



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 20, 1997

EA 97-080

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

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-04544/97-001)

Dear Dr. Jacobson:

This refers to the NRC inspection conducted on January 6-7 and 21, 1997, at several of your facilities in Rockville, Maryland, for which an exit meeting was held with you and members of your staff on February 6, 1997. The inspection was conducted to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. During the inspection, seven apparent violations of NRC requirements were identified, as described in the NRC inspection report transmitted with our letter, dated February 21, 1997. In the February 21, 1997 letter, the NRC provided you an opportunity to either respond in writing to the apparent violations addressed in the inspection report or request a predecisional enforcement conference. You responded to the apparent violations, in a letter to the NRC, dated March 12, 1997.

Based on the information developed during the inspection and the information you provided in your March 12, 1997 response, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involve (1) failure of the Radiation Safety Committee (RSC) to meet on a scheduled basis at intervals not exceeding 3-months; (2) failure of the Radiation Safety Officer (RSO) to conduct an annual audit of each approved project; (3) failure to review the radiation protection program content and implementation at least annually; (4) failure to conduct fixed and removable contamination surveys at least once each month in laboratories where radionuclides are used; (5) failure to provide one hour of annual training to each individual working with radioactive material; (6) failure to conduct a physical inventory every six months to account for all sealed sources and devices containing licensed material; and (7) failure to label each container of licensed material with the required caution label.

These violations indicate a significant lack of attention to licensed activities by the RSO and the Radiation Safety Committee (RSC). In fact, some of the violations that occurred were the direct responsibility of the RSO or RSC. Management attention to the radiation safety program is warranted to ensure that licensed activities are conducted safely and in accordance with requirements. While the violations in question did not have an impact on the health and safety of the public, or your staff, such violations are potential precursors to more serious problems, and therefore, it is important that the RSO and RSC actively look for, identify, and correct



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such problems. At your facility, this did not occur. Therefore, these violations have been classified in the aggregate as a Severity level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, at Severity Level III.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$2,750 is considered for a Severity Level III violation. Because your facility has not been the subject of an escalated enforcement action within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were both prompt and comprehensive. These actions, which were described in your March 12, 1997 letter, and/or during the inspection, included, but were not limited to: (1) scheduling the RSC meetings for the remainder of 1997; (2) conduct of audits of all ten of your approved projects which were completed by February 28, 1997; (3) conduct of a training session with staff on February 4, 1997, and February 20, 1997, with plans for annual training thereafter; (4) plans to have the RSO provide a written report regarding inventory findings during the RSC during the second and fourth quarterly meetings; and (5) appropriately labeling of containers that had not been labelled, and covering the need for such labelling during the February 4, 1997 training session.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized not to propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action.

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 your March 12, 1996 letter. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and any response, if you choose to provide one, and your March 12, 1997 letter, will be placed in the NRC Public Document Room (PDR).

Sincerely,


Hubert J. Miller
Regional Administrator 

Docket No.: 030-04544
License No.: 19-07538-01

Enclosure: Notice of Violation

Center for Devices and Radiological
Health (HFZ-2)

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cc w/encl:
Edward S. Tupin, RSO
State of Maryland

Center for Devices and Radiological
Health (HFZ-2)

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