U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-30954/94001(DRSS)

Docket No. 030-30954

License No. 34-16725-02 Category G Priority 3

Licensee: Good Samaritan Hospital
800 Forest Avenue
Zanesville, Ohio 43701

Inspection Conducted: January 19, 1994

Inspector: Roy A Caniano for 2/11/94
James L. Cameron Date
Radiation Specialist

Reviewed By: Roy A Caniano for 2/11/94
B. A. Holt, Chief Date
Nuclear Materials Inspection
Section 1

Approved By: Roy A Caniano 2/11/94
Roy A. Caniano, Chief Date
Nuclear Materials Safety Branch

Inspection Summary

Inspection on January 19, 1994 (Report No.030-30954/94001(DRSS))
Areas Inspected: This was a special, announced safety inspection conducted to review the circumstances of the brachytherapy misadministration event that occurred at the licensee's facilities on November 10, 1993. The inspection included a review of: organization; scope of program; training, retraining, and instructions to workers; radiological protection procedures; notifications and reporting; and the implementation of the licensee's Quality Management Program (QMP).
Results: Of the areas inspected, five apparent violations were identified and consist of failure to: (1) properly instruct supervised individuals in the principles of radiation protection appropriate to the individuals' use of byproduct material (Section 6); (2) properly follow QMP procedures (Section 7); (3) properly instruct individuals who provide care to patients undergoing implant therapy (Section 9); (4) post certain documents and/or notices required to be posted (Section 9); and (5) keep records of the instruction provided to individuals who provide care to patients undergoing implant therapy (Section 9).

DETAILS

1. Persons Contacted

*Dan Sylvester, Vice President, Professional Services
*Z. Kaka, M.D., Authorized User
*Ray Kaczur, M.S., Medical Physicist
*Dan Phelps, Manager, Radiation Oncology
*Shelley Heagen, Director, Quality Care & Risk Management
Eric Willis, Dosimetrist
Janine Carle, Radiation Therapy Technologist
Donna Porter, RN, Manager, Radiation Oncology Nursing
Linda Mayle, RN, Radiation Oncology Nursing
Adrea J. Bennett, Nursing Technologist, Radiation Oncology Nursing

*Denotes those individuals present at the exit meeting conducted on January 19, 1994.

2. Purpose and Scope of Inspection

This special, announced safety inspection was conducted to review the circumstances of a brachytherapy misadministration reported by the licensee on November 11, 1993.

The inspection included: (1) discussions with the licensee's authorized user, radiation therapy technician, dosimetrist, medical physicist, and patient care staff; (2) evaluation of the licensee's procedures, formal and informal, for implementing its brachytherapy program; (3) review of selected patient care and training records; and (4) evaluation of the licensee's implementation of its Quality Management Program (QMP).

3. Licensed Program and Inspection History

Good Samaritan Hospital (licensee or hospital) is authorized under NRC Byproduct Material License No. 34-16725-02 to possess and use any byproduct material identified in 10 CFR 35.100, 35.200, 35.300, 35.400, and 35.500 for medical use. The hospital performs approximately three to four iridium-192 implants each year. License No. 34-16725-02 was last renewed in its entirety on January 17, 1989, and was due to expire on January 31, 1994. The licensee submitted a timely request for renewal, which is currently under review by NRC Region III Materials Licensing staff.

The licensee was last inspected by the NRC on July 22, 1993 and December 21, 1990. Those inspections did not identify any violations or regulatory concerns.

4. Organization, Staffing, and Qualifications

The responsibility for the control and oversight of licensed activities at the hospital is vested in the licensee's president and CEO, who has

delegated the duties associated with that responsibility to Mr. Dan Sylvester, Vice President for Professional Services. The licensee's radiation safety officer, J. S. Safko, M.D., is responsible for the day-to-day oversight of the implementation of the licensee's radiation safety program. In addition to physicians, the licensee's radiation oncology department employs two part-time medical physicists, a dosimetrist, and several radiation therapy technologists.

The inspection identified an apparent violation regarding the instructions provided to supervised individuals. The apparent violation is fully described in Section 6 of this report.

5. Brachytherapy Misadministration Event - Background

On November 10, 1993, at approximately 2:18 p.m. local time, the licensee performed an iridium-192 therapeutic implant, which consisted of an endobronchial catheter to treat the patient's left bronchial stump for recurrent lung cancer. The radioactive implant included ten seeds encased in a single nylon ribbon and each seed contained approximately 1.5 millicuries (55.5 MBq) of iridium-192. The total prescribed dose was 6000 rads (cGy) at 0.5 centimeters from the sources.

Normally, the licensee's dosimetrist and one of the two consulting medical physicists are the only individuals involved in the actual implant procedure; however, on this occasion, the dosimetrist indicated that he was busy with other duties and one of the radiation therapy technicians requested that she be allowed to substitute for him. Although it appears that the physicist and dosimetrist agreed to this change in personnel, the authorized user was not notified.

The radiation therapy technologist verified the patient's identity and then requested that the physicist allow her to implant the sources in order to gain experience in the procedure, to which the physicist agreed. The technologist inserted the ribbon into the catheter until she felt resistance and deduced that the ribbon was at the end of the catheter. The physicist then attempted to push the ribbon in further, and feeling resistance, he deduced also that the sources were at the end of the catheter.

Following normal licensee procedure, the physicist requested that the attending nurse order a "stat" chest x-ray in order to verify source position. The physicist and the technologist returned to the radiation oncology department and performed other duties until leaving the licensee's facilities at the end of their normal work day.

The "stat" radiograph was completed at approximately 3:00 p.m. and the film was placed on the authorized user's desk for her review and approval. Upon returning to her desk at approximately 5:00 p.m., the authorized user reviewed the film, but could not visualize the seed positions. The authorized user ordered two additional radiographs using different techniques. In the second radiograph, completed at approximately 6:00 p.m., the authorized user located the seeds in

patient's throat and removed the ribbon at 6:05 p.m. The physician successfully re-inserted the ribbon to the proper location at approximately 6:55 p.m. and the source location was verified by another radiograph. The treatment time was recalculated to deliver the total original intended dose and the treatment was completed without further difficulty.

The physician verbally notified the patient of the misadministration following the successful reinsertion of the source ribbon. Licensee management, the physicist, and the patient's referring physician were notified the next day, as was the NRC Operations Center. The licensee submitted its written report to NRC Region III on November 15, 1993. A written report was provided to the patient, which described the incident and indicated that the NRC report could be obtained from the licensee.

6. Brachytherapy Misadministration Event Evaluation

The licensee's evaluation of the incident determined that the catheter developed a crimp at the level of the patient's larynx, which prevented the ribbon from being fully inserted to its proper location in the patient's bronchial stump. During inspector interviews, the physician stated that it would be difficult for an inexperienced person to know the difference between a properly seated ribbon and when ribbon insertion was impeded by a crimp in the catheter.

10 CFR 35.25(a)(1) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user to instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material.

Inspector interview of the dosimetrist indicated that his normal procedure prior to iridium-192 ribbon implants involved comparison of the ribbon and the catheter in order to determine when the ribbon was properly seated within the catheter. According to the dosimetrist, this practice was relayed to him by a former licensee medical physicist and had been employed by the dosimetrist for the last four years. The dosimetrist indicated that this was a "rule of practice" employed by him and was not a formal procedure implemented by the licensee.

Inspector interview of the medical physicist indicated that he had attended six iridium-192 implants previously, but had never physically implanted a ribbon. The physicist further stated that he was not aware of the dosimetrist's "rule of practice" involving comparison of the ribbon and catheter lengths prior to implantation.

Inspector interview of the radiation therapy technologist indicated that she had attended one other iridium-192 implant, approximately two years previous to the November 10, 1993 incident, but had never physically implanted an iridium ribbon. She stated that her "hands-on" brachytherapy experience was limited to loading gynecological implants using cesium-137 sealed sources in rigid metal tandem and ovoid

applicators. As with the physicist, the technologist indicated that she was not aware of the dosimetrist's "rule of practice" involving comparison of the ribbon and catheter lengths prior to implantation.

The licensee's failure to instruct the medical physicist and radiation therapy technologist in the principles of radiation safety appropriate to the implantation of iridium-192 ribbons, including, but not limited to, procedures used to ensure the proper implantation of source ribbons, is an apparent violation of 10 CFR 35.25(a)(1).

The licensee estimates that, due to the mispositioned source, the patient's larynx received a radiation exposure dose of approximately 282 rads (cGy) at a distance of 0.5 centimeters from the sources. The licensee does not expect any clinically significant effects to normal patient tissues due to the misadministration.

An NRC medical consultant, Melvin Griem, M.D., evaluated the medical aspects of the brachytherapy misadministration. His report dated December 17, 1993, is attached. Dr. Griem concluded that the dose to the larynx and surrounding area, resulting from the misadministration, is not clinically significant.

One apparent violation of NRC regulatory requirements was identified.

7. Evaluation of the Implementation of the Written QMP

The licensee submitted its written QMP to the NRC with a letter dated January 21, 1992, and provided a statement that the program had been implemented in accordance with 10 CFR 35.32(f). The program, as submitted, appears to meet the requirements in 10 CFR 35.32.

This inspection included a review of the licensee's implementation of its QMP with regard to its brachytherapy program. 10 CFR 35.32(a) requires the licensee to establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. 10 CFR 35.32(a)(4) requires that the licensee's quality management program include written policies and procedures to meet the objective that each administration is in accordance with the written directive. Item 6 of the licensee's QMP states, in part, that the licensed user or designee will use radiographs as a basis of verifying the position of the brachytherapy sources. Item 8 of the licensee's QMP states, in part, that after insertion of the temporary implant brachytherapy sources, an authorized user will **promptly** (emphasis added) record the actual loading sequence of the radioactive sources implanted and sign or initial the patient's chart or other appropriate record. According to the licensee, radiographs are used to record the actual loading sequence of the implanted radioactive sources and to verify source positioning. Failure of the authorized user to promptly review the radiograph to verify the location of the iridium-192 seeds is an apparent violation of

10 CFR 35.32(a). Had licensee personnel located the authorized user and provided the radiograph for her review, the mispositioned ribbon may have been identified earlier.

One apparent violation of NRC regulatory requirements was identified.

8. Licensee Corrective Actions

The licensee's corrective actions included: (1) formalizing the dosimetrist's "rule of practice" regarding comparison of the ribbon and catheter lengths prior to source implantation in order to ensure that the ribbon is properly seated; (2) providing training to all radiation therapy technologists and each medical physicist in the new procedure; (3) requiring that the authorized user physically implant source ribbons; (4) requiring that each radiation therapy technologist receive hands-on training and instruction in source implantation; and (5) requiring that the "stat" post-insertion radiograph be hand carried to the prescribing physician for evaluation as soon as possible to determine proper source placement.

9. Other Areas Inspected

The inspection included a review of the training and instruction provided to radiation oncology nurses who may provide care to patients who are undergoing implant therapy.

10 CFR 35.410(a) requires, in part, that the licensee provide radiation safety instruction to all personnel caring for the patient undergoing implant therapy. The instruction must describe: (1) the size and appearance of the brachytherapy sources; (2) the safe handling and shielding instructions in case of a dislodged source; (3) the procedures for patient control; (4) the procedures for visitor control; and (5) procedures for notification of the radiation safety officer if the patient dies or has a medical emergency. 10 CFR 35.410(b) requires, in part, that the licensee retain a record of individuals who have received the instruction.

Interviews of nursing management and personnel and a review of instruction records indicated that not all patient care staff who provided care to the implant patient from November 10 through 13, 1993, had received the required instruction. Furthermore, the licensee's records of instruction did not include all patient care staff who had received the instruction. In order to facilitate instruction, the licensee had developed a training video for viewing by all patient care staff. The instruction video included all of the information required by 10 CFR 35.410(a) in addition to instruction required by 10 CFR 19.12.

The inspector's review determined that three individuals who provided implant patient care on November 11-13, 1993, had not viewed the training video and had not been otherwise instructed. Furthermore, licensee records of instruction did not indicate that two other individuals who tended to implant patients had been provided the

required instruction. However, inspector interviews of both individuals determined that they had received the instruction. The licensee's failure to provide instruction to individuals who provided care to a patient undergoing implant therapy is an apparent violation of NRC regulatory requirements. The licensee's failure to keep records of instruction for all individuals who provide care to patients undergoing implant therapy is an apparent violation of NRC regulatory requirements.

The licensee committed to providing the required instruction prior to the next implant therapy and to updating its records of instruction as soon as practicable.

The inspector also reviewed the licensee's posting of notices required by 10 CFR 19.11, with regard to patient care staff. 10 CFR 19.11 requires that each licensee post current copies of 10 CFR Parts 19 and 20; the license, license conditions, or documents incorporated into the license by reference, and amendments thereto; and the operating procedures applicable to licensed activities. If posting of those documents is not practicable, the licensee may post a notice which describes the document and states where it may be examined. In addition, the licensee must post Form NRC-3. The documents, notices, or forms posted must appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies. A review of patient care areas determined that none of the required documents, notices, or forms were posted as required. In addition, none of the patient care staff interviewed by the inspector could remember ever observing any of the required documents, notices, or forms. The licensee's failure to post any of the required documents, notices, or forms is an apparent violation of requirements. The licensee committed to posting the required documents, notices, and forms as soon as practicable.

Three apparent violations of NRC regulatory requirements were identified.

10. Exit Summary

The inspector conducted an exit summary with those individuals denoted in Section 1 of this report. The exit summary included a review of the preliminary inspection findings, including the identified apparent violations and concerns, the licensee's corrective actions, and the NRC Enforcement Policy. The licensee did not identify any of the information provided during the inspection and proposed for inclusion in this report as proprietary in nature.

Attachment: Report from Melvin Griem, M.D.,
dated December 17, 1993

NRC Reg.III, License # 34-16725-02 Docket # 030-30954 page 1
Good Samaritan Med. Ctr. Zanesville,OH Ir-192 Bronchus Brachyth

To: John H. Martin
Regional Administrator
NRC Reg. III
801 Warrenville Rd.
Lisle, IL 60532-4351 FAX 708-515-1259
cc: B. J. Holt ph 708-829-9836
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From: Melvin L. Griem, MD, MS (physics)
University of Chicago, ACMUI NRC
phone discussion 11/21/93
preliminary evaluation 11/25/93
phone evaluation with Dr. Z. S. Kaka 12/9/93

Report date: 12/17/93

Re: Brachytherapy Implant of a recurrent carcinoma of the lung involving the stump of the left bronchus.

1. The event and an opinion on the total dose to the target area.
10 seeds of Ir-192 in a single nylon ribbon were to be placed thru the trachea by way of a catheter. The insertion procedure was done at 2:18 PM on 11/10/93 and an immediate (stat) portable chest x-ray was ordered to confirm the position of the seeds in the chest. There was some delay in getting the x-ray procedure however by 5 PM the films obtained did not show the seeds. Additonal films were obtained and by 6:05 Pm it was determined that the seeds were at the level of the larynx. Further manipulation helped advance the seeds to the planned site and the original plan of treatment was carried out.

The planned tumor dose was delivered to the braonchial stump as planned once the placement of the 10 sources was accomplished. The outcome as far as tumor control should be as planned. In this siutation, such a recurrence has na high probability of having additional tumor at other sites and this procedure may provide local control at the site of this documented recurrence only. Therefore, the overall prognosis remains guarded.

2. Assessment of the dose to the larynx and surrounding area. The dose estimates for the 3 hour 47 minute exposure are a maximum of 2.82 Gy at 0.5 cm from the center of the sources. This dose to the vocal cords is well tolerated. The dose to the surrounding thyroid might be 1 Gy maximum and this dose is also well tolerated. NO thyroic disfunction should be seen. The vascular structures in the neck and the bone and connective tissue are not at risk for either early or long term effects. I

ma not concerned about radiation carcinogenesis in the production of a tumor of the thyroid. The volume of bone marrow at risk is minimal and received only a modest dose. The radiation oncologist reports that the patient is doing very well. There have been no changes in the voice either at the early stage, several days after the event are at this intermediate time period about 1 month afterward when some changes would be observed.

If this patient has total tumor control as the result of this procedure the followup should include an indirect laryngoscopy which is an easy procedure which takes a few minutes in the outpatient clinic. This evaluation could be added to the standard history and physicial examination which the patient recieves in the follow-up visits.