July 14, 2015

Mr. John Miller
Licensing Assistance Team
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

Reference: Control No. 586980
Answers to Technical Review Questions - Renewal of License 19-21091-01

Attached are our answers to your technical review questions for the renewal of our license 19-21091-01. I have included your questions (in black) followed by our reply (in red) to each corresponding question.

Please let me know if you have any questions about our responses.

Thank-You

John Sater Sr.
Sr. Occupational Safety Specialist
Radiation Safety Office
Leidos Biomedical Research, Inc.
NCI Campus at Frederick

Concurrence

Jerry T. Moore
Radiation Safety Officer
Leidos Biomedical Research, Inc.
NCI Campus at Frederick

Responses to NRC Technical Review Questions -

Renewal of License 19-21091-01Leidos Biomedical Research, Inc.

Leidos Biomedical Reseach, Inc.

License No. 19-21091-01

Docket No. 030-19755

Control No. 586980

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”.

Reply

Yes this is correct

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.

Reply

The RSC evaluates applications for new radioactive material use programs based on the experience and training of the requesting PI and other users listed in the application, the necessary equipment being available for the work to be performed (i.e. hoods) and the protocols submitted with the application (evaluates based on safety not scientific merit).

The RSO (under authorization of the RSC) amends new users to existing radiation programs. A majority of the new users are subject to working under direct supervision of an experienced user for the first six months regardless of their past experience and training.

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.

Reply

The Radiation Safety Program consists of Authorized Radiation Programs for research (primarily use of unsealed radioactive material e.g. Isotope Programs) and Authorized Radiation Programs for implementation of the radiation safety program (use of irradiators, radioactive waste handling, processing packaging and disposal).

Annually the RSO and staff review the content and implementation of the NCI Campus at Frederick radiation safety program, with a written report prepared, submitted and presented to the RSC.

As part of the audit program a 3rd party auditor (consultant) audits each authorized Isotope (IS) program at least once every 2 years and each authorized irradiator (IR) program annually. Each of the audits is performed using the following format:

1. Records review: the auditor reviews the records maintained by radiation safety office for each Radiation Program
    - Application (or renewal for the program), current and past personnel, authorized radionuclides and activity, changes in research protocols, and locations of use, decommissioning survey of laboratory or areas removed from the radiation program
2. Visit to the authorized user laboratory location:
    - Interview the PI / Radiation Area Supervisor: discussions of where radioactive material is used, names of current and recent users, performance of radiation surveys, inventory, use, control and security of licensed material, radioactive waste handling and keeping of logs
3. Review aspects of each Radiation Program with particular attention to
    - availability of calibrated radiation survey equipment
    - inventory records of the receipt storage and use of authorized material
    - monthly radiation surveys (methods used and follow-up of any contamination)
    - personnel review of the written research protocol of the use of radioactive material
    - use of external radiation dosimetry and participation in internal dose assessments (if required), practice of ALARA concepts
    - use of process or engineering controls (e.g.: contamination control, shielding)
    - radioactive waste handling (within each program)
    - posting and labeling (NRC Form 3, notice, radiation areas, radioactive material)
4. Confirmatory measurements
    - Survey meter scan and wipe tests for removable contamination
5. Written summary report of audit findings.

6. Audit reports are sent to the RSC chairman and the program PI's for corrective actions.

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.

Reply

At a minimum a fully fastened lab coat or equivalent (i.e. Tyvek coverall) and appropriate gloves will be worn when manipulating radioactive material.

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.

Reply

A Beckman LS6500 liquid scintillation counter is used for counting the samples utilizing a H-3 channel, C-14 channel and a wide-open channel.

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.

Reply

The manufacturer's published efficiency values, when available, or other published source.

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

Reply

$MDA = \frac{2.71+4.65\sqrt{Bt}}{tE}$ Example $MDA = \frac{2.71 + 4.65\sqrt{(51*1)}}{1*0.1} = 359dpm$

B = Background Count Rate 51cpm wide channel average

t = Background Count Time 1 minute

E = Efficiency 10%

0.005uCi = 11100dpm which is greater than the MDA (359dpm) therefore the LS is capable of detecting 0.005uCi. At 1% efficiency the MDA would be 3590dpm which is still well below 0.005uCi.

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.

Reply

A majority of the animals treated with licensed material are euthanized; tissues harvested for analysis, and disposed of as radioactive waste or DIS. Some animals that have been treated with short half-life isotopes may be held for decay until indistinguishable from background with a GM meter and returned to the originating animal facility.

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.

Reply

All animal care personnel who handle radioactive animals are authorized radiation workers and receive the standard New Users Training (Health physics/site specific details). In addition they also receive training on the handling of radioactive animals. Topics covered are dependent on the specific animal facility they will be working in and may include but not limited to:

- Cage selection (disposable vs. reusable depending on half-life)
- Proper cage cleaning/changing procedures
- Appropriate PPE based on procedure being performed
- Post-procedure surveys
- Volatile isotopes
- Animal injection of radioactive materials
- Waste disposal
- Emergency spill procedures
- Appropriate labeling of cages and holding areas
- Post-procedure personal monitoring

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.

Reply

We currently utilize Lab Impex CMS-Pet effluent monitors for the Radiopharmcy chemical fume hoods. The monitoring system performs all of the calculations and expresses the results in pCi/ml with a total release expressed in mCi.

We initially assume that the airborne concentration at the receptor is equal to the airborne concentration measured or calculated at the point of release. We compare the F-18 air release limit in 10CFR20 for F-18 (1E-7uCi/ml) multiplied by the total volume of

air released over the year (1.34E13ml) (the result is 1.34Ci total allowable release for the year) to the actual measured release. If this becomes too constrictive, COMPLY will be used to demonstrate compliance.

The monitoring system will be calibrated annually by the manufacturer or authorized service representative.

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.

Reply

Yes, we are requesting the flexibility authorized in our present license to hold radioactive material for decay-in-storage until it is indistinguishable from background without regard to the number of half-lives.