U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Enforcement Conference Report No. 030-01244/89-003

Docket No. 030-01244

License No. 06-00819-03 Priority No. 1 Category G Program Code 2110

Licensee: Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

Facility Name: Yale-New Haven Hospital

Enforcement Conference Conducted: June 21, 1989

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Nuclear Materials Safety Section A — 9/26/89 date

Approved by: M. S. Shanbaky
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Nuclear Materials Safety Section A — 9/26/89 date

Conference Summary: The findings documented in Inspection Report No. 030-01244/89-002 were discussed. The licensee described planned and completed corrective actions. The NRC's enforcement policy was explained to the licensee.

DETAILS

1. Persons Participating

Licensee

Norman G. Roth, Assistant Vice President, Administration
Virginia D. Roddy, Director, Risk Management and Legal Affairs
Michael J. Bohan, Radiation Safety Officer (RSO)

U.S. Nuclear Regulatory Commission

James H. Joyner, Project Manager, Division Of Radiation Safety and Safeguards
Lee H. Bettenhausen, Chief, Nuclear Materials Safety Branch
Mohamed M. Shanbaky, Chief, Nuclear Materials Safety Section A
John M. Pelchat, Health Physicist, Nuclear Materials Safety Section A

2. Conference Summary

The issues identified in NRC Report No. 030-01244/89-002 were discussed. Particular emphasis was focused on the loss of a 27.53 millicurie cesium-137 brachytherapy source and the licensee's actions to recover the source and to prevent recurrence of such losses. The licensee's initial actions to recover the source were appropriate. The supplemental actions to prevent future losses of brachytherapy sources were prompt and comprehensive. The licensee's completed actions included:

a. Installation of an area radiation monitoring device in the brachytherapy source handling room adjacent to the door to warn staff of the presence of an unshielded source. In order to avoid interfering with the operating room next door, the licensee disabled the audible alarm on the monitoring device, and will depend on the visual alarm (a light) to prevent any inadvertant release of brachytherapy sources from the room.

b. All authorized dosimetrists and radiation safety personnel involved in the handling of brachytherapy sources were instructed to include direct inspection of the Heyman brachytherapy source during source inventory procedures. The previous source inventory procedures were performed by examination of the nonradioactive ends of the source assemblies.

c. Detailed inspection of the brazed joints of each Heyman brachytherapy source by the RSO during quarterly physical inventories and semi-annual leak tests.

d. Establishment of a policy mandating removal of Heyman brachytherapy sources from patients by Therapeutic Radiology staff only. This will reduce the possibility of source assembly damage during removal of the sources from the patient and permit inspection of the sources by experienced personnel upon removal.

The licensee representatives stated that a brachytherapy source failure of this nature was completely unexpected. The licensee cited over 30 years operational experience with brachytherapy sources, the manufacturer's reported statement that this was the first failure of this type to occur, and the lack of any prior notice in medical literature or NRC regulatory publications as the basis for confidence in the previous inventory and survey procedures in place at the time of the incident.

Attention was also focused on the apparent repeat violation concerning the failure to limit radiation exposure levels in unrestricted areas to two millirem per hour (mR/hr). The licensee's representatives stated that access to adjacent rooms was restricted when radiation exposure rates in excess of 2 mR/hr were measured after the violation was identified by NRC in September 1988. These restrictions were relaxed after the installation of permanent lead shields was completed in December 1988. Implementation of these measures was verified during the March 1989 inspection. The RSO acknowledged the existence of areas where radiation exposure levels could exceed 2 mR/hr after the installation of the shields. The RSO also noted that he was aware of radiation levels in excess of 2 mR/hr in unrestricted areas since the use of cesium-137 began in 1986 as well as earlier when brachytherapy procedures were performed with radium. The RSO cited the desire to gain the acceptance of the medical staff for the use of cesium in place of radium as the reason for not taking measures which might have appeared to be disadvantages of using cesium. The licensee representatives stated that an evaluation was under way at the time of the March 1989 inspection to support an amendment request for relief from the radiation exposure limits established in 10 CFR 20.105(b). Subsequent to the March 1989 inspection, the licensee did request and was granted relief as provided in 10 CFR 20.105(a) from the two mR/hr limit provided that no member of the public or the staff, other than the patient being treated, exceed 500 mrem in any calendar year. NRC staff expressed concern that the licensee conducted operations with licensed radioactive material which resulted in radiation exposure levels in excess of regulatory limits prior to acquiring the appropriate authorization from the NRC. It was also pointed out that until specific relief is granted to a regulatory requirement, a licensee is expected to possess and use licensed radioactive material in complete compliance with the requirements of NRC regulations and licenses.

The NRC enforcement policy was explained to the licensee representatives. The licensee stated that Yale-New Haven intended to possess and use licensed radioactive material in full compliance with all applicable regulatory requirements. The NRC staff informed the licensee's representatives that the licensee would be advised of the NRC decision in regard to appropriate enforcement action under separate cover.