

*Lilly*

**Lilly Research Laboratories**

A Division of Eli Lilly and Company

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Indianapolis, Indiana 46285  
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August 26, 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 29, 1985, to Eli Lilly and Company Concerning the Safety Inspection Conducted on July 12, 1985, at Clinton 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. For your convenience, items noted by the Nuclear Regulatory Commission are transcribed below followed by the Company's response.

Nuclear Regulatory Commission Item No. 1

10 CFR 71.5(a) requires each licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, to comply with the applicable requirements of the regulations appropriate to the mode of transport of DOT in 49 CFR Parts 170 through 189.

49 CFR 173.421-1(a) requires radioactive materials instrument or article prepared for shipment under the provisions of 173.422 must be certified as being acceptable for transportation by having a notice enclosed in or on the package, included with the packing list, or otherwise forwarded with the package. This notice must include the statement "This package conforms to the conditions and limitations specified in 49 CFR 173.422 for excepted radioactive material, instruments or articles, UN 2911."

Contrary to this requirement, on January 18, 1984, your Clinton, Indiana facility shipped an excepted radioactive material instrument (a gauge containing a nominal 20 millicurie cesium-137 sealed source) without a notice containing the required statement.

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

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### Lilly Response

Lilly purchasing procedures require that a "Return Shipping Order Form" must be prepared when an item is to be returned to a vendor. When sizeable pieces of equipment containing radioactive material are to be returned to vendors from remote Lilly plant sites, this form is prepared by personnel in the engineering group at that plant site. Information provided in this form is used by the shipping department to determine the appropriate containers, labels, and documents needed for the outgoing shipment. Lilly procedures have been revised to require each engineering group involved to mark the return shipping order for this type of equipment with the following notation:

Contains Radioactive Material  
Radiation Safety Approval Required

This procedural revision will assure that the shipping department will notify the Radiation Safety Office about the pending shipment. The Radiation Safety Office along with the Corporate Traffic Group will determine the applicable NRC and DOT regulations. The appropriate container, labels and documentation will be determined. This information will be provided to the shipping department at the remote plant site. The shipping departments will then package, label and document the outgoing shipment as directed by the Radiation Safety Office and Corporate Traffic Group. A final check of the package, labels, and documentation will be made by an engineering supervisor at the plant site.

To assure that these procedures are understood and are followed, the Corporate Radiation Safety Officer and personnel from Corporate Traffic will meet with engineering and shipping personnel from the remote plant sites on an on-going basis.

### Nuclear Regulatory Commission Item No. 2

License Condition No. 20, amendment No. 39, requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced application dated October 28, 1977, outlines requirements for shipment of radioactive materials as follows:

A supplemental page of the above referenced application entitled "Transportation, Shipment, and Transfer of Radioactive Materials," states that: "Radioactive materials of any type or quantity that are to be transferred outside the company, must be shipped through the Radiation Safety Office, this includes sealed sources, exempt quantities and anti-static devices." This supplemental page further requires that radioactive materials shipped from Eli Lilly and Company are to be packaged and checked by the Radiation Safety Office to ensure compliance with NRC and DOT regulations.

Contrary to these requirements, a radioactive materials package transferred outside Eli Lilly and Company was not shipped through the Radiation Safety Office nor was it packaged and checked by this office to ensure compliance with NRC/DOT regulations. Specifically, on January 18, 1984, your Clinton, Indiana facility shipped an industrial gauge containing a nominal 200 millicurie cesium-137 sealed source directly to Kay-Ray, Inc. in Arlington Heights, Illinois.

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

#### Lilly Response

The license statement concerning the transportation, shipment, and transfer of radioactive materials was written at a time when there was not a high level of use of such gauges.

Currently, level and density gauges such as those manufactured by Kay-Ray are used by Lilly's large scale production facilities at Clinton Laboratories and at Tippecanoe Laboratories. These gauges are shipped directly to the plant site because of their size and weight. Because of this, corporate procedures have been revised to assure that the Radiation Safety Office is notified when a gauge is ordered, received, or to be shipped out of the company.

Outgoing shipments of these gauges are packaged and labeled at the plant site, under the direction of the Corporate Radiation Safety Office and the Corporate Traffic Group to assure that all NRC and DOT regulations are satisfied. Please amend License 13-01133-02 to read as follows:

Radioactive materials of any type or quantity that are to be transferred or shipped outside the Company must have approval by the Corporate Radiation Safety Office. Industrial gauging devices may be prepared for outgoing shipment at the plant site under the direction of the Radiation Safety Office and Corporate Traffic. Unless specific arrangements have been approved by the Radiation Safety Office, all other radioactive materials must be shipped through the Radiation Safety Office; this includes sealed sources, exempt quantities, and anti-static devices. All outgoing packages must comply with NRC and DOT regulations.

#### Nuclear Regulatory Commission Item No. 3

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on July 12, 1985, licensed materials stored in an unrestricted area were not secured from unauthorized removal from their place of storage, nor were they under constant surveillance or your immediate control. Specifically, three industrial gauges, each containing a nominal 200 millicurie cesium-137 sealed source, were stored in an unlocked/unattended equipment storage area in Building C-13. This storage area is an unrestricted area accessible to Eli Lilly employees and visitors.

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

Lilly Response

All industrial gauges which contain radioactive material have been placed in a locked storage area that has restricted access. Supervisory and management personnel are authorized to possess keys to these locked areas and must be present when the areas are unlocked. The Corporate Radiation Safety Officer has discussed requirements for the storage of unused gauges in a locked, restricted area with line management at both facilities. Line management in each area along with appropriate periodic monitoring by Radiation Safety will assure that this request is complied with in the future.

Nuclear Regulatory Commission Item No. 4

10 CFR 20.105(b) requires that radiation levels in unrestricted areas be limited so that if an individual were continuously present in the area, he could not receive a dose in excess of 2 millirems in any hour or 100 millirems in any seven consecutive days.

Contrary to this requirement, on July 12, 1985, radiation levels existed adjacent to cesium-137 density gauges located in Building C-63 of such a magnitude that if an individual had been continuously present in the area, he could have received a dose in excess of 2 millirems in any one hour. Specifically, NRC inspectors measured radiation levels of 3 millirems per hour at approximately 12 inches from two gauges mounted on tank T-10 and tank T-8 bottom, respectively.

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

Lilly Response

A radiation survey has been conducted around all of the accessible density and level gauges containing radioactive material. Gauges producing a radiation field of 2 millirems per hour or more at one foot, have been identified, roped off and posted with temporary signs reading:

Caution Radioactive Materials  
Restricted Area  
Authorized Personnel Only

Since many of these gauges are located outside, permanent, weather-proof signs with the same warning statements have been ordered and will be permanently installed as soon as they are available.

In addition to these precautions, safety procedures to be followed by personnel working near these gauges will be emphasized during employee education programs scheduled for this fall.

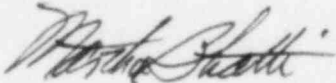
Several of these gauges are located high on production tanks and can be reached only by a catwalk and ladder. Access to these gauges is considered restricted and these were not included in the radiation survey.

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 occurrences are not repeated.

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

Sincerely yours,

ELI LILLY AND COMPANY



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

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