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UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

MAR 17 1994

Docket Nos. 030-02981; 030-00462; 030-30452  
License Nos. 37-01317-01; 37-01317-02; 37-01317-03  
EA 93-309 and EA 94-051

Mr. Tony Sanzo, Chief Executive Officer  
Allegheny General Hospital  
320 East North Avenue  
Pittsburgh, Pennsylvania 15212

Dear Mr. Sanzo:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL  
PENALTIES - \$8,750; AND CONFIRMATORY ORDER MODIFYING LICENSE  
(EFFECTIVE IMMEDIATELY) (NRC Inspection Report Nos. 030-02981/93-  
001, 030-00462/93-001, and 030-30452/93-001)

This letter refers to the NRC safety inspection conducted on December 13 - 20, 1993, at Allegheny General Hospital, Pittsburgh, Pennsylvania, of activities authorized by the above listed NRC licenses. The inspection report was sent to you on January 14, 1994. During the inspection, 23 apparent violations of NRC requirements were identified.

On February 2, 1994, an enforcement conference was conducted with Mr. L. Shapiro and other members of your staff to discuss the apparent violations, their causes, and your corrective actions. A copy of the enforcement conference report was sent to you on February 7, 1994. That report noted that two of the apparent violations were not being cited, for the reasons provided therein. In addition, while the issuance of a temporary authorization to use licensed material does not appear to have been in accordance with Condition 11.A of your license, the NRC staff has concluded that since this practice was terminated and the apparent violation was of minor safety significance, a violation would not be issued.

The remaining 20 violations are being cited and are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties. The violations consist of: (1) 48 examples of failure to prepare written directives prior to the administration of radioactive materials to patients at the facility and a failure to instruct a nuclear medicine technologist in your Quality Management Program, as required by NRC requirements; and (2) numerous other violations (related to such areas as failure to maintain security over licensed material, and violations of radiation safety requirements for irradiators, performing required surveys, providing training to nursing staff, maintaining appropriate procedures, ensuring control of material, and maintaining appropriate records) which collectively are indicative of a significant lack of management attention to, and control of, licensed activities at your facility.

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These inspection findings are of significant regulatory concern because two violations appear to be repetitive and because multiple aspects of the radiation safety program had significantly degraded at your facility, yet these conditions were not identified and corrected by either the Radiation Safety Officer (RSO), Radiation Safety Committee (RSC), or hospital management.

The NRC licenses issued to Allegheny General Hospital entrust responsibility for radiation safety to the RSC and RSO, and require effective oversight of the licensed programs by the management of the hospital. Therefore, incumbent upon the hospital is the responsibility of management in general, and the RSC and RSO in particular, to protect the public health and safety by ensuring that all requirements of the NRC licenses are met and that any potential violations of NRC requirements are identified promptly and corrected expeditiously. This did not occur, in that for the most part, the violations were identified by the NRC. In addition, although the RSO did identify, in January 1993, that written directives were not being prepared as required by the Quality Management (QM) program, and he instituted actions to correct the violations, the actions were not effective in preventing recurrence, as evidenced by the fact that seven additional instances occurred in October 1993 where written directives were not prepared.

The failure to devote adequate time and attention to radiation safety program activities at your facility directly contributed to the violations and the failure by the RSO and/or RSC to detect and correct them sooner. Furthermore, Allegheny General Hospital management should have recognized the importance of appropriate attention to, and control of, the radiation safety program activities since such emphasis was provided by the NRC during a previous enforcement conference conducted on May 4, 1989 to discuss other violations of NRC requirements.

The violations described in Section I of the enclosed Notice are related to Quality Management Program requirements and have been classified in the aggregate at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C. The violations in Section II have been classified in the aggregate at Severity Level III in accordance with the Enforcement Policy since they were indicative of a breakdown in control of licensed activities at the facility.

The NRC recognizes that subsequent to the NRC inspection, actions were taken or planned to correct the specific violations and achieve improvements in the control, oversight, and implementation of the radiation safety program. These actions, which were described at the enforcement conference, include, but are not limited to: (1) securing all radioactive material at the facility; (2) providing training to authorized users on security measures; (3) providing training to nuclear medicine personnel on Quality Management Program requirements; and (4) plans to have an external review of the radiation safety program by outside consultants.

Notwithstanding those actions, to emphasize the importance of aggressive management oversight of the radiation safety program so that licensed activities are conducted safely and in accordance with requirements, and violations, when they exist, are identified promptly and corrected effectively, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the cumulative amount of \$8,750 for the violations set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III problem is \$2,500. After application of the escalation and mitigation factors in each case, two civil penalties in the respective amounts of \$3,750 and \$5,000 are being issued for the Severity Level III problems set forth in Sections I and II of the enclosed Notice. The amount of escalation or mitigation of the respective civil penalties is discussed below.

With regard to Violation I, mitigation of 50 percent for the identification factor is warranted because this violation was identified by your staff in both January 1993 and October 1993. Since your corrective actions in January 1993 did not prevent recurrence of the seven incidents when a new technologist was hired in October 1993, no mitigation on the corrective action factor is warranted. Escalation of 100 percent, however, is warranted based on your poor past performance because one severity level III and five severity level IV violations were identified during the last two NRC inspections at this facility in 1990 and 1989. In addition, an enforcement conference was conducted with Allegheny on May 4, 1989, to discuss the four violations identified during the 1989 inspection. The remaining adjustment factors were considered but no further adjustments were determined to be appropriate.

Concerning the violations in Section II of the Notice, escalation of 50 percent is warranted for the identification factor since these violations were identified by the NRC. Your corrective actions were considered prompt and comprehensive; therefore, 50 percent mitigation for this factor is warranted. Escalation of 100 percent is warranted based on your poor past performance, as noted above. The remaining adjustment factors were considered but no further adjustments were determined to be appropriate.

In addition to the civil penalties, given the significant lack of attention to licensed activities at your facility, the NRC is also issuing the enclosed Confirmatory Order Modifying License (Effective Immediately) (Order) which confirms your commitment to retain the services of an independent expert to assess your program, and to develop an improvement plan based on those assessment findings.

You are required to respond to this letter and Order and should follow the instructions specified in the enclosed Notice and Order when preparing your responses. 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 NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

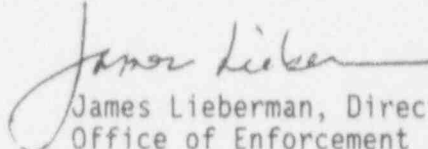
Allegheny General Hospital

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

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,

  
James Lieberman, Director  
Office of Enforcement

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalties
2. Confirmatory Order Modifying License (Effective Immediately)

cc w/encls:

Public Document Room (PDR)  
Nuclear Safety Information Center (NSIC)  
Commonwealth of Pennsylvania