U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02725/85001(DRSS)

Docket No. 030-02725

License No. 34-03831-02 Category G Priority III

Licensee: Christ Hospital
2139 Auburn
Cincinnati, OH 45219

Inspection Conducted: June 26, 1985

Inspector: R. J. Caniano
Radiation Specialist R. J. Caniano 7/11/85
Date

Reviewed By: D. J. Sreniawski, Chief D J Sreniawski 7/11/85
Nuclear Materials Safety
Section 2 Date

Approved By: W. L. Axelson, Chief W L Axelson 7/11/85
Nuclear Materials Safety and
Safeguards Branch Date

Inspection Summary

Inspection on June 26, 1985 (Report No. 030-02725/85001(DRSS))
Areas Inspected: This was an announced special inspection performed to review the circumstances surrounding a reported therapeutic misadministration which occurred on June 17-18, 1985.
Results: No violations were identified. The therapeutic misadministration occurred, in part, due to the lack of formal written procedures regarding the administration of brachytherapy sources.

DETAILS

1. Persons Contacted

Jack Cook, Administrator
*James Tomaszewski, Assistant Administrator
Ralph Scott, M.D., Medical Director of Radiation Medicine
*Clifford Born, M.S., Radiation Safety Officer
*Shirley Tobes, M.S., Physicist
Sunantha Ploysongsang, M.D., Authorized User
Eugene L. Saenger, M.D., NRC Medical Consultant

*Denotes those present at exit interview on June 26, 1985.

2. Purpose of Inspection

This was a special inspection to review the circumstances surrounding a therapeutic misadministration to a patient undergoing iridium-192 treatment to the left lung. The misadministration occurred June 17-18, 1985.

This incident was reported to the NRC Region III office by telephone on June 19, 1985, and was documented in the licensee's followup report dated June 28, 1985 (attachment).

3. Organization

The Administrator and Assistant Administrator of Christ Hospital are Messrs. Jack Cook and James Tomaszewski respectively. Ralph Scott, M.D. is the Medical Director of Radiation Medicine. The hospital's Radiation Safety Officer is Clifford Born, M.S.

The licensee's brachytherapy treatment program is conducted under the Department of Radiation Medicine. The department employs two full time physicists and a full-time dosimetrist. Their duties encompass the brachytherapy program, and the nuclear medicine, teletherapy, and the linear accelerator therapy programs.

No violations were identified.

4. Licensed Program and Inspection History

On April 18, 1963, Christ Hospital was issued NRC License No. 34-03831-02 for possession and use of various licensed materials for diagnostic and therapeutic purposes. The current license, presently being reviewed for renewal, authorizes Groups I-VI, xenon-133, and various other licensed materials for animal studies, in-vitro studies, and instrument calibration.

The licensee has used iridium-192 for 1 or 2 therapy procedures per year, whereas the use of cesium-137 sources was in the range of 2 to 3 procedures per week.

License No. 34-03831-02 was inspected by the NRC seven times since 1963. Ten violations were identified from April 8, 1963 through May 7, 1980. The last inspection, conducted on March 25, 1982, resulted in no violations. In 1970, the licensee lost nine sealed cesium-137 brachytherapy sources which were never recovered. No enforcement action was taken since it appeared that the patient either accidentally, or purposely removed the sources and flushed them down the toilet.

No diagnostic or therapeutic misadministrations, other than the current one, have been reported since the inception of the NRC reporting requirement in 1980.

5. Inspection Findings

The following information was obtained during the June 26, 1985 inspection at the licensee's facility.

In early June, 1985, a 57 year old male patient diagnosed as having recurrent and inoperable lung cancer was being evaluated for possible iridium-192 seed therapy. The patient had gone through two series of cobalt-60 teletherapy treatments approximately one year prior.

On June 10, 1985, the authorized user of Group VI materials discussed the treatment of the patient with a recently appointed physicist. The authorized user decided to treat the upper lobe bronchus with a dose of 5000 rads at a distance of one half centimeter. The physicist then performed a preliminary calculation and determined that 12 iridium-192 seeds at 10 millicuries each should be sufficient for the treatment, and proceeded to order the material from Best Industries, the seed manufacturer.

On June 17, 1985, at approximately 11:45 a.m. the patient was implanted by the authorized user. At this time, the authorized user was under the assumption that the physicist had done the essential dose calculations to determine the length of time required to deliver the prescribed dose. The authorized user recalled the physicist saying that the time for treatment should be 50 hours. The physicist denied making that statement claiming that since no calculations regarding treatment time were performed she could not have quoted a specific time.

On June 18, 1985 at approximately 3:00 p.m., a radiograph of the patient's chest was performed to determine proper placement and distribution of the iridium-192 seeds. Upon reviewing the radiograph, the authorized user stated that the seeds were in good position and the treatment will continue for the planned 50 hours. At that time, the physicist recalled that no calculations had been performed and immediately performed the calculation. The physicist determined that the treatment area of the left upper bronchus had received 14,000 rads, well in excess of the 5,000 rads prescribed dose. At 4:00 p.m. the seeds were removed.

On June 19, 1985, the referring physician, the patient, and NRC Region III were notified of the misadministration. To prevent any recurrence of a therapeutic misadministration, the licensee on June 19, 1985 implemented

an interdepartmental written policy on the administration of sealed sources for therapeutic purposes. A copy of the procedure was sent to Region III as an attachment to the licensee's written report required by 10 CFR 35.42(b). (See attachment for those procedures.)

On June 26, 1985, Dr. Eugene Saenger, the NRC medical consultant, was contacted by the licensee and informed of the misadministration. According to Dr. Saenger's advice, the patient was to be followed closely on a weekly basis and a bronchoscopy was to be performed in approximately 4-8 weeks to determine if any side effects occur due to the excessive radiation administered to the patient.

Although no violations of NRC requirements were identified during this special inspection, the inspector expressed concern that the licensee failed to develop or implement any formal procedures for the administration of brachytherapy sources prior to this incident. If the licensee had implemented procedures prior to this misadministration, the likelihood of the occurrence would have been minimized substantially.

6. Exit Interview

The inspector met with those individuals denoted in Section 1 at the conclusion of the inspection on June 26, 1985. The discussion included a review of the misadministration and the area of concern noted in this report. The licensee also presented the inspector with their corrective action to preclude any similar recurrence. This was reviewed by the inspector and appeared adequate.

7. Enforcement Conference

An enforcement conference was held via telephone on July 10, 1985. The licensee was represented by Mr. J. Cook and members of the Christ Hospital staff. The NRC was represented by Mr. J. A. Hind and others of the NRC Region III staff.

During this conference call, a brief description of the events surrounding a misadministration occurring on June 24, 1985 were discussed. The licensee stated that the procedures outlined in their June 28, 1985 letter to the NRC were already in place.

The licensee was informed that Region III management would recommend that the procedures be incorporated in a Confirmatory Order until such time as the licensee amended their license to reflect the procedural change.