

Phone 317 276 2000

March 12, 2009

Director
Office of Federal and State Materials and Environmental Management Programs
Attention: Angela R. McIntosh, Mail Stop T8-E24
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: January 16, 2009, NRC Demand for Information, EA-09-001

Eli Lilly and Company (Lilly) is submitting the following information in response to the January 16, 2009, Demand for Information concerning Tritium Exit Signs. The following information is organized by a response to each of the NRC questions (Items A–E) in bold below.

Item A. Explain how you ensure compliance with the NRC requirements applying to the possession, transfer, and disposal of tritium exit signs you have acquired. Identify and provide contact information for the individual you have appointed who is responsible for ensuring day to day compliance with these requirements.

Response: Lilly is a research-based global pharmaceutical company headquartered in Indianapolis, Indiana and holds two licenses with the U.S. Nuclear Regulatory Commission (NRC) for the use of radioactive materials at several locations within the State of Indiana. Lilly has both an NRC Broadscope License and an Irradiator License to cover a variety of uses of radioactive materials in biomedical research. Our Corporate Radiation Safety Office is responsible for the administration of the two NRC licenses within Indiana. The Corporate Radiation Safety Office has five degreed Health Physicists on staff with over 50 years of combined radiation safety experience. Stanley D. Hampton, M.S, is the Corporate Radiation Safety Officer for Eli Lilly and Company and is the individual responsible for the day to day compliance with all NRC licenses, including any NRC Generally Licensed materials within Indiana. Mr. Hampton can be contacted at 317-276-7862. Our Radiation Safety Office is very familiar with NRC regulations for the receipt, use, monitoring, and disposal of radioactive materials, including Generally Licensed materials.

The Corporate Radiation Safety Office has the responsibility for the appropriate disposal and reporting of tritium exit signs at Lilly facilities within the State of Indiana.

We understand the primary concern for tritium exit signs is the appropriate disposal and, therefore, have always controlled the disposal of these signs very closely. All tritium exit signs in our facilities within Indiana are disposed of through the Corporate Radiation Safety Office. Radiation Safety is also the responsible shipper since signs are still regulated for shipping, even when expired. Facilities Management personnel are responsible for the installation and removal of tritium exit signs. Facilities personnel attend instructor-lead Radiation Safety Awareness training. In addition to instructor lead training, we use the Environmental Protection Agency's web training, (http://www.trainex.org/web_courses/tritium/index.htm) "Responsible Management of Tritium Exit Signs." Facilities Management personnel routinely contact Radiation Safety for disposal of tritium exit signs. Radiation Safety personnel travel to each Lilly site to manage shipment of tritium exit signs. We also report the brand, model, and serial number of each sign to the NRC when disposed. To date, Eli Lilly and Company has notified the NRC of 1,873 tritium exit signs returned to SRB Technologies, Inc. for reprocessing.

Item B. State the number of tritium exit signs you currently possess and the number of signs that, according to your records, should be in your possession.

Response: Lilly does not currently have a comprehensive inventory of tritium signs. We have regulated internal transfers and disposal of tritium exit signs by our Radiation Safety personnel as our method to assure appropriate disposal. Our facilities have perimeter fencing with access monitored by security guards and are not open to the public, except by escort. Therefore, theft of tritium exit signs is not expected. Moreover, our established processes for notifying our Radiation Safety Office of all building demolitions and/or substantial infrastructure changes, ensures signs are not lost during such activities.

In response to this Demand for Information, we have conducted a physical count of tritium exit signs in our Indianapolis facilities. Our survey identified 2,280 exit signs in use within our Indianapolis facilities. In addition, we are currently developing a database for tracking and inventorying our tritium exit signs. Developing a comprehensive tracking and inventory system is expected to take 6 months.

Item C. Explain the reason for any discrepancy between the number of tritium exit signs you currently possess and the number of signs that should be in your possession.

Response: We have no discrepancies.

Item D. Describe any actions you have taken, or plan to take, to locate tritium exit signs.

Response: We have had controlled disposal of tritium exit signs since inception of their use according to regulation and have no lost signs to locate or report.

We would like to encourage the NRC to require better and more consistent labelling by the manufacturers of tritium exit signs which would improve tracking. We have

returned signs for disposal that did not have a readable serial number, which makes tracking difficult. In addition, some signs have labelling (brand, model, and serial number) on both the trim pieces and the main body; however, these pieces can be switched between units, which can cause problems with tracking the exit sign. We also have signs where the labelling has faded to the extent that the labelling can no longer be read. One particular brand of sign has the label affixed where it is often obscured by the mounting bracket. Labels with hand written information can be difficult to interpret and almost always fades and become unreadable. All of these issues complicate the tracking of tritium exit signs and need improvement. In addition, we believe that more information sharing between the manufacturer, general licensee, and the NRC could improve tracking of tritium exit signs and prevent inappropriate disposal.

Item E. Describe any actions you have taken, or plan to take, to prevent future losses of tritium exit signs.

Response: We believe that Lilly has a robust and compliant process for the proper removal and disposal of tritium exit signs and have not had any issues with lost or improperly disposed-of signs. However, we will take the opportunity of this "Demand for Information" to improve our current process. As stated in section "B" of this document, we are in the process of developing an inventory and tracking database for all tritium exit signs within Indiana in response to this demand for information. In addition to existing training and procedures to prevent loss, we are developing a more focused course for employees and contractors to assure that personnel who have the occasion to remove or exchange tritium exit signs are trained on the proper disposal and tracking procedures for tritium exit signs through Lilly Radiation Safety.

In summary, Lilly has historically addressed the primary issue of tritium exit sign use by controlling and assuring proper disposal of the signs. Tritium exit signs do provide a very economical and practical method to label fire exits. However, based on the expectation of increasing government controls around these signs, we discontinued their primary use in new construction several years ago and our program has therefore been focused on replacing existing expired signs. Tritium exit signs have been used safely for years, and we respectfully request that the agency please consider the life-saving nature of these signs, cost effectiveness and ease of use before adding or increasing regulations of such units.

I certify under penalty of perjury that all information contained herein is true and correct to the best of my knowledge and belief.



Stanley D. Hampton, M.S.
Corporate Radiation Safety Officer
Lilly Research Labs
Eli Lilly and Company