MAY 18 1994

Docket Nos. 030-01867
030-00239

License Nos. 20-03814-80
20-03814-14

Massachusetts General Hospital
ATTN: Maryanne Spicer
Assistant General Director
of Safety and Regulation
Fruit Street
Boston, Massachusetts 02114

Dear Ms. Spicer:

Subject: Combined Inspection No. 030-01867/93-001 and 030-00239/93-001

This refers to your letter dated February 4, 1994, in response to our letter dated December 29, 1993.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

In reference to your comments about the requirement that the Radiation Safety Committee review the implementation of your Quality Management Program, the NRC considers the development and implementation of the quality management program a significant part of licensee's radiation safety program and therefore its development and implementation should be included in the annual review of radiation safety program by the Radiation Safety Committee as required by 10 CFR 35.22(b)(6).

Your cooperation with us is appreciated.

Sincerely,

Jenny M. Johansen, Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts

OFFICIAL RECORD COPY - S:\PENDING\MASSGEN.REP - 05/17/94

IE01

bcc:
Region I Docket Room (w/concurrences)

RI:DRSS	RI:DRSS	RI:DRSS
for Bhalla	Lodhi	Johansen
5/17/94	5/17/94	5/18/94

MASSACHUSETTS GENERAL HOSPITAL

Boston, Massachusetts 02114

February 4, 1994

Jenny M. Johansen, Chief
Medical Inspection Section
Division of Radiation Safety
& Safeguards
Region I
U.S. Nuclear Regulatory Commission
King of Prussia, Pennsylvania 19406

Dear Ms. Johansen:

Enclosed please find the Massachusetts General Hospital's response to the inspection of November 30 through December 3, 1993.

I would especially like to thank you for your help with the licensing amendment that was needed so quickly. Your help is greatly appreciated.

If you have any questions about Mr. Woodleigh's letter, please call me directly.

Thank you again.

Sincerely yours,

Maryanne Spicer
Assistant General Director,
Safety & Regulation

MAS:gs

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MASSACHUSETTS GENERAL HOSPITAL

Boston, Massachusetts 02114

25 January 1994

Jenny M. Johansen, Chief
Medical Inspection Section
Division of Radiation Safety
& Safeguards
Region I
U. S. Nuclear Regulatory Commission,

re: Reply to Inspection of MGH Licenses 20-03814-14 and 20-03814-80
Dockets 030-00239 and 030-01867

Dear Mrs. Johansen,

We send this document in response to your report of the 30 Nov - 3 Dec 1993 NRC inspection of the above referenced MGH licenses. In addition to the three violations cited during the visit, NRC pointed out a more general deficiency in our Radiation Safety Program. We take this as well as the other observations noted very seriously and so have included a discussion of all points, as well as of the violations, in this report. For this reason our response is lengthy.

Violations

A. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commissions regulations and licenses.

Contrary to the above, as of November 30, 1993, individuals working in the Nuclear Medicine scanning room, a restricted area, had not been instructed in the applicable provisions of the regulations and the conditions of the license. Specifically, a Nuclear Medicine technologist was not instructed in the procedure to check the survey meter for proper operation.

Response:

We do not dispute this finding. We had, in fact, identified the need to establish an effective periodic retraining program after the inspection of 1992. By the time of the 1993 inspection we had completed retraining for approximately 1000 workers. Unfortunately due to the large size of the institution we needed to make judgements as to which groups to schedule first. We elected to begin with the research workers and so at the time of the inspection Nuclear Medicine had been neither scheduled or completed.

As of this writing we have scheduled two one hour retraining sessions for the Nuclear Medicine workers with attendance at one session mandatory.

Date:	Time:
02 February 1994	4:00-5:00 PM
10 February 1994	9:00-10:00 AM

Topics included are the new Part 20 requirements relative to MPD and the reporting of personnel exposure, Part 35 requirements relative to misadministrations, the use of dose calibrators and the correct use of survey meters. We plan periodic retraining sessions at regular intervals. For new hires we will provide a training session covering the correct use of dose calibrators and survey meters. This training sessions will be provided within the first two weeks of employment.

B. 10 CFR 35.410 requires that a licensee provide radiation safety instruction to all personnel caring for a patient undergoing implant therapy. This instruction must describe: (1) Size and appearance of the brachytherapy sources; (2) Safe handling and shielding instructions in case of a dislodged source; (3) procedures for patient control; (4) Procedures for visitor control; and (5) Procedures for notification of the Radiation Safety Officer if the patient dies or has a medical emergency.

Contrary to the above, licensees nursing personnel cared for patients undergoing implant therapy and the licensee had not provided the required radiation safety instruction to those individuals concerning the size and appearance of the brachytherapy sources.

Response

We are hard pressed to explain this violation since an effective training program for brachytherapy nurses has been in effect for a number of years and the nurse in question has attended. In all likelihood the nurse simply confused the applicator with the sources within. Most brachytherapy implants conducted at MGH are of the afterloading type. The case in question used two Cs-137 sources in metal ovoids. We can only assume that a specific weakness in our training program is the cause of this incident.

We have examined our curriculum in this regard and find that although the size and appearance of brachytherapy sources is routinely included in the content we have not included such as a specific criteria under brachytherapy competency. Enclosed is a copy of specific sections of the nurses training program that pertain to implants (Appendix A). As a corrective action we have added a tenth performance criteria to page v of that document (Radiation Safety - Implants) The addition is printed in italics. The change is effective as of the date of this correspondence.

C. 10 CFR 35.59(d) requires that a licensee retain records of leakage test results for five years; and that the records contain the model number, and serial number if assigned, of each source tested; the identity of each source radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the signature of the Radiation Safety Officer.

Contrary to the above, as of November 30, 1993, the licensees records of leakage test results did not contain the signature of the Radiation Safety Officer.

Response

This violation was an unfortunate oversight on our part involving only those sources held by our Radiation Oncology section.

During past years the Radiation Oncology physicists have elected to analyze their own samples since that group possesses both the expertise and equipment to complete the task. There has also been some reluctance on the part of the Radiation Safety Staff to enter the source safe since these are relatively high level sources and are unshielded during the actual testing

process. For this reason, the Radiation Oncology sources have been considered as a separate group and have appeared on a different list from other sources. Although all other source test results were signed by the RSO, the sources described above were not. In light of the past set-up it was easy to neglect the signing of the leak test results.

As of this writing all sealed source leak tests records of calendar 1993 have been reviewed and signed by the RSO. Effective 28 January 1994 the RSO will personally conduct such testing on therapy sources. It should be stated here that the present RSO has 10+ years of experience in Therapeutic Physics with specialization in implant therapy. Beginning in June of 1994 the therapy source tests will appear in the same signed report as all other sealed sources possessed by MGH.

Specific Observations

1. The Radiation Safety Committee did neither review nor approve the MGH Quality Management Program

   Response

   We are not aware of any Part 35 requirement that the RSC review or approve our Quality Management Programs. The specific term used is the term "licensee." We took this to mean a group composed of applicable clinical sections, the RSO and management. Final review and approval was communicated by management via letter dated 24 January 1992 to Judy Joustra, Region I, NRC.

   Not withstanding the above comments we presented our QM programs to the RSC during the December 1993 meeting. This was accomplished via oral presentations by representative of the Radiation Oncology and Thyroid Groups as well as by the RSO. Admittedly we found the comments offered by members of the RSC to be most valuable. Should we propose any changes in our QM programs such will be reviewed and approved by the RSC.

2. The results of the annual audits required by the MGH Quality Management Program were not presented to the RSC.

   Response

   We are not aware of a Part 35 requirement that the RSC review the results of the annual QM audits. In preparing our

programs we elected to follow the suggestions listed in Reg. Guide 8.33. entitled "Quality Management Program." Referring specifically to 8.33-8 we quote, "The licensee or designee should regularly review the findings of the periodic reviews to ensure that the QM program is effective." In our program the term designee was taken to signify the applicable clinical group in conjunction with the RSO. The RSO in-turn communicated the review results to management.

Not withstanding the above comments the results of the annual audits were presented to the RSC at the December 1993 meeting. As noted in #1 above, the comments and observations were valuable and we plan to continue RSC review of each periodic audit.

3. The expiration of one of the MGH licenses had remained unnoticed by the staff.

Response

In a large institution it is often necessary for the RSO to delegate work to other individuals. In this case the Chairman of the RSC, a highly qualified individual and previous Interim RSO, had handled the license renewals for a number of years. The RSO was aware of this and erroneously delegated the responsibility to the Chairman. When the Chairman missed the renewal date for one of the licenses the RSO did not detect the error.

We now see this as a specific program weakness. While the RSO must delegate certain tasks to other qualified individuals the RSO cannot delegate responsibility.

Effective as of this writing, the RSO keeps a list of all license renewal dates. It is the responsibility of the RSO to ensure that licenses are maintained.

4. An incident reported by a nurse who provided care to a brachytherapy patient was not fully investigated by the RSO.

Response

The incident was investigated, though in an informal manner. We do realize that a certain degree of formality is required. In the future, all pertinent incident reports will be either...

a) signed and dated on the reverse side with information to include the nature of the incident, the course of the investigation, results of the incident and any corrective actions undertaken, or....

b) reported in the RSO Report which is circulated at each RSC meeting. The same information listed in "a" above will thence appear in the RSC minutes.

5. The therapy physicist and the RSO had different understandings of the use of portable shielding in brachytherapy patient's room.

Response

We do not dispute this finding. To ensure clarity in the future we have formulated a written policy in regards to the use of these devices (Appendix B). This policy has been forwarded to Nursing Sevice for inclusion in the Radiation Safety Training Course for brachytherapy nurses.

6. The RSO was not aware of which of the physicians working in the Radiation Medicine Department were the authorized users or that some authorized users were no longer with the institution.

Response

We do not dispute this finding. As in #3 above we credit this error to an assumption on the part of the RSO that the license had been amended through the efforts of the Chairman of the RSC. The RSO had not been informed that Radiation Oncology had hired new physicians. While the RSO was aware that two authorized users had left the institution he assumed that the RSC Chairman had notified the NRC to that effect.

In order to prevent a recurrence of the situation the RSO has opened up a direct line of communication with the Executive Secretary of the Radiation Medicine Department. (Claire Hunt) This individual is aware well in advance of any new hires. In a letter to NRC dated 3 December 1993 the RSO asked that the two individuals no longer at the institution be deleted as authorized users. We have also submitted an amendment re-request asking that the eight new physicians be added as authorized users. Until the NRC approves the request these eight physicians have been enjoined from issuing written directives for Cobalt teletherapy or brachytherapy treatments.

General Observation By NRC

The NRC views these observations (1-6 above) as a weakness in the MGH Radiation Safety Program and a cause for concern. NRC asks that we include with this response, steps taken to improve the communications between the Radiation Safety Committee, the Radiation Safety Officer and personnel and departments of the hospital involved in the use of radioactive material.

Response

Although each specific observation has been discussed above with corrective measures described, we would like to elaborate further on this general observation by the NRC. We agree that NRC has identified an inherent weakness in our program.

Since July of 1991 when the present RSO joined the MGH staff, a great deal of effort has been put into developing a collegial relationship with the individual permit holders. We thought this a prudent first step in laying a strong foundation for our expanding program. This effort has been rewarding and is evident in the many improvements that we have been able to make. Our next step is to elevate this relationship to one that remains collegial but is at the same time more formalized. As pointed out by the inspectors, this need is particularly obvious in regards to our Radiation Medicine section. To alleviate this problem we have taken or are planning the following steps:

1. The RSO is now a member of the Thyroid Associates QA Committee. This relationship became effective on 26 January 1994.

2. The RSO is now a member of the Radiation Medicine QA Committee. This relationship becomes effective as of next QA Committee meeting. (not yet scheduled)
3. Members of the Departments of Nuclear Medicine, Radiation Medicine and Thyroid Associate now serve on the RSC, guaranteeing frequent contact with the RSO.

4. All radiation incidents, except those of the most minor nature will be reported in writing to the RSC.

We believe that these actions as well as those outlined above will do much to improve communications.

In closing, please rest assured that the MGH is wholly committed to the operation of an effective Radiation Safety Program. We believe that we are on a solid course towards attaining our goals. We do appreciate the guidance and recommendations of the NRC in this regard.

Respectfully,

Rex Woodleigh

Rex Woodleigh, M.M.Sc
Radiation Safety Officer

cc. Maryanne Spicer
Edward Webster, Ph.D
Members MGH RSC

U.S. NRC
attn. Document Control Desk
Washington, D.C. 20555

Appendix A

MASSACHUSETTS GENERAL HOSPITAL

Department of Nursing

RADIATION SAFETY EDUCATION

Overview

The United States Nuclear Regulatory Commission Rules and Regulations require that hospital personnel who participate in the care of patients undergoing treatment with radionuclides receive special instructions regarding the precautions which must be implemented to insure the safety of both personnel and visitors.

All newly employed nurses receive general information concerning Radiation Safety. Nurses on units designated for patients treated with radionuclides for brachytherapy receive additional orientation. This instruction is designed to provide information essential to the safe delivery of nursing care. Orientation is coordinated by the Radiation Safety Educational Coordinator who has specific competencies which the nurse must demonstrate during orientation. Performance criteria and learning options are identified for each competency.

A list of nurses who have demonstrated competency is maintained by the Department of Nursing.

Joan Gallagher, M.S., R.N.
Radiation Safety Educational
Coordinator, Department of
Nursing

Rex Woodleigh, M.M.Sc.
Radiation Safety Officer

2/91

MASSACHUSETTS GENERAL HOSPITAL

Department of Nursing

RADIATION SAFETY ORIENTATION CONTENT

Overview of Radiation Safety Program at MGH and Nursing Implications

Introduction to the following concepts: sealed and unsealed sources of ionizing radiation.

Precautions to minimize exposure to radioactivity. Nursing implications.

Introduction to therapeutic uses of sealed sources eg. Cesium-137 and Iridium-192

Introduction to therapeutic uses of unsealed sources i.e. Iodine-131. Emphasis on precautions to prevent contamination.

MASSACHUSETTS GENERAL HOSPITAL

Department of Nursing

RADIATION SAFETY - RESOURCES

Competency:

Identify resources relative to Radiation Safety

Performance Criteria:

_____1. States the name of the Radiation Safety Officer

_____2. States two ways to contact the Radiation Safety Officer

_____3. States the name of the Radiation Safety Officer, Department of Nursing

_____4. States two ways to contact the Educational Coordinator regarding dosage.

_____5. Locates two radiation safety resource manual on the unit.

Learning Options:

Attend Radiation Safety Orientation Class.

Discuss with preceptor.

MASSACHUSETTS GENERAL HOSPITAL

Department of Nursing

RADIATION SAFETY - FILM BADGES

Competency:

Demonstrate knowledge regarding the use of a film badge.

Performance Criteria:

_____1. States the purpose of the film badge.

_____2. Locates where film badges are kept on the unit.

_____3. Signs out film badges per directions on sign-out sheet.

_____4. Demonstrates how to wear the film badge.

_____5. Identifies the department that supplies the film.

_____6. Identifies the length of time the nurse wears the same badge with consecutive radiotherapy patients.

Learning Options:

Attend the Radiation Safety Orientation Class

Discuss with preceptor.

Review the learning packet entitled Care of the Patients Treated With Radioactive Materials.

MASSACHUSETTS GENERAL HOSPITAL

Department of Nursing

RADIATION SAFETY - IMPLANTS

Competency:

Demonstrate knowledge required to safely care for a patient treated with radioactive implants.

Performance Criteria:

_____1. Name two radionuclides used in implants at MGH

_____2. States the rationale for employing the principles of time and distance in reducing exposure to radioactivity.

_____3. Describes the afterloading techniques.

_____4. Identifies one location where information is found regarding dosage.

_____5. Identifies three ways a nurse can reduce the time he/she spends in the patient room.

_____6. Discusses two ways the nurse could assess that a source has become dislodged.

_____7. Identifies two specific nursing measures the nurse should implement if an implant becomes dislodged.

_____8. Describes two ways a nurse could minimize exposure of personnel during an emergency situation.

_____9. Identifies how to determine the physician to be notified if a problem occurs such as an emergency or a dislodged source.

_____10. *Describes the appearance of the radioactive sealed sources.*

Learning Options:

Attend Radiation Safety Orientation Class

Review the learning packet entitled Care of the Patients Treated With Radioactive Materials.

Appendix B

POLICY FOR USE OF ROLLING LEADED SHIELDS DURING BRACHYTHERAPY.

1. Movable leaded shields will be provided for all radionuclide implant cases.

2. It is the responsibility of the on-duty Brachytherapy Physicist (BTP) to determine if a movable shield is available on an implant patients floor. If not, the BTP will locate a movable shield and deliver it to the implant patients room. If a movable shield is not on site at the time of the implant loading, the physician should contact the on duty BTP to deliver a shield. For evening or weekend implant loadings the physician should check with the on duty BTP to verify that a shield will be on site.