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March 1, 2010

United States Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington D.C. 20555

Re: Eli Lilly and Company, License No. 13-01133-02
Reply to Unresolved Items, Docket Number 030-04330

By letter dated December 31, 2009, Eli Lilly and Company ("Lilly") received from the Nuclear Regulatory Commission ("NRC") an NRC Inspection Report 030-04330/09-001 requesting information on two unresolved items (URIs). In response to that request, Lilly is providing the following information summarizing the results of its analysis:

Unresolved Item 1)
The lack of building 88 pre-decommissioning radiological characterization data that supported your company's decision not to notify the NRC and not to submit a decommissioning plan to the NRC for the remediation and decommissioning activities performed in Building 88 pursuant to 10 CFR 30.36(d); and

Lilly's Response:

Amendment 59 of our broadscope license requested release of eight fourth-floor laboratories for unrestricted use. These eight laboratories, while designated in our license as a "special use facility," are not a physically distinct facility, but are rather part of a larger laboratory building. Lilly does not dispute that, upon cessation of activities, the radiosynthesis laboratories contained residual radioactivity such that they would not have been suitable for unrestricted release. In fact, Lilly's Radiation Safety group maintained years of weekly routine survey records for that area. Rather, Lilly's decision not to notify the NRC of "ceased activities" in this area was based on an interpretation that the notification criteria in 10 CFR 30.36 is twofold: based not only on residual radioactivity but also on the nature of the "facility." Lilly interprets this notification to be required only if the area comprised a stand-alone building or outdoor area. Moreover, Lilly further determined that none of the notification requirements in 10 CFR 30.36 applied. First, the license did not expire (precluding notification per 10 CFR 30.36 (d)). Second, Lilly did not "decide to permanently cease principal activities..., at the entire site or in any separate building or outdoor area...(precluding notification per 10 CFR 30.36 (d)(2)). Third, principal activities were ongoing under our broadscope license in building 88 as well as other facilities included in our license (precluding notification per 10 CFR 30.36 (d)(3)). Finally, principal activities had not ceased in a separate building or outdoor area for greater than 24 months (precluding notification per 10 CFR 30.36 (d)(4)). Lilly's decision not to notify the NRC

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is further supported by NRC Administrative Letter 96-05, Revision 1: Compliance with the Rule "Timeliness in Decommissioning of Material Facilities" dated July 14, 1998, which states in regards to application of the timeliness rule to Broad Scope licenses that "[t]he permanent cessation of principal activities in an individual room or laboratory may require the licensee to Notify NRC if no other licensed activities are being performed in the building," which was not the case in Building 88 as it currently houses one of our interim waste storage facilities.

In addition, our license grants authority to our radiation safety officer to "oversee major decontamination efforts." Decontamination of the radiosynthesis laboratories was initiated through a third-party and consisted primarily of wipe down with a detergent and equipment removal. These remediation activities were not deemed to increase potential health and safety impacts to workers or the public and did not include conditions such as those described in 10 CFR 30.36(g)(i)-(iv) and, therefore, were determined not to require an NRC approved decommissioning plan.

While Lilly planned the decommissioning work and asserts that such work was authorized by our license, Lilly did not intend to free release the radiosynthesis facility without NRC approval. Amendment 59 to our broad scope license requested release of the facility for unrestricted use per the dose criteria in 10 CFR 20.1402 and appropriately provided the NRC with an opportunity to scrutinize Lilly's proposed screening levels for unrestricted release.

Unresolved Item 2)
A lack of information demonstrating that the final status survey conducted by your contractor was adequate to show that eight laboratories located in Building 88 and associated equipment and materials were suitable for unrestricted use pursuant to 10 CFR 20.402.

Lilly's Response:

In amendment 59 to our license, Lilly proposed a removable contamination screening level criteria of 37,000 dpm/100 cm^2 and fixed contamination of 370,000 dpm/ 100 cm^2 for unrestricted release (10% of the screening level values from NUREG-1757 Vol. 1 Rev. 2 Table B.1 "Acceptable License Termination Screening Values of Common Radionuclides.") These are the values our third-party contractor used when decommissioning the radiosynthesis laboratories.

Lilly believes adequate information supports the final survey. The third-party's surveys illustrate, without question, the removal of a substantial amount of contamination (primarily via wipe down of surfaces and removal of contaminated equipment). Lilly did conduct ongoing review of the third party's work, by reviewing surveys and frequently discussing work plans and project status. Due to Lilly's heavy day-to-day involvement with the third-party, duplication of their surveys was not necessary to confirm their final status survey results.

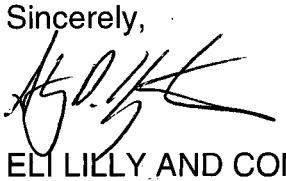
At the time of inspection, the NRC inspectors did communicate that the NUREG-1757 release levels may not be acceptable release criteria and instead used Regulatory

Guide 1.86 release guidelines to determine acceptability of their onsite survey findings. Lilly's position, however, is that because the NUREG-1757 values are isotope specific, and derived from dose based criteria they can and should be used to demonstrate compliance with the 25 mrem dose criteria for unrestricted release in 10 CFR 20.1402. To be clear, laboratory fixtures and structures remaining in the radiosynthesis area were not planned for donation or distribution to local institutions, as was referenced in the inspector's report. These materials were planned for disposal as a controlled waste stream, thus minimizing any obvious pathway to public exposure and further justifying applicability of the NUREG-1757 dose-based screening values. NUREG-1757 is a widely recognized NRC guidance and industry standard, specific incorporation of a screening level criteria into a license seems unnecessary. Thus, Lilly believes that utilization of the 37,000 dpm/100 cm^2 derived from NUREG-1757 was appropriate .

Nevertheless, following the NRC inspectors' communication that Lilly's proposed values may not be acceptable, Lilly cleaned and/or disposed of as radioactive waste all contamination discovered during the inspection above background (background being at or below 200 dpm, as is approved in our license for routine survey clean-up) and re-surveyed labs not surveyed by the NRC and cleaned them to background levels as well. Lilly believes this action removes any doubt as to the appropriateness of releasing the radiosynthesis area for unrestricted use.

To the extent deemed necessary, Lilly welcomes the guidance of the NRC on future decommissioning efforts in regards to acceptability of our proposed release levels and the requirement that such levels be incorporated in our license.

Sincerely,



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cc: Mark Satorius, Regional Administrator, United States Nuclear Regulatory Commission, Region III