U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Report No. 030-01265/94-001

Docket No. 030-01265

EA No. 94-103

License No. 06-06697-02 Priority 3 Category G Program Code 02120

Licensee: Stamford Hospital
P.O. Box 9317 -Shelburne Road
Stamford, Connecticut 06904-9317

Facility Name: Stamford Hospital

Inspection at: Shelburne Road
Stamford, Connecticut 06904-9317

Inspection Conducted: May 23, 24 and June 1 and 6, 1994

Inspector: _____ 6/14/94
Ihor M. Czerwinskyj, Health Physicist date
Nuclear Materials Safety Branch
Division of Radiation Safety
and Safeguards

Approved By: _____ 6/14/94
Jenny M. Johansen, Chief date
Medical Inspection Section
Division of Radiation Safety
and Safeguards

Inspection Summary: Special, unannounced safety inspection conducted on May 23, 24 and June 1 and 6, 1994 to investigate the circumstances of an iodine-131 misadministration reported to the NRC on May 19, 1994 and to review the licensee's corrective actions taken in response to the event, and to review the licensee's quality management program.

Areas Inspected: Iodine-131 misadministration, Quality Management Program, training, licensee's corrective actions.

Results: Five apparent violations were identified. (1) Failure to establish a quality management program for administering diagnostic quantities of iodine-131 (Section 3); (2) Failure to conduct annual reviews of the quality management program (Section 3); (3) Failure to specify in patient records the method used to verify patient identity (Section 3); (4) Failure to have the written directive signed by the authorized user (Section 3); (5) Failure to instruct supervised individuals in the licensee's quality management program (Section 3).

Details

1. Persons Contacted

Andrew H. Banoff, Vice President Ambulatory Services
*Peter Karl, Director Radiology Services
Harvey L. Hecht, M.D., Radiation Safety Officer (RSO)
*Cathy Collman, Chief Nuclear Medicine Technologist
Jim Summers, Consultant (by telephone)
Bruce Kerrick, Nuclear Medicine Technologist
Elizabeth Kelly, Nuclear Medicine Technologist
Susan Wasser, Supervisor of Clinical Chemistry (by telephone)
*Present at exit interview

2. Iodine-131 Misadministration

On May 19, 1994 the licensee notified the NRC Operations Center of a misadministration involving the administration of a 1 millicurie dose of iodine-131 to the wrong patient. On May 23 and 24, 1994 the inspector visited the Licensee's facility to investigate the circumstances surrounding the misadministration and the licensee's actions following the misadministration.

The inspector examined pertinent records and interviewed the licensee's staff. Based on the information obtained, the inspector determined that on May 9, 1994, the referring physician sent a requisition to the Hospital's Nuclear Medicine Department asking for a "Total Red Cell Mass (r/o Polycythemia vera)(Nuclear Medicine)". The scheduling clerk at the Hospital was unfamiliar with this test and she contacted the requesting Health Maintenance Organization (HMO). The Hospital's scheduling clerk, and the HMO's secretary decided that the referring physician was requesting a whole body iodine-131 scan, and the Hospital's scheduling clerk filled out a "Consultation for Nuclear Medicine" form requesting a whole body iodine-131 scan using 1 mCi of I-131 (their standard dose for a whole body scan). The scheduling clerk signed the form with the referring physician's signature and sent it to the Nuclear Medicine Department where it was received on May 13, 1994. The nuclear medicine technologist (NMT) looked at the form and saw that it was for "total red cell mass", but since the NMT knew the referring physician, the NMT assumed that this was a new test using iodine-131 to determine "total red cell mass". It did not occur to the NMT to clarify this matter with an authorized user or the referring physician. The NMT ordered the requested 1 millicurie iodine-131 capsule, which was administered on Monday, May 16, 1994. The patient was scanned on May 17, and on May 18, 1994, the authorized user (AU), who is also the RSO, read the films. The AU immediately noticed the error and notified the referring physician, who notified the patient. NRC was notified within 24 hours of the discovery of the misadministration.

The inspector interviewed the AU and determined that for a "total red cell mass" the patient should have been scheduled for a chromium-51 Blood Volume (RBC MASS) test. At the Stamford Hospital this test is administered not by the Nuclear Medicine Department, but by the Clinical Chemistry Lab. In this test a sample of the patient's blood is incubated with 75-100 microcuries of chromium-51. Half of the blood is reinjected into the patient, and the other half is used as a standard for determining the RBC Mass.

3. Quality Management Program

The licensee submitted to the NRC a Quality Management Program (QMP) dated August 19, 1992, which was received by the NRC on August 24, 1992. The QMP covers iodine-131 therapy, and brachytherapy. It does not address the administration of iodine-131 for diagnostic tests using over 30 microcuries of I-131.

10 CFR 35.32(a) requires, in part, that the licensee shall establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

Failure to establish and follow the procedures of a written quality management program that provides a high confidence that byproduct material will be administered as directed by the authorized user for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131 is an apparent violation of 10 CFR 35.32(a).

The inspector requested copies of the licensee's 1992 and 1993 reviews of the quality management program. The chief nuclear medicine technologist stated that to the best of her knowledge, no such reviews of the QMP had been conducted.

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

Failure to conduct annual reviews of the quality management program is an apparent violation of 10 CFR 35.32(b).

By examining computer print-outs, the inspector determined that between 05/01/93 and 05/01/94, the licensee administered ten iodine-131 therapy doses and performed one iodine-131 whole body scan. The inspector reviewed all iodine-131 patient files for the above period. The inspector determined that the patient files did not contain any indication that the patient's identity was verified by more than one method prior to the administration of the iodine-131 dose. The written directives in all of the

patient records examined were signed by the referring physicians, and not by the authorized user.

10 CFR 35.32(a)(2) requires that prior to each administration of doses of iodine-131 greater than 30 microcuries, the patient's identity must be verified by more than one method as the individual named in the written directive.

Failure to have records of the methods used to verify the patient's identity by more than one method prior to administration of doses of iodine-131 greater than 30 microcuries is an apparent violation of 10 CFR 35.32(a)(2).

10 CFR 35.32(a)(1)(iv) requires, in part, that prior to administration a written directive is prepared for any administration of quantities greater than 30 microcuries of sodium iodide I-125 or I-131. 10 CFR 35.2 defines a "written directive" as an order in writing for a specific patient, dated and signed by an authorized user prior to administration of a radiopharmaceutical.

Failure to prepare a written directive signed by the authorized user for any of the administrations of iodine-131 radiopharmaceuticals is an apparent violation of 10 CFR 35.32(a)(1)(iv)

The inspector interviewed the chief nuclear medicine technologist and the two staff nuclear medicine technologists. They stated that training was provided by the hospital's medical physics consultant in June of 1993. The training was limited to NRC Regulations and ALARA principle. No training was given on the licensee's Quality Management Program. One of the technologists stated that he had never heard of QMP before the May 16 incident.

10 CFR 35.25(a)(1) requires, in part, that the licensee shall instruct the supervised individuals in the licensee's written quality management program.

Failure to instruct the supervised individuals in the licensee's written quality management program is an apparent violation of 10 CFR 35.25(a)(1)

4. Corrective Actions

Extensive training was provided to the whole nuclear medicine staff after the discovery of the misadministration. In addition, the licensee has developed a written corrective action to its quality management plan, requiring that written directives be signed by the authorized user for all iodine-131 administrations, and that an authorized user perform a daily review of all requisitions for the next day.

5. Exit Interview

The inspector met with licensee representatives identified in Paragraph 1 and summarized the scope and purpose of the inspection.