

NOTICE OF VIOLATION

Pfizer, Inc.
Groton, Connecticut

Docket No. 030-03790
License No. 06-05869
EA 89-94

During the inspection conducted on March 27, 1989, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1989), the violations are listed below:

- A. 10 CFR 20.301 requires that no licensee dispose of licensed material except by certain procedures specified in 10 CFR 20.301(a) or (b).

Contrary to the above, at some time on or prior to February 3, 1989, radioactive waste (approximately 500 microcuries of S-35 sulfate) belonging to Pfizer, Inc. was deliberately disposed of at a public site (and was discovered by the State of Connecticut Department of Transportation on February 3, 1989), a method of disposal not specified in 10 CFR 20.301.

- B. 10 CFR 30.9(a) requires that all information submitted to the NRC by a licensee shall be complete and accurate in all material respects.

Contrary to the above, during an interview with an NRC inspector on March 27, 1989, a former licensee employee deliberately provided inaccurate information to the inspector in that he denied any knowledge of the improper disposal of radioactive material as set forth in Violation A. The statement was inaccurate since the employee had personally disposed of the licensed material, as admitted by the individual to licensee management on April 3, 1989.

- C. 10 CFR 19.12 requires that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, and in the applicable provisions of the Commission's regulations and licenses.

Condition 19 of License No. 06-05869-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in an application dated June 10, 1983.

Attachment 9 of this application requires that a series of three presentations on the radiation protection program be given at least once each year to all workers using radioactive material.

Contrary to the above, as of March 27, 1989, at least five individuals who were working in restricted areas had not been instructed in specific procedures required by the license, including required surveys and waste disposal procedures. Further, some workers using radioactive material

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did not receive the series of three presentations at least once each year for 1986, 1987 and 1988.

- D. Condition 19 of License No. 06-05869-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in an application dated June 10, 1983.

1. Attachment 9 of this application requires that areas where radioactive materials are used on an on-going basis be surveyed for radioactive contamination monthly.

Contrary to the above, as of March 27, 1989, Laboratory 112W, where radioactive material is used on an ongoing basis, was not surveyed for radioactive contamination on a monthly basis.

2. Attachment 9 of this application requires the RSO or his assistant to conduct a general inspection of all laboratories at appropriate intervals.

Contrary to the above, as of March 27, 1989, general laboratory inspections were not performed at appropriate intervals in that inspections were conducted no more than twice a year of randomly selected laboratories, and Laboratory 112W had never been inspected.

- E. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the regulations in Part 20 and which are reasonable under the circumstances to evaluate the extent of the radiation hazards that may be present. As defined in 10 CFR 20.201(b), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, surveys were not made to assure compliance with 10 CFR 20.301, which describes authorized means of disposing of licensed material contained in waste. Specifically, as of March 27, 1989, surveys were not made of boxes and containers used to ship or store radioactive materials prior to disposal to unrestricted areas.

- F. 10 CFR 20.203(f)(4) requires that, prior to disposal of an empty, uncontaminated container to an unrestricted area, the radioactive label be removed or defaced, or the container be marked as empty.

Contrary to the above, as of March 27, 1989, containers labeled as containing radioactive materials were transferred for disposal without removing, defacing or marking the labels, as required.

These violations are categorized in the aggregate at Severity Level III (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Pfizer, Incorporated is hereby required to submit a written statement of explanation to the Director, Office

of Enforcement, U.S. Nuclear Regulatory Commission, with a copy to the Regional Administrator, Region I, within 30 days of the date of this Notice. This reply should be clearly marked as "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown.

FOR THE NUCLEAR REGULATORY COMMISSION

Original Signed By
WILLIAM T. RUSSELL

William T. Russell
Regional Administrator

Dated at King of Prussia, Pennsylvania
this 7th day of December 1989