

DES

December 7, 1989

Docket No. 030-03790
License No. 06-05869-01
EA No. 89-94

Pfizer, Inc.
ATTN: Dr. M. von Schach Wittenau
Vice President of Safety Evaluation
Eastern Point Road
Groton, Connecticut 06340

Gentlemen:

Subject: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-03790/89-001)

This letter refers to the NRC inspection conducted on March 27, 1989 at your facility in Groton, Connecticut, to review the circumstances associated with a violation involving the improper disposal of radioactive waste material at a public site. The radioactive material was discovered by a State road repair crew on February 3, 1989 and was reported to the NRC by the Connecticut Department of Environmental Protection. During the inspection, additional violations of NRC requirements were identified. The report of the inspection was sent to you on May 2, 1989. On May 18, 1989 an enforcement conference was conducted with you and members of your staff to discuss the violations, their causes and your corrective actions.

The violations, which are set forth in the enclosed Notice of Violation involve: (1) the willful improper disposal of radioactive material by one of your employees; (2) a willful false statement by the technician who actually discarded the material when he was initially questioned by an NRC inspector; (3) failure to adequately train personnel working in a restricted area; (4) failure to perform monthly surveys and inspections of laboratories; and (5) failure to survey containers prior to disposal to the normal trash or to remove/deface radioactive material labels.

The first violation, involving the improper disposal of radioactive waste (S-35 sulfate), is of particular concern to the NRC because one of your former employees deliberately disposed of the material in a public area, rather than use your centralized waste collection area. The NRC is also concerned that the individual, when initially questioned by the NRC inspector, denied any knowledge of the disposal. Although the individual subsequently admitted to your Radiation Safety Officer that he improperly disposed of the material, the initial lack of candor displayed by this individual is a significant regulatory concern. If the individual subsequently had not been forthright, more severe action would have been considered.

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Notwithstanding these actions by this individual, the NRC is also concerned that management did not exercise adequate control over those laboratories that utilize small quantities of radioactive material. Although the control of the hot laboratory (where curie quantities of radioactivity were used) was good, minimal attention was provided to those other laboratories. These management deficiencies demonstrate the need for increased and improved attention to all licensed activities to ensure these activities are conducted safely and in accordance with the terms of your license.

The NRC would normally classify the violation involving the improper disposal at Severity Level IV given its low safety significance in that only a small amount of material was discarded in this manner, specifically approximately 500 microcuries of S-35 sulfate. The remaining violations, if considered individually, would also normally be classified at Severity Level IV. However, given the circumstances of the violation involving the improper disposal, the individual's initial lack of candor with the NRC, and most importantly, the lack of adequate attention to certain aspects of your program by management, the violations have been classified in the aggregate at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" 10 CFR Part 2, (Enforcement Policy) (1989) in order to focus on the fundamental need for increased management attention to licensed activities.

Although a civil penalty is normally issued for a Severity Level III violation, I have decided, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, not to issue a civil penalty in this case because: (1) while certain of the violations were identified by the NRC and therefore warrant 50% escalation of the base civil penalty amount, your corrective actions (including the clean-up of the disposal site, your actions upon learning of your employee's misstatements to the NRC, as well as your revisions to procedures and practices) were prompt and extensive and therefore warrant 50% mitigation of the base civil penalty amount; and (2) your prior enforcement history has been good, as evidenced by the occurrence of only one minor regulatory violation during the four previous inspections conducted since 1979, and therefore, warrants 100% mitigation of the penalty. The other escalation and mitigation factors were considered and no further adjustment is appropriate.

You are required to respond to this letter and the enclosed Notice and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 20, Code of Federal Regulations, a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

Pfizer, Inc.

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The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Original Signed By
WILLIAM T. RUSSELL

William T. Russell
Regional Administrator

Enclosure: Notice of Violation

cc w/encl:
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David by phone for OE on 12/6 DM