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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 a Notice of Violation, 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 and a Notice of Violation ("NOV"). The NRC alleges in the NOV that Lilly failed to keep a list, as required by 10 CFR 30.35(g)(3), in a single document of all areas designated and formerly designated restricted areas as defined in 10 CFR 20.1003. NRC classified this as a Severity Level IV violation and requested that Lilly provide additional information in response to this allegation. Pursuant to that request, Lilly responds as follows:

NRC Inquiry 1): The reason for the violation or if contested, the basis for disputing the violation or severity level:

Lilly's Response:

Lilly does retain records important to the decommissioning of facilities, including radiation protection program records and survey records as required per 10 CFR 20.2102 and 20.2103. These records, by their nature, document areas approved for use of radioactive materials. To date, Lilly has not consolidated these records into the single document referenced in 10 CFR 30.35(g)(3)(i) as it is Lilly's interpretation that it does not maintain true "restricted areas," but rather "controlled areas" in accordance with the definitions from10 CFR 20.1003:

> **Restricted Area:** an area, access to which is limited by the licensee, for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials.
>
> **Controlled Area:** an area, outside of a restricted area, but inside the site boundary, access to which can be limited by the licensee for any reason.

All Lilly facilities are secured regardless of designation for possession and use of radioactive materials. In fact, personnel access to laboratories approved for radioactive material use is no different than that where no radioactive materials are present. The language in 10 CFR 20.1801 provides that "[t]he licensee shall secure from unauthorized removal or access

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licensed materials that are stored in controlled or unrestricted areas." This language supports an interpretation that radioactive material use areas can exist as controlled areas, and thus supports an interpretive distinction between "Restricted Areas" and "Controlled Areas." For these reasons, Lilly does not believe that 10 CFR 30.35(g)(3)(i) is applicable to Lilly's activities. If a list in a single document is applicable at all to Lilly, then it is Lilly's position that the applicable provision is 10 CFR 30.35(g)(3)(iv,) which requires "all areas outside of restricted areas that contain material such that, if the license expired, the licensee would be required to either decontaminate the area to meet the criteria for decommissioning in 10 CFR part 20, Subpart E, or apply for approval for disposal under 10 CFR 20.2002" be included in such a single document.

Prior to discussions with the inspector during the on-site activities in September, October, and November of 2009 and receipt of the November 6, 2009 NRC Information Notice on this topic, Lilly did not interpret 10 CFR 30.35(g)(3) as being applicable to its activities. Nevertheless, as described below, Lilly is taking corrective steps to generate a list in a single document of areas designated and formerly designated authorized radioactive material use locations.

NRC Inquiry 2)
The corrective steps that have been taken and the results achieved:

Lilly's Response:

The NRC's interpretation that a list of all areas approved via Lilly's internal business processes to use and possess radioactive material under our broad scope materials license be included in the single document record, under 10 CFR 30.35 (g)(3), is now understood. To date, corrective steps have included communication of this expectation to radiation safety personnel and appropriate management representatives in order to secure the resources necessary to generate such a document. Consideration of the best format and location for this document is underway and has included benchmarking with other licensees who have recently undertaken this effort.

NRC Inquiry 3)
The corrective steps that will be taken to avoid further violations:

Lilly's Response:

A complete records review will be conducted in the immediate future and a single document listing all current and previously approved radioactive material use areas under Broad Scope Radioactive Materials License 13-01133-02 will be generated. This single document will also include, pursuant to 10 CFR 30.35(g)(1), any areas with residual contamination from spills or other unusual occurrences involving the spread of contamination regardless of whether or not the area is designated as an approved radioactive material use area. Once generated, the document will be integrated into our business processes such that update will occur at least once every two years as the regulation requires.

NRC Inquiry 4)
The date when full compliance will be achieved.

Lilly's Response:

Given the volume of records to be reviewed and the offsite storage of many of them, Lilly expects to complete its review and generation of the list in a single document by February of 2011. Lilly respectfully requests this length of time to allow for a comprehensive records review and thorough and thoughtful development of the document format and maintenance process.

Sincerely,

ELI LILLY AND COMPANY

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