

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

September 28, 2006

Docket No. 03037338 Control No. 139362 License No. 29-31187-01

Gary Wnorowski President Eurofins Scientific Inc. d/b/a Product Safety Lab 2394 Highway 130 Dayton, NJ 08810

SUBJECT: EUROFINS SCIENTIFIC INC. D/B/A PRODUCT SAFETY LAB, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 139362

Dear Mr. Wnorowski:

This is in reference to your letter received September 6, 2006 applying for a Nuclear Regulatory Commission license. This also refers to the telephone conversation on September 27, 2006 between Peter Barbounis of your company and Lizette Roldán and Betsy Ullrich of this office.

In order to continue our review, we need the following additional information:

- 1. It appears that your proposed Radiation Safety Officer (RSO) does not have any experience in use and handling of radioactive materials. In order to issue a license to your facility, you should choose one of the following options:
 - a. Provide a description of any experience the proposed RSO has, listing the type and quantity of material handled, and the duration of the experience; or
 - b. Identify another individual who has experience in safe use and handling of tritium, and provide the requested information to name that individual as RSO; or
 - c. Identify a consultant, such as a health physicist or radiation safety specialist, who has experience with the types and quantities of materials you propose to use, to assist your RSO or to act as RSO for some period of time not less than one year.
- 2. If you wish to use a consultant as an RSO or to assist the RSO, provide the following information:
 - a. Documentation showing that the proposed RSO is qualified by training and experience as explained in the NUREG-1556, Volume 7, section 8.7.
 - b. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users

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when confronted with radiation safety problems that require implementation of corrective actions.

- c. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.
- d. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).
- e. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.
- f. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.
- 3. In your application, you identify several individuals as authorized users. Please describe each individual's formal training in the following areas:
 - a. principles and practices of radiation protection;
 - b. radioactivity measurements, standardization and monitoring techniques and instruments;
 - c. mathematics and calculations basic to the use and measurement of radioactivity; and
 - d. biological effects of radiation.

In addition, describe the specific isotopes each individual has handled, the maximum quantities of materials handled, where the experience was gained, the duration of the experience and the type of use.

- 4. Your application did not address general rules for emergency procedures. Please confirm that you will develop general rules emergency procedures. Appendix P of NUREG-1556, Volume 7 provides general topics for emergency procedures and may be helpful in developing your procedures.
- 5. If licensed materials are to be used in animals, please submit:
 - a. a description of the animal housing facilities,

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- b. a description of the training that will be provided to individuals caring for animals containing licensed materials,
- c. a copy of the instructions provided to animal caretakers for handling of animals, animal waste carcasses, and cleaning and decontamination of animal cages, and
- d. a description of the amount of material expected to be handled during normal procedures and the amount of mice used at any one time.

Appendix H of NUREG-1556, Volume 7 (enclosed) addresses considerations for laboratory animal uses and may be helpful to you in developing a response.

6. In your application, you stated that waste disposal would follow the procedures in NUREG-1556 Volume 7 Appendix T. However, Appendix T only addresses decay in storage and sewer disposal. Please describe how you will dispose of solid waste contaminant with tritium, including disposable items as well as animal carcasses and bedding. Section 8.11 of NUREG-1556 Volume 7 provides guidance on other methods of disposal.

Current NRC regulations and guidance are included on the NRC's website at <u>www.nrc.gov</u>; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material**; then **Toolkit Index Page.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. 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. 139362. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich Senior Health Physicist Commercial and R&D Branch Division of Nuclear Materials Safety

CC:

Peter Barbounis, Radiation Safety Officer

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SUNSI Review Complete: <u>EUIIrich</u> After declaring this document "An Official Agency Record" it<u>will</u> be released to the Public.

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