U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-12231/92001(DRSS)

License No. 13-17124-01 Category G Priority 2

Licensee: Community Hospital South
1402 East County Line Road South
Indianapolis, IN 46227

Inspection Conducted: November 17, 1992

Inspector: Thomas F. Young 2-12-93
Thomas F. Young Date
Radiation Specialist

Reviewed By: B. J. Holt 2/12/93
B. J. Holt, Chief Date
Nuclear Materials Inspection
Section 1

Approved By: B. J. Holt for 2/12/93
Roy J. Caniano, Chief Date
Nuclear Materials Safety Branch

Inspection Summary

Inspection on November 17, 1992,(Report No.030-12231/92001 (DRSS))
Areas Inspected: This was a routine, unannounced safety inspection conducted to assess the adequacy of the licensee's overall NRC-licensed operation authorized under a limited medical license. The inspection included a review of: organization and management controls, training and instructions to workers, facilities and equipment, personnel radiation exposure monitoring, area survey procedures, sealed source leak tests and inventories, and transportation and waste disposal.

Results: Of the areas inspected, numerous apparent violations were identified including failure to:

- have an individual serve as the Radiation Safety Officer,
- use licensed material in areas authorized by the license,
- convene the Radiation Safety Committee at quarterly intervals,
- establish a quorum at the Radiation Safety Committee meetings,

- review the radiation safety program annually,
- review aspects of the ALARA program,
- provide training to employees,
- check ventilation rates at six month intervals in rooms where radioactive gas is used,
- calculate the amount of time needed after a spill of radioactive xenon-133 gas to reduce the concentration in the room to the regulatory limit,
- post the safety measures to be instituted in case of a spill of a radioactive gas at the area of use,
- possess appropriate radiation detection survey equipment,
- conduct area surveys at the end of the day after use of licensed material,
- conduct surveys for removable contamination each week,
- record removable contamination in disintegrations per minute per 100 square centimeters,
- sign records of daily and weekly surveys on a monthly basis,
- sign records of dose calibrator tests for accuracy, linearity, and geometry dependence,
- sign records of sealed source leak tests and sealed source inventories,
- record the date on which byproduct material was placed in storage for decay-in-storage prior to release to ordinary trash, and record the background dose rate on the date of disposal, and
- record the members who are absent from the meeting in the Radiation Safety Committee minutes.

In addition to the numerous apparent violations, an area of concern was identified. The Radiation Safety Committee members appear to be unfamiliar with pertinent NRC regulations and the conditions of the license, including the model procedures of Regulatory Guide 10.8, Revision 2. The model procedures were to be established and implemented to control the daily operations of NRC-licensed activities. In addition to the aforementioned area of concern, the NRC is also concerned with the failure to implement adequate corrective actions for three violations identified during the previous inspection conducted on February 16, 1989.

These apparent violations and the area of concern are indicative of a management breakdown of the radiation safety program for licensed material.

DETAILS

1. Persons Contacted

** Debra Rasper, Vice President for Hospital Operations
* Jerry Buchman, Director of Medical Imaging
* Susan Joseph, Certified Nuclear Medicine Technologist
Sue Harley, Certified Nuclear Medicine Technologist

* denotes attendance at the exit meeting held on November 17, 1992.
** denotes attendance at the exit meeting held on November 17, 1992, and telephone contact on January 29, 1993.

2. Purpose and Scope of Inspection

This routine, unannounced, safety inspection was conducted to assess the adequacy of Community Hospital South's NRC-licensed activities that are authorized under a limited scope medical license.

The inspection included: (1) discussions with the licensee's management representatives, Radiation Safety Officer (RSO), and nuclear medicine staff; (2) evaluation of facilities and equipment; (3) independent measurements of radiation exposure rates in the nuclear medicine imaging area and the nuclear medicine hot lab; and (4) review of selected records.

3. Summary of Licensed Program and Inspection History

Community Hospital South is authorized to possess and use byproduct material specified in 10 CFR 35.100, 35.200 (except Tc-99m generators), 35.300, and 35.400, for medical uses. The licensee conducts a monthly average of 130 diagnostic nuclear medicine procedures consisting primarily of Tc-99m labeled radiopharmaceuticals. The licensee receives single unit doses of licensed materials from a local radiopharmacy. The licensee uses xenon-133 gas for lung ventilation studies on two or three occasions per week. Nuclear medicine therapy treatments with iodine-131 for hyperthyroidism are conducted on an out patient basis for about five or six cases per year. The licensee does not conduct other nuclear medicine therapy treatments, and does not possess or use brachytherapy sources. The nuclear medicine staff consists of 2.5 full time equivalence for the nuclear medicine technologist positions, and about 1.5 full time equivalence for the nuclear medicine physician positions.

The NRC inspection conducted on February 16, 1989, identified five violations involving failure to: (1) conduct dose calibrator linearity tests over the range between the highest patient dosage and 10 microcuries, (2) survey storage areas weekly, (3) appoint a representative from the nursing service to serve as a member of the Radiation Safety Committee, (4) conduct annual refresher training for employees, and (5) measure at six month intervals the ventilation rates in rooms where xenon-133 gas is used. Corrective action for the above

mentioned items was evaluated during this inspection. Items (1) and (2) appear to be corrected. Items (3), (4), and (5) appear to be unsatisfactory as detailed elsewhere in this report.

4. Organization and Management Controls

Overall responsibility for the conduct of NRC-licensed activities is vested in the hospital administrator. To oversee the use of byproduct material and implement the radiation safety program, the licensee has established a Radiation Safety Committee (RSC) and appointed a Radiation Safety Officer (RSO) as required.

License Condition No. 11 names a specific individual, Thomas G. Belt, M. D., as the licensee's Radiation Safety Officer. The inspector learned that as of October 1, 1992, Dr. Belt was re-assigned to another area hospital and as such no longer served as the licensee's RSO. Although another physician was available and qualified to fill the RSO position, the licensee did not transfer the RSO responsibility to that individual or any other individual. Failure of the licensee to have an individual serve as the Radiation Safety Officer is an apparent violation of License Condition No. 11.

The inspector reviewed the RSC minutes for the period of February 20, 1990, to November 12, 1992. 10 CFR 35.22(a)(2) requires that the Radiation Safety Committee meet at least quarterly. The Radiation Safety Committee met on the following dates that indicate greater than quarterly meeting intervals: January 17, 1991, July 31, 1991, January 31, 1992, and July 23, 1992. Failure of the licensee's RSC to meet at least quarterly is an apparent violation of 10 CFR 35.22(a)(2).

In addition, 10 CFR 35.22(a)(3) requires that to establish a quorum and conduct business, at least one half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative. On July 23, 1992, and November 12, 1992, the licensee's Radiation Safety Committee met and conducted business and the licensee's Radiation Safety Officer was not present. Failure of the licensee to have its RSO present at RSC meetings is an apparent violation of 10 CFR 35.22 (a)(3).

Also, 10 CFR 35.22(a)(4)(iii) requires that the minutes of each Radiation Safety Committee meeting include the members absent from the meeting. The minutes reviewed by the inspector did not indicate the members absent (RSO, nursing service representative) from RSC meetings. Failure to record in the RSC minutes the members who were absent from the meetings is an apparent violation of 10 CFR 35.22(a)(4)(iii).

10 CFR 35.20(c) requires the licensee to develop and implement a written ALARA program that must include, in part, reviews of: (1) summaries of the types and quantities of uses of byproduct material, and (2) continuing education and training sessions for all personnel who work with or in the vicinity of byproduct material. 10 CFR 35.22(a) requires, in part, that the licensee's RSC meet at least quarterly and the minutes

of each RSC meeting must include the ALARA program reviews described in 10 CFR 35.20(c). From a review of the RSC minutes and discussions with the licensee it was determined that although the licensee has an ALARA program, there has not yet been any review of the aforementioned aspects of the program. Failure of the licensee to review the ALARA program is an apparent violation of 10 CFR 35.20(c).

During the previous NRC inspection, a violation of 10 CFR 35.22(a)(1) was cited because the licensee failed to appoint a member to represent the nursing service. Although the nursing service representative was appointed in March 1989, the nursing service representative has not attended RSC meetings from February 15, 1990, to November 12, 1992. Lack of attendance of RSC meetings by this member is an area of concern.

10 CFR 35.22(b)(6) requires the licensee's RSC to review annually, with the assistance of the RSO, the radiation safety program. A review of the effectiveness of the licensee's oversight indicated that the RSC had not reviewed the radiation safety program annually from February 1990 to November 1992. Failure of the RSC to review the radiation safety program annually is an apparent violation of 10 CFR 35.22(b)(6).

The licensee contracts a medical physics consultant to perform limited radiation safety services, e.g. testing of equipment and reviewing records etc. The licensee's consultant audit reports are sent to the RSO and contain the results of tests and inventories, and additional recommendations for the RSC and RSO, but are not intended to substitute for the RSC and RSO review of the radiation safety program.

Six apparent violations and one area of concern were identified.

5. Training and Instruction to Workers

The NRC inspector verified implementation of the licensee's training commitment by discussing elements of the radiation safety program with the RSC members and the nuclear medicine staff. It was apparent that the RSC members were unfamiliar with pertinent NRC regulations and the conditions of the license, including the model procedures of Regulatory Guide 10.8, Revision 2. Since the RSC has responsibilities for implementation of the radiation safety program, this is an area of concern and an apparent weakness in the licensee's radiation safety program. The nuclear medicine staff seemed to be familiar with general radiation safety procedures, but seemed to be unfamiliar with specific NRC requirements.

10 CFR 35.21(a) requires, in part, that the licensee, through the RSO, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for evaluating implementation of the radiation safety program are described in the licensee's application dated February 29 1988, and were approved by License Condition No. 13.

The licensee's application dated February 29, 1988, states in Item 8 that the licensee will establish and implement the model training program that was published in Appendix A of Regulatory Guide 10.8, Revision 2.

Appendix A of Regulatory Guide 10.8, Revision 2, "Model Training Program," requires the licensee to instruct personnel, including ancillary personnel, in specified subjects at the following intervals: (1) before assuming duties with or in the vicinity of, radioactive material, (2) during annual refresher training, and (3) whenever there is a significant change in duties, regulations, or the terms of the license. The inspector learned that training was not conducted by the licensee on the following occasions: (1) before the nuclear medicine technologist first assumed duties on or about July 1, 1992, and (2) from February 1990 to November 1992 no annual refresher training was provided to personnel. Failure of the licensee to provide training to all personnel on the occasions mentioned above is an apparent violation of 10 CFR 35.21(a), and is a repeat violation.

One apparent violation and one area of concern were identified.

6. Facilities and Equipment

10 CFR 35.220 requires, in part, the licensee to possess a portable radiation detection (low range) survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour. The low range survey instrument in possession of the licensee as of the date of this inspection was designed to detect rates over the range of 0.1 millirem per hour to 50 millirem per hour. Failure of the licensee to possess an appropriate low range survey instrument is an apparent violation of 10 CFR 35.220.

Although the licensee did not possess the appropriate low range survey instrument, according to the records reviewed by the inspector and the discussions held with the nuclear medicine technologist, the low range survey instrument in possession of the licensee was calibrated and operable at all times. The nuclear medicine technologists appeared to be familiar with the typical radiation exposure rate values and the survey procedures, and according to the technologist no emergency had occurred, e.g. radioactive spills or unshielded radiation. The licensee also possessed a portable radiation measurement (high range) survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour that is required by 10 CFR 35.220.

During the November 17, 1992, inspection the licensee possessed a Capintec Model 7 dose calibrator. 10 CFR 35.50(e) requires the licensee to retain records of specific dose calibrator tests, including accuracy, linearity, and geometry dependence, and also requires that these records include the signature of the RSO. The NRC inspector reviewed the licensee's consultant reports that indicated acceptable results of the dose calibrator tests, as specified in 10 CFR 35.50. However, the RSO's signature was not included with the results of any of the required dose

calibrator tests. Failure of the RSO to sign the dose calibrator test results is an apparent violation of 10 CFR 35.50(e).

The inspector visited the licensee's nuclear medicine imaging room where radiopharmaceuticals are administered to patients, and the nuclear medicine hot lab where patient dosages are received, stored, and assayed prior to administration to the patient. During the tour the inspector performed independent radiation exposure rate measurements throughout the licensee's facilities. The measurements confirmed the values recorded in the records retained by the licensee, with all levels well below 10 CFR Part 20 limits. Facilities and equipment were found to be adequate and as stated in the licensee's application for the NRC license, except that the licensee added a second imaging system and a second imaging room.

As mentioned in Section 2 of this report, the licensee performs about two or three xenon-133 studies per week. 10 CFR 35.13(e) requires, in part, that the licensee apply for and must receive a license amendment before it adds to or changes the areas of use identified in the licensee's application dated February 29, 1988. The licensee stated that from about April 1, 1992, xenon-133 gas was routinely used in an adjacent room that was not described to NRC in the licensee's application dated February 29, 1988. The licensee did not request an amendment of the license to authorize this imaging room. Failure of the licensee to apply for and receive a license amendment prior to use of xenon-133 gas in an adjacent imaging room is an apparent violation of 10 CFR 35.13(e). The licensee indicated that use of xenon-133 in the adjacent imaging room would be discontinued, with future xenon-133 procedures performed in the authorized location.

10 CFR 35.205(e) requires, in part, that the licensee measure each six months the ventilation rates available in areas where xenon-133 gas is used. Records in possession of the licensee indicate the licensee used radioactive xenon-133 gas in Imaging Room No. 1 and did not measure the ventilation rates therein each six months from July 31, 1991, to November 17, 1992. Failure of the licensee to perform ventilation checks at six month intervals is an apparent violation of 10 CFR 35.205(e), and is a repeat violation.

10 CFR 35.205(c) requires, in part, that before receiving, using, or storing a radioactive gas, the licensee calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit listed in 10 CFR Part 20, Appendix B. From about April 1 to November 17, 1992, the licensee used radioactive xenon-133 gas in an imaging room and the licensee did not calculate the amount of time needed after a spill to reduce the concentration therein to the regulatory limit. Failure of the licensee to perform the required calculation of clearance time for this imaging room is an apparent violation of 10 CFR 35.205(c).

10 CFR 35.205(d) requires, in part, that a licensee post the safety measures to be instituted in case of a spill of a radioactive gas at the

area of use. On the date of this inspection, it was noted that no such posting was placed in the imaging room where xenon-133 gas was used by the licensee from about April 1 to November 17, 1992. Failure of the licensee to post the safety measures in the second imaging room is an apparent violation of 10 CFR 35.205(d).

The inspector learned that the xenon-133 effluent trapping unit is checked monthly by the licensee and that the filter was changed in February and September, 1992. The technologist indicated that no spill or emergency occurred during the period when xenon-133 was used in the second imaging room. During the inspection, the licensee indicated that use of xenon-133 gas in the second imaging room would be discontinued and the lung ventilation procedures would be conducted in Imaging Room No. 1, only.

Six apparent violations were identified.

7. Area Survey Procedures

10 CFR 35.70(a) requires the licensee to survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered. The inspector learned that area surveys are always performed at the beginning of each day's use rather than at the end of the day. Failure to perform daily surveys at the end of the day is an apparent violation of 10 CFR 35.70(a). Review of the records of daily surveys revealed no radiation dose rates in excess of 10 CFR Part 20 limits, and the technologist indicated that no unusual incident had occurred, e.g. a spill of radioactivity or unshielded radiation.

10 CFR 35.70(e) requires the licensee to survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored. Records in possession of the licensee indicated no survey for removable contamination in these areas during the weeks of October 1 and November 4, 1992. Failure of the licensee to conduct surveys for removable contamination once each week is an apparent violation of 10 CFR 35.70(e).

10 CFR 35.70(h) requires, in part, that a licensee retain records of each contamination survey required by 10 CFR 35.70. The records must include, in part, the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters. The records reviewed by the inspector expressed the removable contamination in milliroentgen per hour. However, no removable contamination was indicated on the survey samples. Failure of the licensee to record the results of weekly surveys for radioactive contamination in the proper units is an apparent violation of 10 CFR 35.70(h).

10 CFR 35.21(a) requires the licensee, through the RSO, to ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures for area surveys are

described in the application dated February 29, 1988, and were approved by License Condition No. 13.

The licensee's application dated February 29, 1988, states in Item No. 10.12 that the licensee will establish and implement the model procedure for area surveys that was published in Appendix N of Regulatory Guide 10.8, Revision 2.

Appendix N of Regulatory Guide 10.8, Revision 2 ,"Model Procedure for Area Surveys," requires the licensee's RSO to review and initial the survey records at least monthly and also promptly in those cases in which action levels were exceeded. Records in possession of the licensee and conversations with the technologist indicated that as of November 17, 1992, the RSO did not routinely review and sign or initial the records. Failure of the licensee, through its RSO, to review and sign or initial the survey records on at least a monthly basis is an apparent violation of 10 CFR 35.21(a).

Four apparent violations were identified.

8. Sealed Source Leak Tests and Inventories

10 CFR 35.59(d) and (g) require the licensee to maintain records of sealed source leak tests and inventories that include the signature of the RSO. The NRC inspector reviewed licensee consultant reports that indicate the results of sealed source leak tests and physical inventories. The reports are received and reviewed by the RSO, however, the RSO's signature is not included with the results of sealed source leak tests and physical inventories. Failure of the RSO to sign the results of sealed source leak tests and physical inventories is an apparent violation of 10 CFR 35.59(d) and (g).

One apparent violation was identified.

9. Transportation and Waste Disposal

The licensee returns contaminated syringes containing residual or unused licensed material to the local radiopharmacy, in accordance with the instructions provided to the licensee by the radiopharmacy. The licensee maintains a shielded cubicle for decay-in-storage of contaminated items e.g. gloves, gauze pads, sharps, etc.

10 CFR 35.92(b) requires, in part, the licensee to retain records of byproduct material decay-in-storage prior to disposal in ordinary trash. The records must include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal. The records reviewed by the inspector did not include the date on which the byproduct material was placed in storage, and the background dose rate. The recorded dose rate measured at the surface of each waste container indicated very low

values that are similar to a background dose rate. It is likely that decay-in-storage was adequate to prevent release of radioactivity in ordinary trash. Failure to retain complete records of byproduct material decay-in-storage prior to disposal in ordinary trash is an apparent violation of 10 CFR 35.92(b).

One apparent violation was identified.

10. Other Areas Inspected

In addition to the specific areas described in this report, the inspector also reviewed the licensee's receipt records and current inventory of radioactive material, procedures for ordering and receiving and safely opening packages of radioactive material, survey records for incoming packages, personnel radiation dosimetry program, notification and reports to workers, misadministrations, bulletins and information notices received from NRC, and proper posting and labeling.

No violations of NRC requirements were identified.

11. Exit Meeting

On November 17, 1992, the inspector held an exit meeting with the individuals noted in Section 1 of this report. The preliminary inspection findings, NRC Enforcement Policy, and the licensee's preliminary corrective actions were discussed. On January 29, 1993, the apparent violations were discussed between Mr. Roy Caniano of the NRC and Debra Rasper, Vice President of Operations for the licensee.