

Appendix

NOTICE OF VIOLATION

Eli Lilly and Company

License No. 13-01133-02

As a result of the inspection conducted on July 12, 1985, and in accordance with the General Policy and Procedures for NRC Enforcement Actions, (10 CFR Part 2, Appendix C), the following violations were identified:

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 200 millicurie cesium-137 sealed source) without a notice containing the required statement.

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

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).

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).

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.

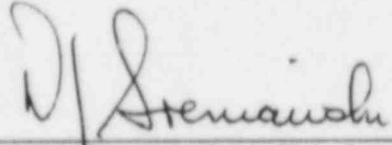
Contrary to this requirement, on July 12, 1985, radiation levels existed adjacent to cesium-137 density gauges located in Building C-63 of such a magnitude that if an individual had been continuously present in the area, he could have received a dose in excess of 2 millirems in anyone hour. Specifically, 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).

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

Dated

7/26/85


D. J. Sreniawski, Chief
Nuclear Materials Safety
Section 2