

**TELEPHONE CONVERSATION RECORD
NRC REGION III
MATERIALS CONTROL, ISFSI, AND
DECOMMISSIONING BRANCH**

PERSON(S) CALLED: Stanley Hampton, MS, Radiation Safety Officer, (317) 276-7862, E-mail: shampton@lilly.com

LICENSEE: Eli Lilly and Company
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LICENSE NO.: 13-01133-02
DOCKET NO.: 030-04330

DATE OF CALL: September 23, 2009

CALLER: Mike McCann, Senior Health Physicist, MCID Branch, (630) 829-9856

SUBJECT: **Amendment to release buildings for unrestricted release attached to letter dated May 4, 2009 (ML091260259) Mail Control Number 318160**

Discussion regarding this amendment request: This action involved both the Materials Licensing and MCIDB Branches. The incoming May 4, 2009, letter involved both routine licensing matters relating to on-going R&D activities, as well as actions relating to decommissioning of facilities. The materials licensing activities were addressed in license amendment 59, issued on August 5, 2009. This review is limited to activities relating to decommissioning, using current NUREG 1757 and related decommissioning guidance.

The NRC staff discussed with the licensee that this amendment will involve

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the writing of an Environmental Assessment (EA), and that a finding of no significant impact (FONSI) will need to be determined by the NRC. The EA and FONSI will be noticed in the Federal Register (FRN). The licensee's amendment will not be issued until after the EA/FONSI have been noticed in the FRN.

The following items were initially discussed. Further discussions will be conducted during the NRC inspection tentatively scheduled for the week of September 28, 2009.

1. Please provide information regarding procedures for the conduct of close-out surveys. Specifically, where in your applications and letters that are tied down in your license are these procedures discussed? A close-out record is attached to your application, but the discussion lacks sufficient detail regarding the processes and procedures used by Lilly in the conduct of the close out surveys.
2. Please identify past information tied down in your license (applications and letters) that indicate what radiological release values have been approved for unrestricted release for buildings, areas, and equipment and materials.
3. Other than simple spill and emergency procedures, please point to past applications and letters that are tied down in your license that discuss NRC reviewed and approved procedures for the conduct of aggressive decommissioning remediation activities, such as procedures such as grinding, cutting, demolition of equipment and structures, acid etching, hammering or activities that go beyond simple cleanup and spill procedures).
4. The areas, and buildings that are being requested for release appear to have ceased activities knowingly or have not been used for a period of greater than 24 months. Please clarify why we did not receive a 60 day notification pursuant to 10 CFR 30.36(d). Typically, the licensee should inform the NRC within

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60 days, when a licensee makes a decision to cease licensed activities or has not conducted license activities in a building or area for a period of 24 months.

5. Provide the evaluation and basis regarding why Eli Lilly's Building 88 remediation and decommissioning activities were not reviewed by the NRC and approved as a license amendment pursuant to 10 CFR 30.36(d) and (g)?
6. Review of your past documents indicate that the Greenfield site has an on-site treatment facility. Are the liquid effluents discharged to a sanitary lagoon, drainage leach field or municipal treatment facility?, Do any of your other sites have such treatment facilities? Did Eli Lilly restrict discharges and or monitor the effluents for radiological contaminants? If on-site sanitary lagoons or drainage fields exist, has there been any sampling performed to ensure that contamination has not buildup in these areas?
7. All the attachments indicate that no environmental sampling was done for the close-out surveys. However, has Eli Lilly ever collected environmental samples from around its incinerators, for example to establish an ambient background? Was environmental sampling done at any other times? If so, please provide the analytical data.
8. The Eli Lilly record being maintained and up-dated every 2 years pursuant to 10 CFR 30.35 (g) was discussed. The inspectors will review this record during its up-coming September 28 through Oct 2, 2009, inspection. The licensee was requested to have available its historical site assessment records that documents the types and quantities of past material uses for current and past locations of use.
9. The licensee's Decommissioning Funding Plan (DFP) on file was discussed. The licensee was advised that the inspectors will evaluate and compare the DFP against the licensee's

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current records for current and past buildings and areas that may be decommissioned at a future date.

10. Provide additional information regarding Lilly's cessation of licensed activities at the Lilly Clinic. Specifically, the licensee needs to provide additional information regarding the close-out of this facility. It is indicated that another licensee is responsible for the material and residual contamination potentially remaining in these laboratories. If this is the case, provide documentation from the other licensee acknowledging this, and that they accept the material under their license. There needs to be clear records so that 10 CFR 30.35(g) can be satisfied by this licensee.
11. Review of Final Status Survey Attachments.
 - A. Attachment 1 "Final Status Survey Methods and Results Building 253 Incinerator, Greenfield Labs
 - i. When did the use of the incinerator stop? If the final status survey occurred and all materials were removed during 2003, why weren't the results sent to us before now? Were materials incinerated after August 2003? What are the implications for this facility with regards to NRC licensed activities?
 - ii. Is the incinerator still on site? What is the condition of the incinerator?
 - iii. Need additional descriptive information regarding the incinerator building (number of floors, area size in square feet or meters), and the surrounding area, and neighborhood. Is the incinerator a stand alone building, or is it integral to another building? Where is the stack release point and were any samples taken on the roof and near the stack release point?

- iv. The licensee's procedure for meter calibration needs to be discussed in greater detail in the amendment request, or provided or identified in past tied down license information. The licensee needs to provide information regarding the determination of scan sensitivity, and corrections for detector area, surface correction factors, and meter detection efficiencies. This information must be discussed in general for all the survey packages.
- v. The licensee needs to provide additional information to support doing a 25% survey of building surfaces. Also, did the licensee focus on potentially bias areas, that is areas with higher potential for buildup of radiological contamination? Recognized survey guidance documents typically indicate that a 100% surface survey should be done. Provide a copy of the Lilly survey procedure. We discuss Figure 8.1 in NUREG 1757 vol1, MARSSIM and other survey guidance documents. This information must be discussed in general for all the survey packages.
- vi. Direct survey measurements are a required component of the survey. If there was a wipe with a positive result, the direct measurement needs to be available. This information must be discussed in general for all the survey packages.
- vii. The licensee's wipe test procedure was discussed. The licensee needs to discuss the analysis in greater detail, clarify the report, and make sure that the records are properly labeled to match the area being released. Also, the licensee may want to provide a table of the results rather than submitting

raw data reports. The raw data will need to be maintained. This information must be discussed in general for all the survey packages.

- viii. Did Eli Lilly maintain an inventory of the waste transferred to the incinerator for disposal? There should be a record. How much material was incinerated?

B. Attachment 2 "Final Status Survey Methods and Results Clinton Labs Rotary Kiln Incinerator (C40)"

- I. Same as A.i above, it appears that the last use of materials in this facility occurred on September 2004. The final status survey was done August 11, 2007. Please confirm, and indicate the current status of the facility.
- ii. Provide similar information as requested in A. ii, iii, iv, and viii, above.

C. Attachment 3, Final Status Survey Methods and Results Building 19, Clinton Labs

- I. Discuss the evaluation that supports the HSA statement that is no materials greater than 120 days were stored in this area. Instrument statement indicates meter calibrated for carbon-14.
- ii. Same as above, if this facility was specifically tied down in license, why wasn't a notification made and license amendment submitted sooner? "The final survey described below was conducted on June 2, 2004 at which time all radioactive material had been removed from the C-19 facility."

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- iii. Same as above in A and B, need more detailed description of building and area.
- D. Attachment 4, Final Status Survey Methods and Results, Building 41, Tippecanoe Labs
- i. Same as above, discuss notification requirement. Materials removed from facility on July 21, 2006. Did all activities cease then in the building?
 - ii. Survey form has two background values, 45 and 160 cpm? The meter background is indicated as 45, where as the area background is indicated as 160, which greater than 3 times instrument background?
 - iii. The diagram for this survey package identifies a drain. Did the licensee's survey include checking this drain?
 - iv. Checklist for Closeout survey indicates survey meters N/A? Clarify. 20.1501 and 30.36(j) survey requirements would require a direct survey.
- E. Attachment 5, Final Status Survey Methods and Results Building 88 Radiosynthesis Facilities, Lilly Corporate Center, Indianapolis, IN
- i. Same as above, provide information regarding why a notification was not made to the NRC, and also basis for not submitting a decommissioning plan.

From consultants report: Section 1.0 Site Information. Page 3: "Project Scope Eli Lilly and Company contracted Energy Solutions, LLC (Energy Solutions), to decommission and release eight (8) labs on the Fourth Floor of Building 88 (B

88) located at the Eli Lilly Indianapolis, Indiana facility. The laboratories contained multiple hoods, sinks, and cabinets that were used for radiosynthesis and are potentially impacted from the use of Carbon-14 (^{14}C) for research.”

- ii. The licensee needs to discuss the history of the entire building in greater detail. Were the 8 laboratories in the building the only laboratories where licensed materials used?
- iii. Who supervised the remediation work and controlled access? Was the contractor personnel trained pursuant to Lilly training requirements, and who monitored the contractor personnel?
- vi. Provide a copy of the contractor work instruction. Was the work plan and procedures reviewed and formally approved by Lilly?

From Attachment 5, Section 2 Work Overview

“All work was performed under the Eli Lilly license with Energy solutions work plans and procedures. Eli Lilly provided and operated a fully functional liquid scintillation counter as well as personnel dissymmetry.

- vi. Provide additional information regarding the vacuum line to be left in the wall spaces. The use of the screening value is not appropriate for this material. The vacuum line would be considered as a material or associated equipment. Need additional discussion regarding future contamination potential and impacts should this line be removed or accessed at some future date.

End of record.