U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-09964/94001(DRSS)

Docket No. 030-09964

License No. 13-15882-01 Category G Priority III

Licensee: The Community Hospital
901 MacArthur Boulevard
Munster, IN 46321

Inspection Conducted: May 2 and 3, 1994

Inspector: James L. Cameron 5/26/94
James L. Cameron
Radiation Specialist
Date

Reviewed By: W. J. Shamit for Holt 5/26/94
B. J. Holt, Chief
Nuclear Materials Inspection Section 1
Date

Approved By: Roy J. Caniano 5/27/94
Roy J. Caniano, Chief
Nuclear Materials Safety Branch
Date

Inspection Summary

Inspection on May 2 and 3, 1994 (Report No. 030-09964/94001(DRSS)
Areas Inspected: This was a routine, unannounced safety inspection 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 inspector's review and findings in the areas of: organization and management controls; scope of program; internal audits and inspections; radiological protection procedures; and the licensee's development and implementation of a Quality Management Program (QMP) as required by 10 CFR 35.32. Other program areas reviewed and not discussed in this report include: training, retraining, and instructions to workers; facilities and equipment; materials; personnel radiation protection - external and internal; radioactive effluents and waste disposal; area surveys; posting and labeling; and notifications and reports.
Results: Two apparent violations were identified and consist of failure to: (1) establish and implement a written quality management program for all pertinent diagnostic and treatment modalities (Section 6); and (2) wear gloves during the handling and injection of a radiopharmaceutical patient dosage (Section 5).

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Two concerns were also noted. These pertained to the oversight of licensed activities and the licensee's audit/self-assessment programs for quality management matters.

DETAILS

1. Persons Contacted

*Eric Zickgraf, M.S., Radiation Safety Officer
*Wayne Wcislo, Manager, Nuclear Medicine Department
*John Gorski, Director of Ancillary Services
Jackie Fengya, Nuclear Medicine Technologist
Caroline Dyer, Nuclear Medicine Technologist
*Domenico Lazzaro, M.D., Authorized User and Director, Pathology Department and Nuclear Medicine
*Sue Boulden, Director, Diagnostic and Therapeutic Radiology
*Andrej Zajac, M.D., Authorized User

*Denotes those individuals present during the exit summary conducted on May 3, 1994.

2. Program Summary and Inspection History

The Community Hospital (licensee or 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 450 diagnostic studies per month with unit dosages of radiopharmaceuticals supplied by a local nuclear pharmacy. In addition, the nuclear medicine department administers approximately 20 iodine-131 patient dosages each year in individual quantities that are less than 30 millicuries (1100 mBq).

The radiation oncology department administers approximately 100 HDR treatments each year using the remote afterloader, in addition to one cesium-137 and two iridium-192 manually afterloaded temporary brachytherapy treatments each year. The licensee has performed one permanent implant using palladium-103 seeds since 1993. The radiation oncology department also administers approximately two iodine-131 thyroid carcinoma (quantities greater than 30 millicuries (1100 mBq)), one phosphorus-32, and six strontium-89 radiopharmaceutical therapy dosages each year.

The NRC last inspected the licensee's program on February 27, 1991. No violations of NRC requirements were identified during that inspection.

No violation of regulatory requirements was identified.

3. Organization and Management Controls

The overall responsibility for licensed operations rests with the hospital's Administrator. The licensee's radiation safety officer, who is also the licensee's radiation oncology medical physicist, is responsible for daily oversight of the radiation safety program. The radiation safety officer estimates that he spends approximately 10 percent of his time fulfilling the duties of that position.

The nuclear medicine and radiation oncology departments each have one authorized user who supervises virtually all use of licensed material within those departments. The RSO has delegated responsibility for implementation of the daily radiation safety program in the Nuclear Medicine Department to the department manager and chief technologist, and has retained implementation in the Radiation Oncology Department. Although there is some occasional communication between the radiation safety officer and the chief nuclear medicine technologist regarding program implementation, neither appeared to be aware of the licensee's failure to establish and implement a quality management program, as required by 10 CFR 35.32. An apparent violation regarding that failure is described more fully in Section 6 of this report. As evidenced by this problem, radiation safety program oversight with regard to quality management program issues has not been sufficient.

No violation of regulatory requirements was identified; however, a program oversight concern was noted.

4. Internal Audits and Inspections

The licensee employs a health physics consultant to perform quarterly radiation safety programs and annual ALARA audits of licensed activities conducted within the nuclear medicine department. The consultant also audits the licensee's "QMP for nuclear medicine activities." (This "QMP" audit is more fully described in Section 6 of this report.) The licensee's radiation safety officer reviews each consultant audit report as it is made available. Consultant audit reports for 1993 to date disclosed no problems with the licensee's "QMP." Similarly, discussions with the manager of the nuclear medicine department indicated that the apparent violations discussed in this inspection report had not been previously identified.

The licensee's radiation safety officer performs monthly audits of the radiation safety program for the radiation oncology department. In addition, he performs the annual QMP audit for radiation oncology activities. Discussions with the radiation safety officer indicated that the apparent violations discussed in this inspection report had not been previously identified by him.

Although the licensee and its consultant routinely audit program implementation as required, the audits failed to identify significant QMP problems with respect to the implementation of 10 CFR 35.32. Consequently, the audit program has not been sufficiently effective and is in need of improvement.

No violation of NRC requirements was identified; however, a weakness in the licensee's audit/self-assessment program was noted.

5. Radiological Protection Procedures

10 CFR 35.21(b)(2) requires, in part, that the radiation safety officer establish and implement written policies and procedures for using byproduct material safely. The licensee's procedures for the safe use of byproduct material are described in the application dated October 1, 1989, and were approved by License Condition No. 21.A. The application dated October 1, 1989, states in Item 10.4 that gloves are to be worn at all times while handling radioactive materials.

During the inspection, the inspector observed a licensee nuclear medicine technologist exit an imaging room carrying an empty syringe in an ungloved hand. Inspector interview of the technologist indicated that she had not worn gloves while she assayed and injected the patient dosage (approximately 4.0 millicuries (150 mBq) of technetium-99m labeled macroaggregated albumin (MAA)). The technologist was aware of the requirement to wear gloves, but was in a hurry to inject the patient and had forgotten. The technologist stated that she normally wears gloves and that this was an isolated occurrence. There was no indication that the technologist had contaminated her hands during the handling and administration of the patient dosage. The dosage was properly labeled and shielded.

The technologist's failure to wear gloves during the handling of radioactive materials constitutes an apparent violation of 10 CFR 35.21.

One apparent violation of NRC regulatory requirements was identified.

6. Quality Management Program (QMP)

10 CFR 35.32(a) requires that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. 10 CFR 35.32(f)(2) requires that each licensee submit to the appropriate NRC Regional Office by January 27, 1992, a written certification that the quality management program has been implemented along with a copy of the program.

In preparation for the inspection, the inspector was not able to locate a copy of the licensee's written quality management program for its use of radiopharmaceuticals for therapy and quantities of sodium iodide iodine-131 in excess of 30 microcuries (1.1 mBq). During the

inspection, discussions with the radiation safety officer and the manager of the nuclear medicine department indicated that each believed that the other had prepared and submitted the quality management program for the aforementioned modalities used in the nuclear medicine department. However, neither individual could provide a written copy of the licensee's QMP or describe the licensee's policies and procedures to meet the QMP objectives required by 10 CFR 35.32.

Prior to the exit summary, the licensee provided the inspector with a copy of a QMP that had been transmitted via facsimile from its consultant. The QMP had reportedly been submitted to the consultant for review and submittal to the NRC at an unspecified time prior to the inspection. Although the QMP indicated an effective date of January 27, 1992, there was no indication of the date it had been submitted to the consultant or the individual who had prepared the QMP. There was no evidence that the QMP provided to the inspector had been previously submitted to the NRC. Furthermore, licensee personnel who were responsible for implementing the QMP were not aware of QMP objectives required by 10 CFR 35.32. Specifically, nuclear medicine personnel, including the authorized user, were not aware that, prior to administration, a written directive must be prepared for any administration of quantities greater than 30 microcuries (1.1 mBq) of sodium iodide iodine-131 or iodine-125 or any therapeutic administration of a radiopharmaceutical other than sodium iodide iodine-131 or iodine-125.

The licensee's procedures in the nuclear medicine department called for the authorized user to consult with the patient's referring physician prior to ordering any dosage of sodium iodide iodine-131 to confirm the appropriateness of the administration. Prior to consulting with the referring physician, the authorized user would review the results of the patient's thyroid uptake scan and, together with his estimation of the patient's thyroid gland size, would determine the appropriate dosage of sodium iodide iodine-131 to administer to the patient. In approximately 10 percent of cases reviewed by the inspector, the authorized user had documented the dosage to be administered to the patient. However, in the remaining 90 percentile of cases, there was no written record of the dosage intended to be administered.

In each case, after receipt of the sodium iodide iodine-131 dosage by the licensee, the authorized user observed the dosage assay in the dose calibrator and then personally administered the dosage to the patient. The authorized user relied on his memory to ensure that the dosage administered was in agreement with the dosage he intended to administer when the order was placed with the nuclear pharmacy. The inspector did not identify any misadministrations in those cases independently reviewed, for which a written record of the intended dosage was available. As noted above, however, this comprised only a small percentage of the licensee's overall cases. According to the licensee, no misadministrations have occurred since promulgation of the QMP rule in 1992.

Evaluation of the licensee consultant's audit findings disclosed that the consultant reviewed a licensee form entitled "Quality Assurance Form for Therapeutic and Diagnostic Administration of Sodium Iodide I-125 or I-131 Doses Above 30 Microcuries" (refer to attachment). That form is completed by nuclear medicine technologists after each administration and includes an entry to indicate whether a written directive was present for each case. Although the licensee completed a form for each administration and indicated that a written directive was present in each case, licensee personnel were generally unaware of the intent and purpose of a written directive as delineated in 10 CFR 35.2. Licensee personnel assumed that the written directive was their documentation of the medical appropriateness of the treatment, not a written order from the authorized user for the treatment. The consultant's audit also failed to identify that the licensee had not developed written policies and procedures to meet the QMP objectives of 10 CFR 35.32(a).

The inspector's review of other therapeutic administrations of radiopharmaceuticals, including sodium iodide iodine-131 in excess of 30 millicuries indicated that a written directive is prepared prior to each administration. Such administrations are conducted in the licensee's Radiation Oncology Department. Although a written QMP had not been established for those administrations either, the licensee's procedures of practice in radiation oncology substantially met all of the objectives for quality management programs required by 10 CFR 35.32.

The licensee's written quality management program for brachytherapy, including HDR treatments, had been established, maintained, and submitted to the NRC, as required by 10 CFR 35.32.

The licensee's failure to: (1) establish and maintain a written quality management program to provide high confidence that byproduct material consisting of sodium iodide iodine-131 in quantities between 30 microcuries (1.1 mBq) and 30 millicuries (1100 mBq) will be administered as directed by the authorized user; and (2) establish a written quality management program for administration of sodium iodide iodine-131 in excess of 30 millicuries and for therapeutic administration of other radiopharmaceuticals, constitute an apparent violation of 10 CFR 35.32(a).

Following the inspection, the licensee prepared and submitted to the NRC a quality management program for radiopharmaceutical therapy administrations, including administrations of quantities of sodium iodide iodine-131 in excess of 30 microcuries (1.1 mBq). The submitted QMP appears to meet all of the objectives required by 10 CFR 35.32.

The QMP problems identified during this inspection appear attributable to three root causes, as follows:

(a) The licensee, including the RSO, authorized users and technologists, do not have sufficient knowledge of QMP requirements in 10 CFR Part 35.

(b) The licensee overrelies on its consultant and does not adequately audit QMP related activities.

(c) The RSO is not adequately involved nor provides sufficient oversight of all necessary nuclear medicine department activities.

One apparent violation of NRC regulatory requirements was identified.

7. Exit Summary

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

Attachment: As stated

The Community Hospital

901 MAC ARTHUR BLVD. MUNSTER, INDIANA 46321

TELEPHONE 219/836-1600

QUALITY ASSURANCE FORM FOR THERAPEUTIC AND DIAGNOSTIC ADMINISTRATION OF SODIUM IODIDE I-125 OR I-131 DOSES ABOVE 30 MICROCURIES

THIS SURVEY IS TO ENSURE THAT ALL REQUIREMENTS OF THE NUCLEAR MEDICINE QUALITY MANAGEMENT PROGRAM ARE FOLLOWED AND TO EVALUATE THE QUALITY MANAGEMENT PROGRAM.

Patient Name: _____

Name of Therapy or Radioiodine Procedure Ordered:

_____ Date: _____

A. Written Directive Present: Circle One Yes No

B. Patient Identification By Name: Circle One Yes No

C. Comparison Identification: Circle One

1. Birth Date 2. Address 3. Social Security Number
4. Signature 5. Bracelet 6. Hospital ID Card
7. Insurance Card 8. Driver's License

D. Dosage Within 20% of Written Directive: Circle One

Yes No If No Explain _____

E. Dose Administered _____ I-125 _____ I-131

_____ Other _____

F. Route Of Administration _____

G. Was There Any Deviation From The Written Directive. Circle One

Yes No If Yes Explain _____

Form Completed By: _____ Date: _____

_____ _____

Sign And Print Last Name

Reviewed By: _____ Date: _____