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UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D. C. 20555-0001

APR 08 1994

Docket No. 030-01204
License No. 01-00643-02
EAs 92-204 and 93-174

Department of Veterans Affairs
ATTN: Mr. William Mountcastle
Medical Center Director
700 South 19th Street
Birmingham, Alabama 35233

Gentlemen:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - \$10,000
(NRC OFFICE OF INVESTIGATIONS REPORT NO. 2-91-013R)

This refers to your November 9, 1993 letters in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice), the Confirmatory Order Modifying License (Order), and Demand for Information (Demand) sent to you by our letter dated September 13, 1993. Our letter and Notice described violations which were identified during an NRC Office of Investigations inspection conducted on October 9, 1991, through September 14, 1992.

To emphasize the importance of taking necessary effective steps to ensure that NRC regulations are followed and that noncompliance with regulatory requirements is not tolerated, a civil penalty of \$10,000 was proposed.

In your responses to the Notice, you admitted Violations A and C.1, denied Violations B and C.2, and requested mitigation of the civil penalty based on your prior performance and lack of evidence of actual harm to any patient or member of the public.

After review and consideration of your responses, we have concluded, for the reasons given in the Appendix to the enclosed Order Imposing Civil Monetary Penalties, that the violations occurred as stated in the Notice and that you have not provided an adequate basis for mitigation of the civil penalty. Accordingly, we hereby serve the enclosed Order on Department of Veterans Affairs imposing a civil monetary penalty in the amount of \$10,000.

Payment should be made within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to Mr. James Lieberman, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. ATTN: Document Control Desk, Washington, 9404120049 940408
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D.C. 20555. We will review the effectiveness of your corrective actions during a subsequent inspection.

In addition, after review and consideration of your response to the Demand, we have concluded that your response to Items VI.E and VI.F of the Demand does not address the information requested by the Demand. The response to Item VI.E failed to provide a statement as to why the NRC should not modify your license to limit the scope of your program until you demonstrate that you can sustain the required level of management oversight to properly manage a broad scope program. The response to Item VI.F failed to provide a statement as to why the NRC should have reasonable assurance that you will take prompt and lasting corrective action when a violation of NRC requirements is identified. While the decline in the record-keeping errors you assert in response to Item VI.F is important for the NRC to consider, the staff needs information regarding your management procedures which ensures that corrective actions, when taken, are prompt and lasting.

Therefore, you are required to submit to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, within 30 days of the date of this letter, a written supplemental response, under oath or affirmation, which provides an explanation as to how the data provided in Exhibit A of your response to Item VI.D of the Demand demonstrates that patients received the appropriate doses for diagnostic nuclear medicine studies and which provides the information required by Items VI.E and VI.F of the Demand.

In your response to Item VI.E of the Demand, you objected to the requirement contained in the Confirmatory Order Modifying License issued on September 13, 1993, that four audits of licensed activities be conducted during the first year. Because you agreed to the audit requirement before the Order was issued, the NRC is treating your objection as a request to relax the requirement of the Order (your objection does not operate to withdraw your earlier agreement nor can it function as a request for a hearing). The frequency of audits, as specified in the Order, was appropriate given the results of our investigation. Therefore, it would be premature to change the audit frequency at this time. We may reconsider your request after you have received and evaluated the results of your first two audits. We expect you to fully comply with the terms and conditions of the Order.

As indicated during the enforcement conference and our September 13, 1993 letter, as a licensee, you have the responsibility to ensure that licensed activities are performed in accordance with

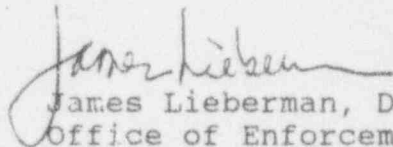
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approved procedures and regulatory requirements. This includes taking appropriate steps to assure that doses are adequately measured prior to administration to patients and that deviations from procedures or requirements are adequately investigated to implement necessary corrective actions. We will continue to review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosure 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. 96-511.

Sincerely,


James Lieberman, Director
Office of Enforcement

Enclosure: As Stated

cc w/encl:
State of Alabama

James W. Holsinger, Jr., M.D.
Chief Medical Director (10)
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420