



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 2, 2008

Docket No. 03034862
Control No. 141454

License No. 29-30483-01

Heidi L. Tomenchok
HSE Senior Manager
Merial Limited
631 Route One South, NB500
North Brunswick, NJ 08902

SUBJECT: MERIAL LIMITED, REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO.
141454

Dear Ms. Tomenchok:

This is in reference to your application dated December 18, 2007 requesting to renew Nuclear Regulatory Commission License No. 29-30483-01. In order to continue our review, we need the following additional information:

1. 10 CFR 30.32(g) requires that an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains a sealed source must either identify the source or device by manufacturer and model number as registered with the U.S. Nuclear Regulatory Commission under 10 CFR 32.210 or with an Agreement State; or contain the information identified in 10 CFR 32.210(c). Please provide this information for the sealed source(s) requested in your application.
2. You have requested that Paul M. Thwaites, Ph.D. be named as an authorized user on your license. In support of this request, provide documentation of training and experience for this individual. Describe the individual's experience in safe handling and in supervision of radioisotopes including the isotopes and quantities (in curie units) which he has handled, the types of use, and the location(s) and date(s) where this experience was received.
3. Please confirm that you wish to remove Krishan Kumar, Ph.D. as an authorized user.
4. Currently, we have a description of NB-500 in your mailing address and at your location a building description of The Technology Centre of NJ/Tech One. Your application either did not include these descriptions or was stated differently. Please state if any of the above address descriptions are accurate or confirm the proper mailing address and building nomenclature.
5. The Attachment IV of your Radiation Safety Manual had some inaccurate numbers. The carbon 14 value to tagging is 100 microcuries. The lowest level of Annual Limit of Intake on injection for sulfur 35 is 6,000 microcuries. Please confirm you will use the correct values as listed in 10 CFR 20.

6. Describe the facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) to be made available at each location where licensed material will be used. Submit a description of the areas assigned for the receipt, storage, preparation, and measurement of licensed materials. Submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. For facilities where licensed materials may become airborne, include schematic descriptions of the ventilation system, with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Diagrams should be drawn to a specified scale, or dimensions should be indicated. For facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted. If radioactive materials will be used with animals, include a description of the animal handling housing facilities. Referring to Appendix H of NUREG-1556, Volume 7, Consolidated Guidance About Materials Licenses Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope, may be of assistance.
7. Describe the types and numbers of survey and monitoring instruments available at your facility. Instruments should be appropriate for the types and quantities of materials requested on your license application, and you should have instruments for both quantitative as well as qualitative measurements.
8. In your application you did not give enough information about your instrumentation and calibration. Please provide one of the following:

A description of the instrumentation (as described above) that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Laboratory Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."

OR

A description of the instrumentation (as described above) that will be used to perform required surveys and a statement that: "We will use instruments that meet the radiation monitoring instrument specifications published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. Additionally, we will implement the model survey meter calibration program published in Appendix M to NUREG - 1556, Vol. 7, 'Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope,' dated December 1999. We reserve the right to upgrade our survey instruments as necessary."

OR

A description of alternative equipment and/or procedures for ensuring that appropriate radiation monitoring equipment will be used during licensed activities and that proper calibration and calibration frequency of survey equipment will be performed.

Further, the statement "We reserve the right to upgrade our survey instruments as necessary" should be added to the response.

9. Your application was not clear about performing leak test of sealed sources. Please make one of the following statements:

“Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer’s (distributor’s) and kit supplier’s instructions.”

OR

“Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate. Leak tests will be performed by an organization authorized by NRC or an Agreement State to provide leak testing services to other licensees or using a leak test kit supplied by an organization authorized by NRC or an Agreement State, to provide leak test kits to other licensees and according to the sealed source or plated foil manufacturer’s (distributor’s) and kit supplier’s instructions. As an alternative, we will implement the model leak test program published in Appendix R to NUREG - 1556, Vol. 7, “Consolidated Guidance about Materials Licenses: ‘Program-Specific Guidance About Academic, Research and Development, and Other Licensees of Limited Scope’ dated December 1999.”

OR

Submit description of alternative equipment and/or procedures to evaluate a radiological hazard and for determining whether there is radioactive leakage from sealed sources or plated foil.

Current NRC regulations and guidance are included on the NRC’s website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material; Regulations, Guidance, and Communications**. 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 7:00 a.m. to 8:00 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. 141454. 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 and R&D Branch
Division of Nuclear Materials Safety

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SUNSI Review Complete: DLawyer

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