the ability to detect 0.005 microcuries.

6. On page 9 of your application, you stated that animals treated with licensed material are housed separately from other animals. Please specify the release criteria that you will use to determine when an animal may be returned to the uncontrolled or general population. Please consider the dose rates from the animals, the quantity of radioactive material in urine and feces, and the amount of contamination in the animal cage in establishing your release criteria.

In addition, please describe the training that is provided to individuals that care for the animals that have been administered radioactive material. Appendix H of NUREG-1556 Vol. 7, Appendix H, provides guidance on topics that should be covered in training for animal care personnel.

7. On page 11 of your application, you stated that an effluent release monitoring system will be utilized to ensure compliance with effluent releases. Please describe you air monitoring equipment and explain your methodology for calculating releases and demonstrating compliance with the constraint rule in 10 CFR 20.1101(d) based on your measurements. Appendix O of NUREG-1556 Vol. 11 recommends that air monitoring equipment, including airflow or volume metering devices should be calibrated annually. Please confirm that the air monitoring equipment will be calibrated annually or provide justification for calibrating the equipment less frequently.

8. Condition 22. of your current license authorizes you to hold radioactive material with a half-life less than or equal to 120 days for decay-in-storage before disposal. The number of half-lives that the radioactive material must be held is not specified in the license condition. You have indicated in your renewal application that you plan to hold radioactive material for a minimum 10 half-lives for decay-in-storage. Please confirm that you are requesting the flexibility authorized in your present license to hold radioactive material for decay-in-storage until it is indistinguishable from background without regard to the number of half-lives.

Please respond in **writing with a signed letter.** You may submit the signed response document by hard copy, or as a pdf copy attached to an email, or by facsimile to 610-337-5269. Please be sure to include the Control No. 586980 on your response. We would appreciate a response within 30 days in order to expedite review of the license renewal application.

Thank you for your cooperation.

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Health Physicist
Division of Nuclear Materials Safety

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