Lilly

Lilly Research Laboratories
A Division of Eli Lilly and Company

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August 21, 1985

Mr. D. J. Sreniawski, Chief
Nuclear Materials Safety
United States Nuclear Regulatory
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Mr. Sreniawski,

Re: U. S. Nuclear Regulatory Commission Letter of July 22, 1985, to Eli Lilly and Company Concerning the Safety Inspection Conducted on June 25-26, 1985, at the Corporate Center and at Greenfield Laboratories.

Eli Lilly and Company (Lilly) has carefully evaluated the issues discussed in the Nuclear Regulatory Commission's letter and has instituted specific procedures to further assure adherence to applicable regulations and license conditions concerning radioactive materials. As a result of the citations noted in your letter, a memorandum was sent out on July 1, 1985 by the Director responsible for Radiation Safety to director level personnel in all corporate areas utilizing radioactive materials to emphasize the importance of compliance with all applicable regulations and license conditions. In addition, the Corporate Radiation Safety Officer, along with appropriate support personnel, has made arrangements to meet with each director together with the director's staff during the next two months. These meetings are for the purpose of reviewing regulatory requirements with senior staff members and to emphasize the need for strict regulatory compliance with regard to the handling of radioactive materials. In addition, Corporate Radiation Safety, with the full cooperation of line and senior management in the areas mentioned, is working to correct all the points noted and to prevent their reoccurrence.

For your convenience, the items noted by the Nuclear Regulatory Commission are transcribed below, followed by the Company's response.

1. During the discussions at the conclusion of the inspection, our inspectors expressed concern that laboratory areas found contaminated during routine monthly radiation safety surveys, do not appear to be decontaminated and resurveyed expeditiously. The inspectors noted a few instances in 1984 and 1985 where the

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Radiation Safety Offices recommended remedial actions, as described in your "Laboratory Survey System Result Form," were not heeded by research laboratories for up to six months. Laboratories in which contamination exceeding action levels is found, should be decontaminated and resurveyed immediately. Please describe what actions you plan to take regarding this concern.

Lilly Response

The Lilly Corporate Radiation Safety Office is taking the following steps to assure that laboratories which exceed contamination action levels will be decontaminated and resurveyed on a timely basis. All laboratory surveys conducted by Radiation Safety are evaluated by the Corporate Radiation Safety Officer. Any laboratory found to have contamination exceeding action levels will be promptly notified and advised to decontaminate the area within three working days of such notification. This notification will be in written form and directed to the individual involved together with that person's immediate line manager with copies to their immediate line director and radiation safety management. Decontaminated areas will be resurveyed by Corporate Radiation Safety within two working days after the area has been decontaminated in order to assure compliance and verify decontamination.

2. License Condition No. 23 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in the application dated May 25, 1983; and the letter dated April 19, 1984.

Volume I, page 64 of the above referenced application states the following:

- To establish a baseline, an individual should have a thyroid check prior to starting work with radioactive iodine or radioiodinated materials.

- Individuals handling 500 microcuries or more of radioiodine for labeling or inorganic radioiodine salts for research and development must have a thyroid check every two weeks, for three consecutive months.

Contrary to this requirement, not all individuals performing iodinations using greater than 500 microcuries of radioactive iodine had baseline thyroid checks prior to starting work, nor checks every two weeks for three consecutive months. Specifically, two individuals routinely performing iodinations since January 1985, using 5-20 millicuries of iodine-125, had their initial (and sole) thyroid bioassay's on June 4 and 12, 1985, respectively.

This is a repeat violation.

This is a Severity Level V violation (Supplement VI).

Lilly Response

In the July 1, 1985 memorandum sent out to director level personnel in all corporate areas which handle radioactive materials, the Director responsible for Radiation Safety emphasized line management's responsibility to assure that all investigators handling radioactive iodine comply with the requirements for bioassay. Specifically the memorandum emphasized that employees should:

- have thyroid baseline determinations made prior to their initial handling of radioactive iodine or iodinated materials
- participate in the thyroid bioassay program conducted by Radiation Safety to monitor for possible radioiodine uptake

In addition current procedures will be revised as follows:

Investigators who plan to use radioactive materials in their research and development work are currently required to submit a "Request for Authorization to Use Radioactive Materials" to the Radiation Safety Office. This request is evaluated and referred to the Radioisotope and Use Safety Committee for approval. Under the revised procedures, release of radioiodine materials by the Radiation Safety Office will not occur until approval has been received and base thyroid checks have been made on the individual who will use the material. In addition each such individual will be required to report for timely follow-up checks as required by our license. Failure to comply with the periodic thyroid checks will result in a written notice of non-compliance to the investigator's line management and withholding of shipments of future iodionated materials until the matter is resolved.

3. License Condition No. 23 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in application dated May 25, 1983; and letter dated April 19, 1984.

Volume II of the above referenced application includes your Radiation Safety Manual. Page 25 of this manual states, "never pipette radioactive solutions by mouth. Mechanical pipetting devices are mandatory."

Contrary to the above, on June 26, 1985, a Building 88 researcher stated to the NRC inspector that he occasionally pipettes radioactive solutions by mouth.

This is a Severity Level IV violation (Supplement VI).

Lilly Response

Subsequent to the June, 1985 inspection, management has met with the researcher who indicated during the inspection that he occasionally pipetted radioactive solutions by mouth. The hazards of pipetting by mouth were discussed and the individual was instructed to comply with corporate and NRC procedures. The individual was also instructed to use mechanical pipetting devices.

In the July 1, 1985 memorandum to director level personnel in all corporate areas utilizing radioactive material, the Director responsible for Radiation Safety emphasized that corporate radiation procedures and guidelines prohibit the pipetting of radioactive materials by mouth. These issues are currently being thoroughly emphasized and reviewed by Radiation Safety personnel at all director level staff meetings in all areas with scientific personnel utilizing radioactive materials.

Eli Lilly and Company appreciates the help and suggestions from Region III of the U.S. Nuclear Regulatory Commission concerning these matters and is taking appropriate action to assure that similar instances do not occur in the future.

Should you have questions regarding any of the above comments please contact me.

Sincerely yours,

ELI LILLY AND COMPANY

Martha Bhatti

Martha Bhatti, Ph.D.
Radiation Safety Officer and
Regulatory Representative

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