04902-4

PROPOSED RULE PR-MISC Notice

Eli Lilly and Company

307 East McCarty Street Indianapolis Indiana 46285

Cornelius W Pettinga, Ph D.

EXPRESS MAIL

August 4, 1980

Dr. Robert Alexander Occupational Health Standards Branch United States Nuclear Regulatory Commission Washington, DC 20555

Dear Dr. Alexander:

DRAFT REGULATORY GUIDE AND VALUE/IMPACT STATEMENT, TASK OH-902-1, INSTRUCTION CONCERNING RISK FROM OCCUPATIONAL RADIATION EXPOSURE

Eli Lilly and Company submits in quintuplicate the following commentary on the above Draft Regulatory Guide. Lilly is engaged in the research, development, manufacture, and distribution of various pharmaceutical, health care, cosmetic, and agricultural products. Radioactive materials and sources of ionizing radiation are used throughout the Company. These uses include:

Cesium-137 gauges to monitor homogeneity of mixing (density) and fill levels of liquids in stainless steel vats for antibiotic production

X-ray scatter gauge to accurately and quickly sort by weight, filled hard-gelatin capsules

Radiolabeled materials for basic research

Radiolabeled pharmaceuticals for metabolic, toxicological and bioavailability studies

Radiolabeled agricultural products for studies of soil metabolism, crop plant residues, animal metabolism, residues in meat products, and ecological distribution

Americium-241 gauges to detect the absence of rubber stoppers in multidose vials of injectible products

Secoal gauges (Radium-226) to monitor coal flow into powerhouse facilities

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Eli Lilly and Company is committed to ensuring the occupitional safety and welfare of its employees.

- 1. Lilly supports the premise that consideration of risk is an appropriate aspect of radiation-safety education, and further, that employees' understanding of the risks may provide better compliance with safety procedures, resulting in decreased radiation exposure.
- 2. Lilly supports the preparation of an active Regulatory Guide containing comparative information about occupational risks which include exposure to ionizing radiation.
- 3. Lilly suggests that the Regulatorv Guide should serve as a reference about risks from exposure to ionizing radiation to be used for safety education programs.

Employees have a broad spectrum of education and experience. The breadth and depth of information provided in the Draft Guide may not be within the comprehension of all employees.

Lilly suggests that it is inappropriate to require that all the information in the Draft Regulatory Guide be presented to all employees. Instead, the Regulatory Guide should provide information that would be appropriately adapted by the licensees to the level of perception and understanding of particular groups of employees.

4. Lilly suggests that the Regulatory Guide be expanded to include consideration of benefits from uses of ionizing radiation. This would provide perspective to employees and promote an awareness of benefits as well as risks. Employees should balance positive factors (benefits) with the negative factors (risks).

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5. Lilly suggests that the Regulatory Guide include a brief glossary which defines the major terms and units used throughout the text. The Regulatory Guide may be copied and distributed to employees as part of their safety education. Inclusion of a glossary would make the Regulatory Guide more meaningful.

Very truly yours,

C. W. Pettinga

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