

February 21, 1997

Docket No. 030-04544
EA No. 97-080

License No. 19-07538-01

Elizabeth D. Jacobson, Ph.D.
Deputy Director for Science
Center for Devices and Radiological Health (HFZ-2)
9200 Corporate Blvd.
Rockville, MD 20850-4030

SUBJECT: INSPECTION NO. 030-04544/97-001

Dear Dr. Jacobson:

This refers to the inspection conducted on January 6-7 and 21, 1997 at 1350 Piccard Drive, 1220 Wilkins Avenue, 12709 and Buildings 1 and 2 at 12720 Twinbrook Parkway in Rockville, Maryland. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The findings of the inspection were discussed with you, Edward Tupin, Don Thompson, and Orhan Suleiman of your staff by Pamela J. Henderson and John D. Kinneman of this office on February 6, 1997.

Areas examined during the inspection are identified in the report. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observation of activities in progress.

Based on the results of this inspection, seven apparent violations were identified and are being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600. The apparent violations indicate a lack of management oversight of the radiation safety program and a potential programmatic breakdown. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and members of your staff at the inspection exit meeting on February 6, 1997. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision. However, a Notice of Violation is not presently being issued for these inspection findings. Before the NRC makes its enforcement decision, we are providing you an opportunity, within 30 days of the date of this letter, to either (1) respond to the apparent violations addressed in this inspection report or (2) request a predecisional enforcement conference.

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Your response should be clearly marked as a "Response to Apparent Violations in Inspection Report No. 030-04544/97-001" and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Two of the apparent violations (failure to perform monthly contamination surveys in laboratories using radionuclides and failure to conduct a physical inventory of sealed sources every six months) were identified during a previous inspection of your licensed activities and documented in a Notice of Violation given to you on NRC Form 591 on February 10, 1995. From this inspection, it appears that your corrective actions were not effective since these items have recurred. Recurrent and uncorrected violations are given additional weight in the consideration and selection of appropriate enforcement action. Therefore, if you choose to respond to this letter, you should give particular attention to those actions taken or planned to ensure that identified items of noncompliance will be completely corrected and will not recur. Your response should be submitted under oath or affirmation and may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

If you choose not to provide a response and would prefer participating in a predecisional enforcement conference, please contact John D. Kinneman at (610) 337-5252 as soon as possible.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response (if you choose to provide one) will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

E. D. Jacobson, Ph.D.
Center for Devices and Radiologic Health

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The responses to the apparent violations described in the enclosed inspection report 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:
Charles W. Hehl

Charles W. Hehl, Director
Division of Nuclear Materials Safety

Docket No.: 030-04544
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Enclosures:

1. Inspection Report No. 030-04544/97-001
2. NUREG 1600 (Enforcement Policy)

cc w/enclosures:
Edward A. Tupin
Radiation Safety Officer
Food and Drug Administration
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

State of Maryland

E. D. Jacobson, Ph.D.
Center for Devices and Radiologic Health

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