U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-03078/94-001

EA 94-061

Docket No. 030-03078

License No. 37-06855-01 Priority 2 Category G

Licensee: Osteopathic Medical Center of Philadelphia
Philadelphia College of Osteopathic Medicine
4150 City Avenue
Philadelphia, Pennsylvania 19131-1696

Facility Name: Osteopathic Medical Center of Philadelphia
Philadelphia College of Osteopathic Medicine

Inspection At: 4150 City Avenue
Philadelphia, Pennsylvania

Inspection Conducted: March 16, 1994

Inspectors: Richard W. McKinley — 4/1/94
Richard W. McKinley, Health Physicist — date

Approved by: Jenny M. Johansen — 4/4/94
Jenny M. Johansen, Chief — date
Medical Inspection Section

Inspection Summary: Unannounced safety inspection conducted March 16, 1994 (Inspection Report No. 030-03078/94-001).

Areas Inspected: Licensee action on previous violations; scope of licensed program; radiation safety committee: nuclear medicine program; radiation therapy program; personnel radiation protection; quality management program; waste disposal; and misadministrations.

Results: Five apparent violations were identified: 1) failure to include a nursing representative on the Radiation Safety Committee per 10 CFR 35.22(a)(1) (Details, Section 4); 2) failure of the Radiation Safety Committee to meet quarterly per 10 CFR 35.22(a)(2) (Details, Section 4); 3) failure to make records available for inspection and failure to retain or maintain certain records (Details, Section 5); 4) failure to prepare written directives for all administrations of greater than 30 microcuries of iodine-131 (Details, Section 8); and 5) failure to develop procedures for and conduct a review of the quality management program (Details, Section 8).

DETAILS

1. Persons Contacted

* Thomas J. Campione, Vice President of Clinical and Support Services
* Adrienne Kittka, Administrative Business Manager
George Popky, M.D., Radiation Safety Officer
* Henry J. Helak, D.O., Nuclear Medicine Physician
Yvette Lindo, Nuclear Medicine Technologist
* Anna Saunders, Chief, Nuclear Medicine Technologist
Kenya Lofton, Nuclear Medicine Technologist
Dawn Faulk, Agency Nuclear Medicine Technologist
Jim Paslawski, Scheduler and Aide

* Present at Exit Conference on March 16, 1994

2. Licensee Action on Previous Violations

2.1 (Closed) Violation (Inspection 91-001); failure to secure radioactive material against unauthorized removal when it was not under constant surveillance and immediate control of the licensee, per 10 CFR 20.207(a)(b). Specifically, the doors to the Nuclear Medicine suite and the Hot Lab, which contained millicurie quantities of radioactive materials, were routinely left open.

The inspector observed that on March 16, 1994, the Hot Lab and Nuclear Medicine suite were either under constant surveillance and immediate control of the licensee, or they were locked.

2.2 (Closed) Violation (Inspection 91-001); failure to supply appropriate personnel monitoring equipment to an individual who entered a restricted area to work with millicurie amounts of radioactive materials in violation of 10 CFR 20.202. Specifically, a temporary nuclear medicine technologist was not supplied with appropriate monitoring equipment for a period of greater than one year.

The inspector noted on March 16, 1994 the temporary nuclear medicine technologist had been issued and had used appropriate personnel monitoring equipment since the last inspection.

3. Scope

The licensee currently has an NRC license (License No. 37-06855-01) that authorizes: nuclear medicine diagnostic and therapeutic activities; brachytherapy treatments; depleted uranium for shielding; prepackaged kits for in vitro studies; and hydrogen-3, carbon-14,

sulfur-35, chlorine-36, calcium-45, iodine-125, phosphorus-32, cadmium-109, and strontium-90 for research and development and teaching of students. The licensee stated that they no longer possess brachytherapy sources.

The scope of the inspection was restricted to nuclear medicine diagnostic and therapeutic activities.

4. Radiation Safety Committee

The inspector reviewed the minutes of the Radiation Safety Committee (RSC) meetings since the last NRC inspection.

A review of the membership attending RSC meetings failed to identify a nursing representative as an RSC member. In addition, minutes were missing for meetings in the first and second quarters of 1992, and the second, third, and fourth quarters of 1993. Reviews of memoranda written by a previous Radiation Safety Officer (RSO) and statements made to the inspector by the current RSO indicate that the meetings were never held.

10 CFR 35.22(a)(1) requires, in part, that a representative of the nursing service be a member of the Radiation Safety Committee.

Failure to designate a representative of the nursing service as a member of the Radiation Safety Committee is an apparent violation of 10 CFR 35.22(a)(1).

10 CFR 35.22(a)(2) requires that the Radiation Safety Committee meet at least quarterly.

Failure of the Radiation Safety Committee to meet at least quarterly is an apparent violation of 10 CFR 35.22(a)(2).

5. Nuclear Medicine/Nuclear Cardiology Programs

The inspector toured the nuclear medicine and the nuclear cardiology departments, interviewed nuclear medicine technologists and the Radiation Safety Officer, reviewed area radiological survey records, dose calibrator quality control tests, xenon delivery system quality control tests, survey instrument quality control tests, and patient dosage records. The inspector identified several apparent violations described below in the licensee's nuclear medicine program.

The inspector reviewed records of dose calibrator accuracy and linearity tests, records of survey instrument calibrations, and attempted review of records of monthly xenon trap checks and semi-annual ventilation measurements. Dose calibrator accuracy test records were not available for 1991 and 1993. Dose calibrator linearity test records were not

available for the second calendar quarter in 1991, and the second, third, and fourth calendar quarters in 1992. Records of survey instrument calibrations were not available for 1991 and 1992. Records of monthly trap checks and semi-annual ventilation checks for use of xenon were not available for any month since the last inspection on March 12, 1991. The inspector noted that the licensee's consultant indicated in his audit reports dated 1991 through 1993 that these records were available.

10 CFR 30.52(b) requires that records kept of licensee activities pursuant to the regulations be made available to the inspector at the time of inspection. 10 CFR 35.50(e) requires, in part, that the licensee retain records of dose calibrator tests and checks for three years. 10 CFR 35.51(d) requires, in part, that the licensee shall retain a record of each survey instrument calibration for three years. 10 CFR 35.205(e) requires that a licensee shall check the operation of reusable collection systems for use of xe-133 each month, and measure the ventilation rates available in areas of radioactive gas use each six months. License Condition 14 of License No. 37-06855-01 requires, in part, that records will be maintained of all monitoring and disposal.

Failure to make records available for inspection, retain records of dose calibrator linearity and accuracy, and survey instrument calibration for three years, and maintain records of the checks of reusable collection systems for use of xe-133 and measurements of ventilation rates is an apparent violation of 10 CFR 30.52(b), 35.50(e), 35.51(d), 35.205(e) and License Condition 14 of License No. 37-06855-01.

6. Radiation Therapy Program

The inspector toured the radiation therapy department and interviewed a radiation therapy technologist, and reviewed Radiation Safety Committee meeting minutes regarding radiation therapy. It was determined that no brachytherapy administrations had been performed since the last inspection, and that the licensee was no longer in possession of their brachytherapy sources.

No safety concerns were identified.

7. Personnel Radiation Protection

Records of personnel exposure were reviewed from January, 1992 to December, 1993. The licensee uses vendor dosimeters which are exchanged monthly. No doses were found in excess of the licensee's "As Low As Reasonably Achievable" (ALARA) levels. Bioassays are not performed because no iodine-131 is used in excess of 30 millicuries.

8. Quality Management Program

The inspector verified that the licensee had submitted a quality management program (QMP) in their letter dated January 22, 1992. A review of files of patients receiving more than 30 microcuries of iodine-131 revealed that none of the 9 cases performed in 1992 and 1993 included a written directive maintained in the file. The licensee had not administered doses greater than 30 microcuries of I-131 or I-125 from January 1, 1994 to the date of the inspection. A nuclear medicine physician stated that he did not believe that directives were ever written. The patient files did show that the technologist had verified the dose ordered and did use more than one method to identify patients. There was no documentation showing audits of the QMP and the nuclear medicine physician stated that he was unaware of any having been done.

10 CFR 35.32(a) requires, in part, that prior to administration of any quantity greater than 30 microcuries of iodine-131, a written directive be prepared. 10 CFR 35.2 defines, in part, a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. For any administration of quantities greater than 30 microcuries of sodium iodide I-131, the written directive must contain the dosage.

Failure to prepare a written directive prior to administration of any quantity greater than 30 microcuries of iodine-131 is an apparent violation of 10 CFR 35.32(a).

10 CFR 35.32(b) requires, in part, that the licensee develop procedures for and conduct a review of the QMP at intervals no greater than 12 months.

Failure to develop procedures for and conduct a review of the QMP at intervals no greater than 12 months is an apparent violation of 10 CFR 35.32(b).

9. Waste Disposal

The inspector reviewed the licensee's waste disposal methods and records. The inspector noted that radiopharmaceutical waste from the nuclear medicine and nuclear cardiology laboratories was held for ten half-lives and that it was surveyed and found to be at background when disposed.

No safety concerns were identified.

10. Misadministrations

The licensee's RSO stated that no misadministrations had occurred since the 1991 inspection. The nuclear medicine physician confirmed this. Records reviewed supported the licensee's statements. No misadministrations were identified.

11. Exit Interview

The inspector met with the licensee's representatives designated in Section 1 of this report at the conclusion of the inspection. The inspector summarized the scope and findings of the inspection.

The findings of the inspection were further discussed in a telephone conversation on March 25, 1994, between Ms. Jenny M. Johansen, Chief, of the NRC's Region I Medical Inspection Section and Dr. George L. Popky, the licensee's Radiation Safety Officer. From this conversation it is our understanding that:

a. You will ensure that the procedures outlined in your Quality Management Program, dated January 22, 1992, are carried out and the procedures sent to us by facsimile on March 25, 1994 (Attachment 1) are instituted.

b. We understand that prior to any future treatment of patients with greater than 30 microcuries of sodium iodide I-125 or I-131 a written directive signed and dated by an authorized user and that identifies the dosage to be administered will be generated.

This understanding was documented in our letter dated March 28, 1994 (Attachment 2).

ATTACHMENT 1

GRADUATE
HEALTH SYSTEM

CITY AVENUE HOSPITAL

DEPARTMENT OF RADIOLOGIC SCIENCES

TO: Mr. McGinley

FROM: Dr. Popky

DATE: 3-25-94

NUMBER OF PAGES (INCLUDING COVER SHEET) 4

Therapeutic I-131

Date:
Time:

Patient:

Interviewing Doctor:

Technologist:

1. No Therapeutic dosage of I-131 may be administered without the technologist verifying the identity of the patient with the individual named on the written directive. This may be verified in at least, two methods:

    A) The patient will be asked his name; address and social security number - confirm this with the written directive.

    B) Ask the patient to produce two of the following: A photo I.D., Social Security Card, drivers license, insurance cared, or in the case of inpatients check the patients I.D. bracelet or hospital I.D. card.

2. No dose of I-131 may be given without a written prescription from the radiologist.

3. No dose of I-131 may be given to a patient without a radiologist present to conduct an interview and examination.

4. The technologist shall measure the dosage in a dose calibrator and the results shall be compared to the radiologists written prescription. Also the dose shall be recorded in all appropriate logs.

5. A signed and dated written record documenting the administered dosage shall be placed in the patient's chart and/or other appropriate record by or under the supervision of the technologist.

6. The patient shall be informed that the department will need to conduct follow-up examinations. An appointment shall be made at this time for the first follow-up interview (to be conducted two weeks from the initial appointment). Subsequent appoints to follow in 8 to 12 weeks.

7. All cases involving patients reveiving theraputic I-131 will be presented to the Radiation Safety Committee at the next quarterly meeting following administration.

Patient:

Patient identification:

Patient's signature:

Doctor:

Doctor's signature:

Technologist:

Technologist's signature:

Technologist's Checklist

A) Dated and signed written directive by authorized user.

B) Verification of radiopharmaceutical type, route of administrating and dosage.

C) Dated and signed documentation of the administered dosage placed in the appropriate logs/record.

D) Follow-up appointment made.

E) Attached prescription copy.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

ATTACHMENT 2

MAR 28 1994

Docket No. 030-03078
License No. 37-06855-01

Osteopathic Medical Center of Philadelphia
City Avenue Hospital
ATTN: Melvyn E. Smith, D.O.
President
4150 City Avenue
Philadelphia, Pennsylvania 19131

Dear Dr. Smith:

SUBJECT: INSPECTION 94-001

On March 16, 1994, Mr. Richard W. McKinley of this office conducted a routine inspection at your licensed facility in Philadelphia, Pennsylvania. An apparent violation of NRC requirements was identified in that no written directives are produced by an authorized user prior to the administration of greater than 30 microcuries of iodine-131 sodium iodide to patients, in violation of 10 CFR 35.32(a).

Pursuant to a telephone conversation between Dr. George L. Popky, Radiation Safety Officer on your staff, and Ms. Jenny Johansen, Chief, Medical Inspection Section of this office, on March 25, 1994, it is our understanding that you have taken or will take the following actions, which will be completed as specified:

1. You will ensure that the procedures outlined in your Quality Management Program dated January 22, 1992, are carried out and the procedures sent to us by facsimile on March 25, 1994, are instituted.

2. We understand that prior to any future treatment of patients with greater than 30 microcuries of sodium iodide I-125 or I-131 a written directive signed and dated by an authorized user and that identifies the dosage to be administered will be generated.

Notify me immediately if your understanding differs from that set forth above.

Sincerely,

Jenny M. Johansen, Chief
Medical Inspection Section A
Nuclear Materials Safety Branch