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License Nos. 20-03814-80
20-03814-84

Priority II III

Category G1 E

Licensee: Massachusetts General Hospital (MGH)

Fruit Street

Boston, Massachusetts 02114

Facility Name: Massachusetts General Hospital

Inspection At: Boston, Massachusetts

Inspection Conducted: October 1, 2 and 3, 1986

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Approved by: John R. White
John R. White, Chief, Nuclear Materials Safety Section C — 10/17/86 date

Inspection Summary: Inspection conducted October 1, 2 and 3, 1986 (Combined Report No. 030-01867/86-01, 030-15211/86-01)

Areas Inspected: The inspection consisted of a routine unannounced inspection of a medical institution group program for medical diagnosis and therapy; and a broad scope medical research program. The inspection included a review of the organization, internal audits, radiation protection procedures, use of materials and instruments, storage of materials, receipt and transfer of materials, personnel protection - external, personnel protection - internal and effluent controls.

Results: Sixteen apparent violations were identified: (1) Failure to have management representative on the Radiation Safety Committee since January of 1986; (2) Failure to perform annual review of radiation safety program; (3) Failure to provide required training to individuals working in a restricted area; (4) Failure to use vial shields in dose preparation; (5) Failure to survey patients containing cesium-137 or iridium-192 implants to ensure that all implants have been removed; (6) Failure to calibrate the dose calibrator according to the licensee's procedures; (7) Failure to survey the brachytherapy source transfer cart after loading the sources; (8) Failure to secure licensed material; (9) Failure to perform an adequate survey to ensure that non-fixed radioactive contamination of packages presented for transport are below DOT regulatory limits; (10) Failure to provide an evaluation of the radiation dose to the hands and fingers of personnel who prepare and administer patient doses of iodine-131; (11) Failure to provide finger rings to individuals handling one millicurie or more of phosphorus-32; (12) Failure to survey the waste storage and patient imaging areas in nuclear medicine; (13) Failure to immediately notify users of laboratory contamination; (14) Failure to perform thyroid uptake measurements on individuals performing iodinations using iodine-125; (15) Failure to perform thyroid uptake measurements on an individual preparing and administering therapeutic doses of iodine-131; (16) Failure to perform an adequate survey of radioactivity released in effluents to unrestricted areas.

DETAILS

1. Persons Contacted

*Frank P. Castronovo, Jr., Ph.D., Radiation Safety Officer
*Edward W. Webster, Ph.D., Chairman, Radiation Safety Committee
*Maryanne Spicer, Director of Therapeutic Services
*Ronald Lamont-Havers, M.D., Deputy General Director for Research
John Hergenrother, Nuclear Medicine Area Manager
George Desko, Assistant Chief Technologist, Nuclear Medicine
H. William Strauss, M.D., Director, Nuclear Medicine Division
Stephen C. Dragotakes, Radiopharmacist
Robert A. Beh, Radiation Safety Techician
Linda Ardisson, Endocrinology Technician
Miriam Gitterman, Ph.D., Radiation Medicine, Biophysics Division
Paul Imbergamo, Radiation Medicine, Biophysics Division
Linda Kent, Physics Technician

Other professional and support personnel in the clinical and research areas were also contacted during the inspection.

*Present at exit interview.

2. Organization

The radiation safety program is administered under the institution's Safety Department with the Radiation Safety Officer (RSO) reporting to the Director of Safety. A radiation safety technician reporting to the RSO performs laboratory audits, room surveys, package receipt surveys and instrument calibration. The licensee has contracted with Harvard University Health Services to perform monthly surveys of research laboratories, to provide a film badge service to the research laboratories, and to handle and dispose of all radioactive waste. In addition to the RSO's responsibilities regarding byproduct material, he is responsible for radiation safety of machine produced ionizing radiation and non-ionizing radiation produced by lasers.

10 CFR 33.13(c)(1) requires that the licensee establish a Radiation Safety Committee composed of the RSO, a representative of management and individuals trained and experienced in the safe use of radioactive materials.

The inspectors reviewed the membership of the Radiation Safety Committee. It is comprised of representatives from nursing, authorized users for each type of use permitted by the license and the Radiation Safety Officer (RSO). However, the individual who represents the institution's management on the committee left the employ of the hospital and as of the time of the inspection had not been replaced by the institution. No representatives of management have been involved with or participated in activities of the Radiation Safety Committee since January 1986.

The finding that the Radiation Safety Committee was without management representation since January of 1986 is an apparent violation of 10 CFR 33.13(c)(1).

3. Licensee Internal Audits

From a discussion with the RSO and a review of records, the inspectors determined that the Radiation Safety Committee issues permits, of two year duration, to principal investigators after a review by that committee regarding the type, quantity and use of material proposed. The Radiation Safety Office has an audit program in which each permit user is audited with respect to regulatory requirements and specific permit conditions. The frequency of audit is established according to priorities based upon the type and quantity of radioactive material used. The licensee has 20 Priority-1 permit users who are audited yearly, 26 Priority-2 permit users who are audited every 18 months and approximately 75 Priority-3 permit users who are audited every 3 years. The radiation safety technician indicated to the inspectors that the radiation safety office was at least 6 months behind in audits of Priority-1 and -2 permit users in part due to the lack of staff to perform the audits.

While reviewing the minutes of the Radiation Safety Committee, the inspectors read a memo dated January 1986 from the RSO to the Chairman of the Radiation Safety Committee which indicated the RSO's belief that with the present staff he would not be able to comply with the regulatory requirements of the hospital's license.

According to procedures sent to the NRC in a license renewal application dated June 29, 1983, the Radiation Safety Committee is committed to perform an annual review of the entire radiation safety program to assure that all activities are conducted in accordance with NRC regulations and license conditions.

In discussion with the RSO and review of documentation, the inspectors learned that the last formal review of the radiation safety program was performed in March 1985. This is an apparent violation of Condition 28 of License No. 20-03814-80.

4. Training and Qualification of Personnel

The inspectors questioned whether the licensee had provided the required initial training in radiation safety. Initial training is required for all employees who frequent restricted areas, and in accordance with Condition 28 of License No. 20-03814-80 includes permit holders, research assistants, paramedical and other ancillary personnel. The Radiation Safety Officer stated that the required course for permit holders and other authorized users is presented two times per year by Massachusetts General Hospital (MGH). Individuals, who arrive between these sessions

may attend the Harvard Training Course or are given one to two hours of radiation safety orientation by the Radiation Safety Officer to enable work, under supervision, until the MGH course can be completed. The Radiation Safety Officer also provides routine training for incoming nurses and nurses attending brachytherapy and radionuclide therapy patients. A guide for individuals attending patients after the diagnostic administration of radiopharmaceuticals, "Radiodiagnostic Health Physics Guide for Patient Care Units", is provided to all clinical care units.

Through discussions with and observations of nuclear medicine technologists, an endocrinology technician, research permit holders and other research personnel, the inspectors determined that the licensee had not provided the necessary training in daily quality control of the dose calibrator, use of vial and syringe shields, requirements for personnel dosimetry, waste disposal procedures, survey requirements and routine radiation safety procedures, particularly as pertain to the handling of phosphorus-32.

The failure to provide the required training to individuals working in a restricted area constitutes an apparent violation of 10 CFR 19.12.

5. Radiation Protection Procedures

A procedure manual was available and procedures implemented in the Nuclear Medicine Division which identified the radiopharmaceutical, dose and handling of patients receiving diagnostic doses, emergency procedures for spills, and some required quality control procedures. Additionally, procedures are available on the handling of patients receiving therapeutic doses of radionuclides and the handling of cadavers. The inspection revealed no deviations from the procedures.

The inspectors reviewed the procedure for monitoring patients who have received iodine-131 therapy for carcinoma and for monitoring the room before release for unrestricted use. Documentation and discussions with the Radiation Safety Technician confirmed that the procedure was being followed.

The licensee's "General Rules for the Safe Use of Radioactive Material" require the use of vial shields for dose preparations. On October 1, 1986, the inspectors observed the preparation of an iodine-131 carcinoma therapy dose. The technician preparing the dose withdrew approximately 140 millicuries from two stock vials using an unshielded syringe and transferred the activity to an unshielded patient administration vial which she held in her hand. In discussion with this technician, she stated that she prepares approximately fifty percent of the iodine-131 hyperthyroid and carcinoma therapy doses using the procedure observed by the inspectors. She also indicated that she was never instructed on the use and availability of syringe and vial shields.

The failure to use vial shields in dose preparation is an apparent violation of Condition 28 of License No. 20-03814-80.

The licensee's procedures for "Loading and Unloading Brachytherapy Patients" require that a note be written in the medical record stating that "patient and room have been surveyed with a geiger counter and has been found to be free of radioactivity." In reviewing the patient log books, the inspectors observed approximately ten cases where the performance of room surveys was not indicated. The medical records of five of these patients were obtained and reviewed for the required medical record entry. One medical record had no indication that the required patient and room surveys had been done, nor was the licensee able to provide any other evidence that such surveys had been performed.

The failure to survey patients containing cesium-137 or iridium-192 implants to insure that all implants have been removed is an apparent violation of Condition 16 of License No. 20-03814-80.

e. Use of Materials, Instruments

The inspectors reviewed the calibration and use of the licensee's dose calibrators with the individuals who work in the Radiopharmacy, Nuclear Medicine and Endocrinology facilities.

The licensee's dose calibrator checks are the procedures described in Section 2 of Appendix D of Regulatory Guide 10.8. These procedures require the assay of at least one relatively long-lived reference source before each day's use of the instrument to verify constancy.

As of October 3, 1986, Nuclear Medicine Technologists used the dose calibrator to assay patient doses when called in on weekends without performing the required constancy test.

Additionally, these procedures require that the daily constancy checks be plotted on a graph which shows the predicted activities of each standard with the specified ±5 percent limits. This procedure was not being followed by the Radiopharmacy personnel, Nuclear Medicine Technologists and Endocrinology Technician.

The procedures also require that the cesium-137 source be assayed daily at all the commonly used radionuclide settings, with variations greater than ±5 percent from the predicted activity being indicative of the need for instrument repair.

As of October 3, 1986 this procedure had not been performed since February, 1986, even though the dose calibrators in Nuclear Medicine and the Radiopharmacy were used on a regular basis during the intervening period.

The failure to calibrate the dose calibrator according to the licensee's procedures is an apparent violation of Condition 28 of License No. 20-03814-80.

The inspectors reviewed the survey meter calibration procedure and records in the Radiation Medicine Division, and spot-checked survey instruments in Nuclear Medicine, Radiation Medicine and Research for last calibration date. No deviations from the procedure were identified.

Licensee representatives identified a leaking cesium-137 brachytherapy source in a leak test performed on September 25, 1986 but counted on October 1, 1986. The source contained approximately 19 millicuries of cesium-137 (7.5 mg Ra equivalent). The leak test performed by the licensee indicated removable contamination in excess of 2 microcuries. The source had been implanted in a patient by an after-loading technique on September 30, 1986 but removed before treatment end to perform an EKG. The sources were returned to the Brachytherapy Storage Area when the leak test results became known on October 1, 1986 and the leaking source isolated. The inspectors surveyed the transport cart which had an exposure level of 12 mR/hr at the surface of the storage pig. A survey of the patient performed by licensee representatives was background. The patient's treatment was continued on October 2, 1986 using new sources with treatment completed the morning of October 3, 1986. The licensee performed a gynecological swab of the patient after the sources and applicators were removed. The results indicated no measurable radioactive contamination of the patient.

The licensee's "Procedures for Loading and Unloading Brachytherapy Patients" requires that a survey meter always accompany the source transport cart to the patient's room and that, after loading the sources, the transport cart is surveyed to ensure that all sources are out of the cart and in the patient. In a telephone conversation with the Radiation Safety Officer on October 8, 1986, the inspectors confirmed that the source transport cart is not surveyed pursuant to this procedure.

The failure to survey the brachytherapy source transport cart after loading the sources is an apparent violation of Condition 28 of License No. 20-03814-80.

7. Storage of Materials

The inspectors observed the storage of licensed material in the Nuclear Medicine Division, Radiation Medicine Division, waste storage areas and research laboratories.

10 CFR 20.207 requires that licensed material stored in an unrestricted area be secured from unauthorized removal.

The inspectors observed that Room 17B of the Edwards Research Building, which contained millicurie quantities of strontium-85 and a 900 curie cobalt-60 sealed source in a large lead storage container, was unlocked and unattended. This is an apparent violation of 10 CFR 20.207.

8. Receipt and Transfer of Material

The inspectors interviewed licensee representatives and reviewed records regarding the receipt of radioactive material packages. The licensee receives most licensed material at the shipping and receiving desk. The radiopharmacy also receives diagnostic radiopharmaceuticals and shipments of therapeutic quantities of iodine-131. Molybdenum-99/technetium-99m generators are prepared for return shipment to the vendor by individuals in the radiopharmacy while other licensed material is held for decay and disposed of by Harvard University Health Services.

10 CFR 71.5 requires that licensees who deliver licensed material to a carrier for transport to comply with Department of Transportation regulations, 49 CFR Parts 170 through 189. 49 CFR 173.475(i) requires that the level of non-fixed radioactive contamination be kept below 22 dpm/cm^2, as determined by wiping a 300 cm^2 area of the surface of the package.

The inspectors, in discussions with individuals in the radiopharmacy determined that wipes for ascertaining non-fixed radioactive contamination on packages containing used molybdenum-99/technetium-99m generators are counted using a GM area monitor, a method which is not sensitive enough to detect 22 dpm/cm^2 of technetium-99m. This is an apparent violation of 49 CFR 173.475(i).

9. Personnel Protection - External

According to the Radiation Safety Committee minutes reviewed by the inspectors, reports of whole body and extremity exposures were evaluated by the Committee as required by the licensee's ALARA program. No doses in excess of regulatory limits were noted.

The inspectors observed that personnel from the Endocrinology and Research areas who handled therapy doses of iodine-131, and greater than 1 millicurie quantities of phosphorus-32, had not been issued TLD finger dosimeters, and no evaluation of their extremity dose had been made. Specifically, as of November 1985, an Endocrinology technician routinely prepared hyperthyroid and carcinoma doses of iodine-131 by holding unshielded vials and syringes containing up to 150 millicuries of iodine-131 in her hands.

The failure to provide an evaluation of the radiation dose to the hands and fingers of personnel who prepare and administer patient doses of iodine-131 is an apparent violation of 10 CFR 20.201(b).

Additionally, the licensee's procedure, "Personnel Monitoring Devices", requires that finger rings be worn by individuals handling doses of 1 millicurie or more of phosphorus-32. The inspectors, through discussions and observations, determined that some research investigators handling quantities of one to twelve millicuries of phosphorus-32 do so without extremity dosimeters and, in two cases, without benefit of any shielding or remote handling devices.

The failure to provide finger rings to individuals handling one millicurie or more of phosphorus-32 is an apparent violation of Condition 28 of License No. 20-03814-80.

The licensee's "General Rules for the Safe Use of Radioactive Material" requires that patient injection areas be surveyed and that the Nuclear Medicine Radiopharmacy radiation survey procedures be similar to those described in Appendix I of Regulatory Guide 10.8. These procedures require that waste storage areas and all other laboratory areas be surveyed weekly. These surveys are required to consist of measurement of radiation levels with a survey meter and a series of wipe tests to measure contamination levels. As of October 3, 1986, surveys of the waste storage area in Nuclear Medicine and patient imaging areas where radiopharmaceuticals are also occasionally administered were not surveyed.

The failure to survey the waste storage and patient imaging areas in Nuclear Medicine is an apparent violation of Condition 28 of License No. 20-03814-80.

The licensee's "General Rules for the Safe Use of Radioactive Material" also require that a user be notified immediately of the presence of contamination, that the affected area be immediately decontaminated upon notification that contamination exists, and that followup surveys be made to determine the effectiveness of the decontamination procedures. The inspectors observed that research areas are surveyed monthly, but results are not immediately available to the user. In some cases, wipe test results indicating phosphorus-32 contamination were not known until two months after the survey, making immediate decontamination impossible.

The failure to immediately notify users of laboratory contamination is an apparent violation of Condition 28 of License No. 20-03814-80.

10. Personnel Protection - Internal

Bioassay records of individuals who prepare therapeutic doses of iodine-131 were reviewed.

The procedures submitted by the licensee in their license renewal application dated June 29, 1983, require that a thyroid uptake measurement be performed within one month on those individuals performing iodinations using iodine-125.

The inspectors ascertained through interview and record review that an individual in the Endocrine Research Laboratory had routinely performed iodinations with iodine-125 for the last 9 months, but had thyroid uptake measurements on only two occasions during that period of time. This is an apparent violation of license Condition 28.

10 CFR 20.201(b) requires that surveys be made to evaluate the exposure of individuals to concentrations of radioactive materials in air in restricted areas pursuant to 10 CFR 20.103. 10 CFR 20.103(a)(3) requires that, as appropriate, such surveys will consist of measurements of radioactivity in the body.

Through interviews and record review the inspectors determined that the exposure to airborne radioactivity of one individual in endocrinology, who has routinely prepared and administered therapeutic doses of iodine-131 since November of 1985, had not been evaluated by thyroid uptake measurements. This is an apparent violation of 10 CFR 20.201(b).

11. Effluent Controls

The inspectors toured the licensee's primary iodination facility in the basement of the Edward's Research Building. The hood in this laboratory is used for iodinations by several different research groups. Effluents released through this hood are measured by air sampling in the ventilation conduit in the penthouse of the building before the effluent leaves the conduit. The air sampling is performed by the use of a regulated vacuum pump and a charcoal filter cartridge. The cartridges are reused, if they are judged to be "clean". No determination of iodine trapping efficiency is made on individual cartridges and 100% trapping efficiency is assumed in the calculation of effluent release concentrations. An assumption of 100% trapping efficiency, when it may be less than 100% due to prior use, will lead to an underestimate of the concentration of radioactivity released to unrestricted areas. The concentration released as of September 30, 1986 was approximately 106% MPC for the first nine months of the year. In 1985 the hood was shutdown in October, November and December in order to maintain the releases below 1 MPC for the year.

10 CFR 20.201(b) requires the licensee to make surveys, pursuant to 10 CFR 20.106, to ensure that radioactivity released in effluents to unrestricted areas shall be less than that specified in Appendix B, Table II of Part 20 when averaged over a year.

The assumption by the licensee of 100% trapping efficiency of the reused charcoal filter cartridges constitutes an inadequate survey, in that it may lead to an underestimate of the concentration of radioactivity released to unrestricted areas, and, as such, is an apparent violation of 10 CFR 20.201(b).

12. Exit Interview

The inspectors discussed the results of the inspection with the individuals identified in Section 1 of this report. The inspectors expressed their concerns regarding the large number of apparent violations and the apparent lack of management oversight of the program. The Commission's enforcement options were reviewed and the licensee representatives were encouraged to correct the apparent items of non-compliance as expeditiously as possible.