

ENCLOSURE

NOTICE OF VIOLATION

Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Rockville, Maryland

Docket No. 030-04544  
License No. 19-07538-01  
EA 97-080

During an NRC inspection conducted on January 6-7 and 21, 1997, at various of your facilities in Rockville, Maryland, for which an exit meeting was held on February 6, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) NUREG-1600, the violations are listed below:

A. Condition 22 of License No. 19-07538-01 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in a letter, dated November 2, 1994.

1. Enclosure 1 of the November 2, 1994 letter states that the radiation safety committee shall meet on a scheduled basis not exceeding 3-month intervals.

Contrary to the above, the radiation safety committee did not meet on a scheduled basis not exceeding 3-month intervals. Specifically, during calendar year 1996, the radiation safety committee did not meet between March 29 and October 2, an interval exceeding 3 months. (01013)

2. Item 5.b on page 2 of the November 2, 1994 letter states that an audit of each approved project and the individuals working on that project will be conducted annually by the RSO or his designee. The audit will include, but not be limited to: inventory records, user survey records, evaluation of training needs, independent work area surveys, and authorization terms compliance.

Contrary to the above, in 1995 and 1996, the RSO did not conduct an audit of each approved project, and the individuals working on that project. (01023)

3. Enclosure 7 of the November 2, 1994 letter states that each laboratory should be surveyed for fixed and removable contamination at least once each month in which radionuclides are used by the radiation users in that laboratory.

Contrary to the above, on several occasions in 1995 and 1996, surveys for fixed and removable contamination were not performed at least once each month for certain laboratories in which radionuclides were used by the radiation users. Specifically, radionuclides were used at the 12709 Twinbrook facility in Room 23 in September, October, and December 1996; in Room 37 in November 1996; and in Room 4C in March, July, September, November 1995 and February 1996 and contamination wipe surveys were not performed during those months. (01033)

4. Enclosure 3 of the November 2, 1994 letter, Item 2.b, states that each individual working with radioactive materials is expected to receive at least one hour of continuing education each year. This may be met through attending short courses, seminars, briefings or topical presentations, on subjects relevant to radiation safety, given by the RSO or other individuals knowledgeable in radiation safety.

Contrary to the above, in 1995 and 1996, individuals working with radioactive material did not receive at least one hour of continuing education. Specifically, short courses, seminars, briefings or topical presentations, on subjects relevant to radiation safety, were not given by the RSO or other individuals knowledgeable in radiation safety in 1995 and 1996. (01043)

- B. 10 CFR 20.1101(c) requires that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, as of January 21, 1997, the licensee did not review the radiation protection program content and implementation at least annually. Specifically, a review of the radiation protection program content and implementation for 1995 had not been completed at the time of the inspection. (01053)

- C. Condition 15 of License No. 19-07538-01 requires that the licensee conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material received and possessed under the license.

Contrary to the above, in 1995 and 1996, physical inventories were not conducted to account for all sealed sources and devices containing licensed material. (01063)

- D. 10 CFR 20.1904(a) requires the licensee to ensure that each container of licensed material bears a durable, clearly visible label bearing the words "CAUTION, RADIOACTIVE MATERIAL," or "DANGER, RADIOACTIVE MATERIAL." The label must also provide sufficient information (such as the radionuclide(s) present, an estimate of the quantity of radioactivity, the date for which the activity is estimated, etc.) to permit individuals handling or using the containers, or working in the vicinity of the containers, to take precautions to avoid or minimize exposures.

Contrary to the above, as of January 21, 1997, six containers of liquid licensed material stored in the radioactive waste storage area did not bear labels that identified the radionuclides or the quantity of radioactivity, and an additional container of liquid waste did not identify the radionuclide, nor did these containers otherwise bear sufficient information to permit individuals handling or using the container, or working in the vicinity of the containers, to take precautions to avoid or minimize exposure. (01073)

These violations are classified in the aggregate as a Severity Level III problem. (Supplements IV and VI)

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be achieved, are already adequately addressed on the docket in the licensee's March 12, 1997 letter in response to Inspection Report No. 30-04544/97-01. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region 1, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

Dated at King of Prussia, Pennsylvania  
this 20th day of March 1997