UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket Nos. 030-02981
Allegheny General Hospital	)	030-00462
Pittsburgh, Pennsylvania	)	030-30452
	)	License Nos. 37-01317-01
	)	37-01317-02
	)	37-01317-03
	)	EA 94-051

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

Allegheny General Hospital (Licensee), Pittsburgh, Pennsylvania, is the holder of Byproduct/Source Material Licenses Nos 37-01317-01; 37-01317-02; 37-01317-03 (Licenses), issued by the U. S. Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 33. The Licenses authorize the Licensee to use radioactive material under a broad scope license, possess an irradiator for calibrations of instruments, and possess an irradiator for irradiation of blood products and biological samples.

License No. 37-01317-01 was issued on October 25, 1956, and was due to expire on January 31, 1989, but is currently under timely renewal pending staff action based on a licensee request to renew the license, dated December 15, 1988. License No. 37-01317-02 was issued on July 19, 1957, was renewed on March 23, 1992, and is due to expire on March 31, 1997. License No. 37-01317-03 was issued on May 31, 1988, was recently renewed on October 4, 1993, and is due to expire on October 31, 1998.

II

On December 13-20, 1993, the NRC performed an inspection of licensed activities at the Licensee's facility. During the inspection, numerous violations of NRC requirements were identified. The violations are described in detail in a Notice of Violation and Proposed Imposition of Civil Penalties issued concurrently on this date. The violations, which demonstrate a significant lack of management attention to, and control of, licensed activities at the facility, included: (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 the Licensee's Quality Management Program, as required by NRC requirements; and (2) many 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.

The violations are of significant regulatory concern since the Licensee possesses a large broad scope license which places a significant responsibility on the Radiation Safety Committee (RSC), as well as the Radiation Safety Officer (RSO), to ensure that licensed activities are conducted safely and in accordance with NRC requirements.

The Licensee's failure to maintain sufficient control of radioactive materials raises significant questions regarding the adequacy of the Licensee's oversight of activities at its facility, as well as its ability to assure that activities at those facilities are conducted safely and in accordance with NRC requirements. Accordingly, without independent assessments of the Licensee's radiation safety program and a performance improvement plan, there is a substantial question as to whether licensed activities will be adequately controlled at the Licensee's facilities.

III

During an enforcement conference on February 2, 1994, as well as in telephone conversations on February 4 and 9, 1994, and March 16, 1994, between Mr. Lou Shapiro of the Licensee's staff and Dr. Ronald Bellamy of the NRC Region I staff, the Licensee committed to retain the services of an independent consultant to perform an assessment of its radiation safety program and to develop a performance improvement plan based upon the assessment findings. The Licensee has consented to the terms of this Order.

I find that the Licensee's commitments are acceptable and necessary and conclude that, with these commitments and the implementation of an appropriate performance improvement plan, the public health and safety are reasonably assured. In view of the foregoing, I have determined that the public health and safety require that the Licensee's commitments be confirmed by this Order. Pursuant to 10 CFR 2.202, I have also determined, based on the Licensee's consent and on the significance of the violations described above, that the

public health and safety require that this Order be immediately effective.

V

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Parts 30 and 33, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSES NOS. 37-01317-01, 37-01317-02, AND 37-01317-03 ARE MODIFIED AS FOLLOWS:

A. The Licensee shall retain the services of a consultant, with extensive experience in the management and implementation of a broad scope radiation safety program, including activities similar to those authorized under the Licensee's program, to perform an assessment of the Licensee's radiation safety program. Within 30 days from the effective date of this Order, the Licensee shall submit the name and qualifications of the consultant to the Regional Administrator, NRC Region I, for approval.

B. Within 90 days of NRC approval of the consultant selection as described under Section IV.A of this Order, the assessment shall be completed, and a copy of the assessment report shall be submitted to the NRC within the following 15 days. The assessment of the Licensee's radiation safety program shall include, but not be limited to, a review of:

1. the Licensee's organization, and assigned responsibilities and authorities within that organization;

2. the Licensee's program for training and retraining individuals working with NRC-licensed materials, in NRC regulations, in the conditions of the Licenses, and in radiologically safe practices for using licensed material;

3. the Licensee's methods of approving individuals for the use of licensed materials and developing procedures for the safe use of licensed materials;

4. the Licensee's program for training and qualifying all individuals involved in managing, supervising, inspecting and auditing licensed activities;

5. the Licensee's program of surveillance and audits to determine compliance by individual users of licensed materials with NRC regulations, the conditions of the NRC Licenses, and the Licensee's own procedures for the safe use of radioactive materials;

6. the adequacy of the existing staffing within the Radiation Safety Department, to ensure that the items set forth in Sections IV.B.2 through V.B.5 of this Order are adequately performed; and,

7. the Licensee's management of the radiation safety program, including the function of the Radiation Safety Committee and its methods of monitoring the program to ensure that problems, when they exist, are promptly identified and effectively corrected.

C. Within 120 days of NRC approval of the consultant selection described under Section IV.A of this Order, the Licensee shall submit a performance improvement plan to the Regional Administrator, NRC Region I, describing its methods of implementing the recommendations of the assessment report, or providing justification for alternate or no corrective action, if any specific recommendations are not adopted. This plan shall include:

1. action items completed or to be performed;

2. schedules for, or dates of, completion of each specific action item; and

3. a system for monitoring and tracking the status and completion of the action items.

D. Upon completion of all action items, a final report shall be submitted by the Licensee to the Regional Administrator, NRC Region I. During implementation of the performance improvement plan, the Licensee shall provide written quarterly status reports to the Regional Administrator,

NRC Region I, concerning the implementation of the plan, until such time as all items in the performance improvement plan have been implemented and the final report issued.

The Regional Administrator, NRC Region I, may relax or rescind, in writing, any of the above conditions upon demonstration by the Licensee of good cause.

V

Any person adversely affected by this Confirmatory Order, other than the Licensee, may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406, and to the Licensee. If such a person requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), (57 Fed. Reg. 20194) May 12, 1992, any person adversely affected by this Order, other than the Licensee may, in addition to demanding a hearing, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 17th day of March 1994

Allegheny General Hospital

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