U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-17335/94001(DRSS)

Docket No. 030-17335

License No. 13-18881-01 Category G Priority III

Licensee: Memorial Hospital
615 North Michigan Street
South Bend, IN 46601

Inspection Conducted: May 4 and 5, 1994
Additional information obtained by telephone on May 10, 1994 and June 24, 1994

Inspector: _____ 7/8/94
James L. Cameron Date
Radiation Specialist

Reviewed By: _____ 7/8/94
B. J. Holt, Chief Date
Nuclear Materials Inspection Section 1

Approved By: _____ 7/14/94
Roy J. Caniano, Chief Date
Nuclear Materials Safety Branch

Inspection Summary

Inspection on May 4 and 5, 1994 with additional information obtained by telephone on May 10, 1994 and June 24, 1994 (Report No. 030-17335/94001(DRSS))
Areas Inspected: This was a routine, unannounced safety inspection conducted to review the adequacy of the licensee's overall NRC-licensed operations authorized under a medical use license of limited scope. This report summarizes the NRC's review and findings in the areas of: organization and management controls; scope of program; misadministration review; notification and reporting; and transportation. Other program areas that were reviewed include: training, retraining, and instructions to workers; facilities and equipment; materials; audits and inspections; radiological protection procedures; personnel radiation protection - external and internal; radioactive effluent and waste disposal; area surveys; posting and labeling; and the licensee's implementation of the quality management program requirements contained in 10 CFR 35.32.

Results: The inspection identified a misadministration that occurred during a manually afterloaded cesium-137 brachytherapy implant in April 1992 (Section 4). In addition, three violations were identified and consist of failure to: (1) properly evaluate a misadministration with respect to its cause and the subsequent corrective actions taken (Section 4); (2) furnish a written report to the patient within 15 days after discovery of a misadministration; and (3) monitor packages of radioactive material for external removable contamination levels prior to shipment (Section 6).

DETAILS

1. Persons Contacted

*Alex Hashemi, M.S., Radiation Safety Officer
*Richard Selle, Chief Nuclear Medicine Technologist
*Patrick Miller, Director, Radiation Oncology and Radiology
David A. Hornback, M.D., Authorized User
Dewey Bringedahl, Nuclear Medicine Technologist
*Billie Shook, Manager, Radiation Oncology Department
*Becky Starzynski, Director, Risk Management/Occupational Safety
*R. Johnson, M.D., Authorized User
*George Soper, Senior Vice President
Candy Walters, R.N., former licensee employee (by telephone on May 10, 1994)

*Denotes those individuals present during the exit summary conducted on May 5, 1994

2. Program Summary and Inspection History

Memorial Hospital is authorized to possess and use byproduct material for medical use as described in 10 CFR 35.100, 10 CFR 35.200, 10 CFR 35.300, 10 CFR 35.400, and 10 CFR 35.500. In addition, the licensee is authorized to use iridium-192 as sealed sources in a Nucletron Corp. MicroSelectron-HDR remote afterloading brachytherapy unit for interstitial and intracavitary radiotherapy.

In its nuclear medicine department, the licensee performs approximately 325 diagnostic studies per month with unit dosages of radiopharmaceuticals supplied by a local nuclear pharmacy. In addition, the licensee administers approximately 78 iodine-131 patient dosages each year consisting of 15 whole body scans utilizing 2 to 5 millicuries (74 to 185 MBq) each, 60 hyperthyroidism treatments utilizing 10 millicuries (370 MBq) each, and 3 thyroid carcinoma therapies utilizing up to 150 millicuries (5550 MBq) each. Each iodine-131 dosage administered is in solution form. The licensee also has administered 6 strontium-89 chloride patient dosages since the radiopharmaceutical became commercially available in July 1993 and has administered 2 phosphorus-32 patient dosages in 1994, to date.

In the radiation oncology department, the licensee has administered only one HDR treatment using the remote afterloader. The licensee administers eighteen cesium-137 and six iridium-192 manually afterloaded temporary brachytherapy treatments each year. The licensee has not performed any permanent brachytherapy implants.

The NRC last inspected the licensee on April 9, 1992. Three violations were identified during that inspection and consisted of fai ire to: (1) notify the NRC that the individual designated as the radiation safety officer had permanently discontinued the performance of the duties of that position; (2) measure ventilation rates available in areas of radioactive gas use; and (3) include all required information in records of the results of daily area surveys. This inspection determined that each of the previously identified violations had been corrected.

No violations of NRC regulatory requirements were identified.

3. Organization and Management Controls

The responsibility for overall licensee operations rests with the hospital's President. To oversee the use of byproduct material, the licensee has established a radiation safety committee. The licensee's radiation safety officer, who is also the licensee's radiation oncology medical physicist, implements the radiation safety program on a daily basis. With the exception noted in Section 4, the licensee's radiation safety officer and radiation safety committee have fulfilled their radiation safety duties and responsibilities delineated in 10 CFR 35.21 and 10 CFR 35.22, respectively.

No violations of NRC regulatory requirements were identified.

4. Misadministration Review

The inspector identified a misadministration that occurred during a manually afterloaded cesium-137 brachytherapy implant performed in April 1992. Although the licensee identified that the incident had occurred, it was not aware that the incident resulted in a misadministration as defined in 10 CFR 35.2, involving a brachytherapy radiation dose to an unintended treatment site. The results of the inspector's review of the misadministration are described below.

Background Information

On April 13, 1992, a licensee authorized user physician prepared a written directive for a manually afterloaded cesium-137 brachytherapy implant. The written directive called for two implant procedures to be performed, each delivering 1500 rads (15 Gy) to a specified point in the patient's cervix. The first procedure, to be performed over 25.9 hours, involved five sources to be implanted into the patient later that day using a Fletcher-suit gynecological applicator. Three sources (two 28 millicurie (1040 MBq) sources and one 35 millicurie (1300 MBq) source) were to be loaded into the tandem and one source (46 millicurie (1700 MBq)) was to be loaded into each of two ovoids. The sources were loaded into the afterloader devices by a dosimetrist. The afterloaders were then loaded into the applicator by the authorized user physician at 2:25 p.m. that day. Due to the patient's large size, the physician stated that she had difficulty in loading the applicator. After loading

the applicator device, the licensee conducted area surveys at the patient's bedside and at one meter from the patient. Those surveys did not indicate any unusual radiation levels.

Discovery of Incident

At 10:15 p.m. on April 13, 1992, the patient's care provider discovered a cesium-137 implant source on the floor approximately 30 centimeters from the foot of the patient's bed. The care provider discovered the source after she had changed the patient's bed linens. The source was discovered under the pile of linens on the floor. The care provider retrieved the source with a pair of long handled forceps and placed the source into a shielded container that had been provided in the patient's room. The care provider then contacted the dosimetrist. The dosimetrist immediately contacted the authorized user physician and the radiation safety officer. The care provider stated that she had attempted to contact the authorized user and radiation safety officer first; however, the telephone numbers that were provided to her were in error. The delay in contacting the physician and radiation safety officer (approximately 30 minutes after discovery of the displaced source) did not appear to adversely affect the licensee's response to the incident or compromise the patient's health.

Upon their arrival, the physician and radiation safety officer determined that the afterloader in the left ovoid was empty and that the source had never been implanted. The displaced source was reloaded into the afterloader and the afterloader was replaced in the applicator at midnight on April 13, 1992, 7.5 hours after the initially intended implant time. The licensee prepared a revised treatment plan, to account for the 7.5 hours that the source was displaced, and determined that the final dose from that procedure to the treatment site would be 1383 rads (13.83 Gy), a difference of 8 percent.

The second procedure was performed on April 27 - 28, 1992, without incident, and delivered the prescribed radiation dose of 1500 rads (15 Gy). The final dose to the intended treatment site was 2883 rads (28.83 Gy) versus the prescribed dose of 3000 rads (30 Gy), a difference of 4 percent.

Initial Licensee Follow-up

The licensee immediately initiated an investigation of the incident. On April 15, 1992, the licensee's radiation safety committee met regarding the incident. The committee determined that since the dose to the intended treatment site differed only 8 percent from the prescribed dose, that a misadministration had not occurred. The committee concluded that the source had fallen on the floor of the patient's room during the improper loading of the afterloading devices by a licensee dosimetrist.

Licensee procedures called for the sources to be loaded in the afterloader devices in the cesium-137 storage room and then transported to the patient's room for loading into the applicator devices by the physician. Due to a miscommunication, however, the dosimetrist believed that the physician wanted the sources loaded into the afterloader device in the patient's room, and he did so. The licensee believed that the source fell to the floor, unbeknownst to the dosimetrist, during the loading of the afterloader devices. The committee concluded that the source was on floor for the duration of time that it was displaced. The dosimetrist was verbally reprimanded for not loading the afterloaders in the cesium-137 storage room. Other than loading the sources in the patient's room, it appears that the dosimetrist followed proper radiation safety procedures, with regard to shielding and handling equipment used. No further action was taken by the licensee regarding the incident.

Inspector Followup

After reviewing the committee's report of the incident, the inspector questioned the conclusions arrived at by the committee and requested additional information. Based upon a review of the additional information provided, it appears that the licensee's radiation safety committee and radiation safety officer did not evaluate the possibility that the source was displaced during implant and remained in the patient s bed for the duration of time it was displaced.

After comparing the results of area surveys conducted by the licensee after source implantation on April 13, 1992 and April 27, 1992, the inspector determined that it is unlikely that there was an unshielded 46 millicurie (1700 MBq) cesium-137 source located in the patient's room on April 13, 1992. The survey results were comparable in each case, and do not indicate any elevated or unusual radiation levels. Therefore, it appears unlikely that the dosimetrist's loading of the afterloader devices in the patient's room, although a poor practice, contributed to the incident. A more likely scenario involves displacement of the source during implant.

A review of the patient's chart, including the patient care provider's notes, indicated that after the displaced source was found, the patient stated that she had felt a small metal object fall down between her buttocks while the sources were being implanted earlier that day. The patient further stated that she had not mentioned it at the time because she thought that the physician knew what was happening. The committee was made aware of the patient's statements during their review, but discounted the statements due to possible influences of anesthetic on the patient.

Inspector interview of the patient's care provider by telephone on May 10, 1994 indicated that she had not observed the source at any time during her shift, which began at 3:00 p.m. She stated that she had been in the patient's room for approximately 5 minutes at least once each

hour. The care provider indicated that she was confident that the source was not on the floor at any time prior to her changing the patient's bed linens at 10:00 p.m. that evening.

It appears, based on the results of licensee surveys, patient comments to the care provider, and the care provider's recollection of the events, that the source may have fallen out of the ovoid afterloader during implant. That could occur if the physician tilted the source "bucket" at the end of the ovoid afterloader during implant. Because of the patient's large size, the authorized user physician may not have been able to observe the source fall out of the afterloader and drop between the patient's buttocks. In a worse case scenario, the source then remained proximal to the patient's posterior upper thigh for 7.5 hours. During the changing of the bed linens, the source fell onto the floor where it was discovered by the care provider.

Using a worse case scenario, the licensee estimates that the patient's thigh received approximately 1034 rads (10.34 Gy) for the 7.5 hours that the source was displaced. 10 CFR 35.2 defines a misadministration as a brachytherapy radiation dose involving, among other things, the wrong treatment site. The patient's posterior upper thigh was not the intended treatment site. Therefore, it appears that a misadministration did occur.

10 CFR 35.21(b)(1) requires, in part, that the licensee's radiation safety officer investigate accidents, misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary. 10 CFR 35.22(b)(5) requires, in part, that the licensee's radiation safety committee review quarterly all incidents involving byproduct material with respect to cause and subsequent actions taken.

In their review of the April 13, 1992 brachytherapy incident/ misadministration, the licensee's radiation safety officer and radiation safety committee did not adequately investigate the incident, in that they did not consider possible radiation doses to an unintended treatment site when they concluded that a misadministration had not occurred. After the inspection, the licensee reevaluated the April 13, 1992 incident and determined that a misadministration, involving a wrong treatment site, had occurred. The licensee made the required 24 hour notification to the NRC on May 5, 1994 and provided the required report on May 18, 1994. A copy of the May 18, 1994 report from the licensee is attached to this inspection report. The licensee also notified the patient and the patient's referring physician of the misadministration.

<u>The failure of the licensee's radiation safety committee and radiation safety officer to adequately investigate a possible misadministration, to include consideration of possible radiation doses to unintended treatment sites, constitutes a violation of 10 CFR 35.22 and 10 CFR 35.21</u>.

The licensee's preliminary corrective actions include placing a pillow under the pelvis of future patients to facilitate afterloader insertion, for those patients who are very large. In addition, investigations of similar incidents in the future will include an evaluation of possible radiation doses to unintended treatment sites when making a determination of whether a misadministration has occurred.

An NRC medical consultant, Melvin Griem, M.D., evaluated the medical aspects of the brachytherapy misadministration. His report dated June 9, 1994 is attached. Dr. Griem concluded that the dose to the patient's thigh, resulting from the misadministration, could result in late tissue reactions, consisting of dermal changes, telangiectasia, and induration.

One violation of NRC regulatory requirements was identified.

5. Notification and Reporting

10 CFR 35.33 requires, in part, that the licensee notify the NRC, the referring physician, and the patient, unless the referring physician determines that notifying the patient would be medically harmful to the patient, within 24 hours after discovery of a misadministration. 10 CFR 35.33 also requires, in part, that the licensee provide the NRC a written report of the misadministration within 15 days after discovery of the misadministration. Also, if the patient was notified, the licensee shall furnish a written report to the patient within 15 days after discovery of the misadministration.

The inspector determined, during a telephone interview of licensee personnel on June 24, 1994, that the licensee notified the referring physician and the patient on May 6, 1994. However, the licensee had not provided the required written report to the patient as of June 24, 1994. The licensee explained that an authorized user physician, who was not familiar with NRC reporting requirements, had been tasked with providing the patient and referring physician notifications. Due to an apparent oversight, the required written report was not provided to the patient. The licensee committed to providing the written report to the patient by June 27, 1994.

The licensee's failure to provide a written report to the patient within 15 days after discovery of a misadministration constitutes a violation of 10 CFR 35.33.

The licensee notified the NRC on May 5, 1994, the same day that it discovered the misadministration. The written report was provided to the NRC by letter dated May 18, 1994.

One violation of NRC regulatory requirements was identified.

6. Transportation

10 CFR 71.5 requires, in part, that a licensee who delivers licensed material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.475(i) requires that before each shipment of any radioactive materials package, the shipper ensure by examination or appropriate tests that external radiation and contamination levels are within the allowable limits.

Interviews of licensee nuclear medicine department staff indicated that packages containing residual and/or unused radiopharmaceuticals are not monitored for external contamination levels prior to being delivered to the nuclear pharmacy's carrier for transport to the pharmacy. The radiopharmaceuticals consist of microcurie to millicurie quantities of technetium-99m. The packages are shipped on a routine, daily basis. Licensee staff were not aware of the requirement to monitor for external contamination levels. The licensee was not aware of any instances in which the pharmacy notified it of excessive contamination levels being identified on packages shipped from the licensee to the pharmacy. The licensee committed to performing external contamination surveys immediately on all radioactive material packages shipped by it.

The licensee's failure to perform external contamination surveys on any radioactive materials packages prior to shipment constitutes a violation of 10 CFR 71.5 and 49 CFR 173.421.

One violation of NRC regulatory requirements were identified.

7. Other Areas Inspected

In addition to the above, the inspection included a review of the following program areas: training, retraining, and instructions to workers; facilities and equipment; materials; audits and inspections; radiological protection procedures; personnel radiation protection - external and internal; radioactive effluent and waste disposal; area surveys; posting and labeling; notifications and reports; and the licensee's implementation of the quality management program requirements contained in 10 CFR 35.32. No violations or concerns were identified within the other areas reviewed.

No violations of NRC regulatory requirements were identified.

8. Exit Summary

At the termination of the inspection, the inspector conducted an exit summary with those individuals denoted in Section 1 of this report. The summary included a discussion of the identified apparent violations, the licensee's proposed corrective actions, and the NRC Enforcement Policy. The inspector also discussed the NRC's notification and reporting requirements regarding misadministrations. The licensee did not identify any information reviewed during the inspection and proposed for inclusion in this report as proprietary in nature.

Attachments:

1) Licensee's letter dated May 18, 1994
2) Dr. M. Griem's report dated June 9, 1994

ATION ONCOLOGISTS
H.F. Johnson, M.D.
J.A. Hornback, M.D.
C. King, M.D.

ATION PHYSICIST
Hashemi, M.S.

Memorial
Regional Cancer Center
RADIATION ONCOLOGY

ACCREDITED BY:
American College of Radiology
American College of Surgeons

May 18, 1994

Licensee: Memorial Hospital
License Number: 13-18881-01

Wayne Slawinski
U.S. NRC Region III
801 Warrenville Road
Lisle, Illinois 60532-4351

Dear Mr. Slawinski:

This is a written report describing the misadministration that was reported to you on May 5, 1994.

On [redacted] a patient [redacted] was inserted with the Fletcher-Suite applicator for GYN implant (two ovoids and a tandem with total of 5 radioactive sources) and loaded with CS-137 sources by Dr. Kanta Desai, (prescribing physician) at 14:25 in Room 1034 of the Oncology floor.

At about 22:00, Candy Walters, RN and Tammy Melpolder, nursing aid, changed the sheet on the patient's bed and saw one of the sources on the floor. They contacted Denise Mead, a dosimetrist, and then picked up the source with a long forceps and placed it in the lead container (PIG). Denise arrived at the hospital at about 22:45 and she immediately notified Dr. Desai and the radiation safety officer, Alex Hashemi. After the arrival of Dr. Desai and Alex Hashemi, all sources in the patient were checked and it was determined that the source in the left ovoid was missing and never placed in the patient. Dr. Desai believes that the source came off when she was placing the left ovoid afterloader in the patient. At 12:00 AM, the source was placed in the patient and the room was surveyed for a possible leakage or contamination, but none was detected.

A new computerized treatment plan was done for this implant and it was determined that a dose of 1383 cGy was delivered to Point A instead of an intended dose of 1500 cGy, a deviation of 8%. The total intended dose was 3000 to cGy to Point A and the difference 117 cGy was made up for with the second implant.

The film badges for the two above mentioned nurses were sent to Landauer for emergency reading. The results were 10 mrem and minumum readings.

On April 15, 1992 the Radiation Safety Committee met regarding this incident. The commmittee concluded that no misadministration occurred to the patient's cancer area (cervix). The committee was so concerned about adequate delivery of the prescribed dose to the cancer region that failed to consider the possibility of unintended dose delivered to any other parts of the patient's body. We were made aware of such possibility by an NRC inspector during a routine inspection at our institution on May 4, 1994.

A meeting was held by the Radiation Safety Committee on May 5, 1994. The individuals present were: Alex Hasehmi (Physicist and Radiation Safety Officer), Dick Selle (Supervisor, Nuclear Medicine), Patrick Miller (Administrative Director), George Soper (Senior Vice-President), Becky Starzynski (Director of Risk Management and Occupational Safety), Russell Johnson, M.D. (Radiation Oncologist) and Billie Shook (Department Manager, Radiation Oncology). The committee concluded that the misplaced source was in the patient's bed next to her upper thigh for about 7.5 hours and fell on the floor during the changing of the patient's bed sheet, therefore, a misadministration was announced by the committee. The unintended dose to the patient's upper thigh was estimated to be 1034 cGy, as a result of the misplaced source. The dose to the patient's upper thigh would have been about 16 cGy during the first implant if the source was not misplaced.

The committee concluded that the major contributor to the cause of this incident was the patient's large size (326 lbs) which made it difficult to insert the afterloaders. The Radiation Safety Committee recommended that in situations where the patient is very large (greater than 300 lbs) more radiation workers should be involved in preparing the patient for source loading. A pillow may be inserted under the patient, to raise her pelvis to facilitate the source insertion.

Medical follow-up of the patient did not indicate any adverse effects to the patient shortly and long after the incident. Additional medical follow-up of the patient is planned.

The referring physician Dr. Gregory Sutton of Indianapolis was notified about the misadministration. He expressed no concern regarding notifying the patient. The patient and the Indiana State Board of Health were also notified about the misadministration.

Should you have any questions, please contact me at (219) 284-7461.

Sincerely,

Patrick Miller
Administrative Director
Department of Radiology and Radiation Oncology

PM/pls

Attachment #2

Medical Evaluation, Cs-137 sealed source, Brachytherapy, 4/13/92
License No.13-18881-01, Memorial Hosp. South Bend, IN. Pg 1

To: Ms. B. J. Holt ph708-829-9836
Chief, Nuclear Materials Inspection
U.S. Nuclear Regulatory Commission
Nuclear Materials Safety Branch Region III
801 Warrenville Rd.
Lisle, IL 60532-4351
FAX 708-515-1259

Deliver to → J. Cameron, 708-829-9833 2 Pages
Wayne Slawinski 629-9820
Roy Casniano 829-9836

From: M.L. Griem, M.D, Member ACMUI USNRC
Professor, Univ. of Chicago
FAX 312-702-0610
ph 312-702-6883

Re: License 13-18881-01 PNO -III-94-35

Misadministration due to dislodged Cs-137 radioactive sealed tube source resulting in exposure to skin of the thigh of the patient. Memorial Hospital (MH) South Bend, IN.
On April 13, 1992 the event occurred which was discovered on May 4, 1994 on a Region III inspection at MH.

Date: June 9, 1994 (case review and preliminary report)

Signed: M L Griem

Persons contacted: Alex Hashemi, M.S. Radiation Safety Officer (MH)

Summary: According to the licensee, the source came out and was found on the floor during the first of two brachytherapy treatments of a tumor of the pelvis. The second treatment was adjusted to take care of the under-dose of the first treatment. The source may have been close to the skin of the upper thigh for 7 hours. Dose estimate is 10.34 Gy to the skin as a result of this event. No adverse skin reaction has been reported during the initial evaluation period or at the March 1994 follow-up visit. In the middle of May, 1994 a detailed report was made to Region III, NRC. I have not seen that report.

Event description and dose estimate:

According to the preliminary notification, the source containing 44 mc Cs-137, (17 mg eq radium) came out of a brachytherapy application being used to treat a cancer in the pelvis. Treatment was to be in two applications. As this event occurred during the first procedure, the second treatment plan was modified to compensate and deliver an equivalent dose as initially planned. The source may have

been adjacent to the skin of the upper thigh delivering a dose to the skin of 10.34 Gy. The two nurses who cared for the patient had film badges which were checked. These showed exposures of less than 10 mr.

Medical Evaluation:
The tumor treatment should not be affected by the change in procedure. The follow-up of March 1994 shows no evidence of recurrence.

The dose to the bone marrow should not change significantly.

The main concern is the skin and the potential injury to the epidermis and dermis. A dry reaction may be seen at about 10 Gy in a single exposure. No reaction was observed in the initial evaluation. The skin of the patient is dark so that erythema may be difficult to detect. Hair loss could be seen if the area has growing hair. Late tissue reaction can be seen at this dose consisting of dermal changes, telangiectasia and induration. The condition may be progressive if observed, it could occur over a period of years. If this should occur, the lesion is a localized one and could be removed with plastic surgery. Follow-up at the March 1994 visit showed no skin change.

There is the statement " The licensee is attempting to notify the referring physician of the misadministration and a determination will be made, based on medical judgement, whether the patient will be notified."

Given that there still could be some late tissue reaction, should the patient be informed?

At this point I would like to evaluate the additional report of May 1994 made by MH.