U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report Nos. 030-02981/94-001
030-00462/94-001
030-30452/94-001

License Nos. 37-01317-01
37-01317-02
37-01317-03

EA No. 93-309

Docket Nos.	Priority	Category
030-02981	1	G
030-00462	3	E
030-30452	3	E

Licensee: Allegheny General Hospital
320 East North Avenue
Pittsburgh, Pennsylvania 15212-9986

Facility Name: Allegheny General Hospital

Enforcement Conference Conducted At: King of Prussia, Pennsylvania

Enforcement Conference Conducted: February 2, 1994

Prepared By: Penny Nessen 2-7-94
Penny Nessen, Health Physicist — Date
Medical Inspection Section

Approved by: 2/7/94
Jenny M. Johansen, Chief — Date
for Medical Inspection Section

Conference Summary: An Enforcement Conference was held at the NRC Region I Office in King of Prussia, Pennsylvania on October 25, 1993 to discuss violations identified during the inspection conducted December 13-20, 1994 and the licensee's taken and planned corrective actions since the inspection. Enforcement options available to the Commission were also discussed.

9402230117 940207
PDR ADOCK 03000462
C PDR

DETAILS

1.0 Attendees

Allegheny General Hospital:

Lou Shapiro, Vice President of Clinical Services
Joseph Och, Radiation Safety Officer
Gilbert Isaacs, M.D., Chairman of Radiation Safety Committee

NRC:

Charles W. Hehl, Division Director, Division of Radiation Safety and Safeguards
Ronald R. Bellamy, Chief, Nuclear Materials Safety Branch
Jenny M. Johansen, Chief, Medical Inspection Section
Daniel J. Holody, Enforcement Officer
Penny Nessen, Health Physicist

2.0 Summary

On February 2, 1994, representatives of Allegheny General Hospital met with NRC representatives in the Region I Office at King of Prussia, Pennsylvania. In an opening statement, the NRC Division Director of the Division of Radiation Safety and Safeguards explained the purpose of the Enforcement Conference.

Mr. Lou Shapiro, the licensee's Vice President of Clinical Services provided opening remarks and reiterated the licensee's commitment to meeting all regulatory concerns. Mr. Shapiro also described the licensee's organization, policy for mock inspections of licensee personnel using licensed material, and radiation safety training program.

Mr. Joseph Och, the licensee's Radiation Safety Officer, distributed a written response to all apparent violations and addressed each violation separately. The licensee agreed with nineteen of the twenty three apparent violations described in the 93-001 inspection report. The four violations that the licensee took exception to are described below:

1. Failure to ensure that a physician designated to use licensed material in or on humans met the training criteria established in 10 CFR 35, Subpart J.

   The licensee provided additional information indicating that the physician had met the required training criteria at the time of authorization, therefore, upon

review, the NRC has withdrawn this apparent violation.

2. Failure to instruct nuclear medicine technologists on the licensee's written Quality Management Program (QMP) from January 1992 to October 1993.

The licensee stated that they had provided training to all nuclear medicine technologists in January 1992 when the QMP was established. During their first audit of their QMP in January 1993, the licensee identified 41 cases where a written directive had not been prepared when required. As a result, the licensee provided re-training on the QMP to all nuclear medicine technologists. In August of 1993, the licensee stated that a new nuclear medicine technologist was hired and was not provided the required QMP training prior to beginning work. During an audit of the QMP program in October of 1993, the licensee identified 7 cases where a written directive had not been prepared when required. The licensee stated that all seven cases were the result of the new nuclear medicine technologist not being trained that a written directive was required for these cases. Subsequently, the licensee stated that the new nuclear medicine technologist was trained on all QMP requirements. Since, following QMP training, 41 cases where a written directive was not prepared occurred and, following the failure to provide QMP training to a new technologist, 7 cases where a written directive was not prepared occurred, this item is not being withdrawn as an apparent violation.

3. Failure to maintain records for sanitary sewer disposals made under 10 CFR 20.203.

The licensee provided additional information indicating that if all their inventory of radioactive material was disposed of through the sanitary sewerage system, they would never exceed 10 CFR 20.203 limits. The licensee stated that on a monthly basis they calculate the concentration of radioactive materials disposed of through the sanitary sewer to ensure that Appendix B limits are not exceeded. Therefore, upon review, the NRC has withdrawn this apparent violation.

4. Failure to train all therapy nurses on the appearance and size of brachytherapy sources.

The licensee stated and provided documentation that the nurse questioned by the inspector had been provided two training courses where she was permitted to handle mock sources and applicators. However, the adequacy of the training is questionable, because the nurse, when questioned by the inspector, was unable to describe the size and appearance of brachytherapy sources and could not recall receiving training on this subject. Therefore this item is not being withdrawn as an apparent violation.

Dr. Gilbert Isaacs, the licensee's Radiation Safety Committee Chairman, concluded by describing steps taken by the licensee to improve oversight of the radiation safety program including a commitment to have an annual audit performed by an outside consultant. Mr. Shapiro confirmed that such an audit would be performed.

All new forms and the licensee's written response to each of the apparent violations are attached.

Enforcement options available to the Commission were discussed by the Enforcement Officer.

The meeting was then adjourned.