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Administrator
U.S. Nuclear Regulatory Commission, Region III
801 Warrenville Road
Lisle, IL 60532-4351

RE: Written report required by 10 CFR Part 20.2201, Report of theft or loss of licensed material

On July 19, 2002, Eli Lilly and Company reported the loss of 9.4 mCi of C-14 to the NRC Operations Center by telephone as required by 10 CFR Part 20.2201(a)(1)(ii). We have not been able to locate the C-14 or further information on the disposition of the material and therefore are submitting this written report as required by 10 CFR Part 20.2201(b)(1). The following information represents our best reconstruction of how the material was lost and is organized by a response to each section of Part 20.2201(b)(1).

Item 1. 10 CFR Part 20.2201(b)(1)(i) A description of the licensed material involved, *including kind, quantity, and chemical and physical form;*

> **Response:** The lost material was 167 mg of a Lilly research compound in dry powder form. The Lilly compound was labelled with 9.4 mCi of C-14 and was contained in one small vial (less than 20 ml in volume).

Item 2. 10 CFR Part 20.2201(b)(1)(ii) A description of the circumstances under which the loss or theft occurred;

> **Response:** In December 1999, one of our scientific groups vacated an old research building in order to occupy a new facility. An inventory of radioactive materials was performed at that time and all compounds were transferred to the authorization of a single scientist. In April and May of 2001, one of our scientists under this authorization was discontinuing his use of radioactive materials and he used the opportunity to separate the Lilly research compounds that were still under development from the compounds that were no longer under development and could be disposed as radioactive waste. A significant portion of his radioactive inventory was disposed (as

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radioactive waste) and recorded correctly at this time. The 9.4 mCi of C-14 was intended to be saved but can no longer be located.

Item 3. 10 CFR Part 20.2201(b)(1)(iii) A statement of disposition, or probable disposition, of the licensed material involved;

Response: We believe that the 9.4 mCi of C-14 was incinerated along with other radioactive waste, but was not properly documented.

Item 4. 10 CFR Part 20.2201(b)(1)(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent of persons in unrestricted areas;

Response: Compound vials are disposed for incineration without opening and therefore present no radiation dose to Lilly personnel. A maximum off-site dose of 0.027 mRem from incineration was estimated using Comply Version 1.6.

Item 5. 10 CFR Part 20.2201(b)(1)(v) Actions that have been taken, or will be taken, to recover the material;

Response: Several person-weeks of effort have gone into looking for this material and/or documentation of disposition. All compound storage areas within the department were searched. Closely related departments within the company also searched their storage areas and could not find the material. Lab notebooks, e-mail, and HIS-Protégé (the electronic database for tracking radioactive material transactions) were searched for records which could document disposition. Unfortunately, the lost material or disposition records were not found.

Item 6. 10 CFR Part 20.2201(b)(1)(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

Response: A review of the incident included director level management personnel from the department that lost the material, Research Administration, and Radiation Safety. No actions are planned against specific individuals since it was impossible to determine a responsible individual(s), thus our actions will be more generic in nature. Actions we have taken and will take are broken down for the department that has lost the material and the Radiation Safety group. Departmental actions listed below are specific to the department that lost the radioactive compound.

Departmental Responsibility

The first required retraining class for the department was conducted August 14, 2002. The class was given by Radiation Safety personnel and emphasized the importance of proper inventory, documentation, and security for radioactive materials. Additional classes will be conducted until the entire department has attended this class.

An additional semi-annual inventory of radioactive Lilly compounds will be conducted in addition to the annual physical inventory required by Radiation Safety.

Radiation Safety Responsibility

Assure the departmental actions listed above are implemented.

Develop a formal standardized procedure for tracking radioactive material within Lilly labs. Our current procedures leave the tracking of radioactive materials within labs to the discretion of each Principal Investigator (PI). We will provide researchers model forms and procedures for their use in tracking radioactive materials within their possession. We will provide training on the new system during the 2003 retraining classes.

Provide a standard definition of "physical" inventory during our annual inventory audit (Nov – Dec 2002 and subsequent years).

Emphasize radioactive material inventory during our next annual PI audit (summer 2003).

Discuss this incident during our 2003 retraining session for all Lilly employees approved to use radioactive materials.

Emphasize importance of disposing radioactive compounds when they are no longer needed. Add this as a discussion item to our annual PI audits. Since this incident occurred, Radiation Safety has already received 615 mCi of C-14 labelled compounds for disposal.

Sincerely,

Stanley D. Hampton, M.S.
Radiation Safety Officer