APPENDIX A

NOTICE OF VIOLATION

Holy Family Hospital and Medical Center
Methuen, Massachusetts 01844

Docket Nos. 030-00247
030-13728
License Nos. 20-13916-01
20-13916-02

As a result of the inspection conducted on June 26-27, 1990, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1990), the following violations were identified:

A. 10 CFR 35.21(a) requires that medical licensees appoint a Radiation Safety Officer responsible for implementing the radiation safety program. 10 CFR 35.21(b)(2) requires that the Radiation Safety Officer establish and implement written policy and procedures for the use and disposal of byproduct material.

The licensee's Radiation Safety Officer has established for these procedures those which are described in NRC Regulatory 10.8, Revision 2, Appendices I and R.

1. Item 9 of Appendix I requires that radioactive waste be disposed of only in designated, labeled, and properly shielded receptacles.

   Contrary to the above, on June 26, 1990, radioactive waste was not disposed of in a designated, labeled, and properly shielded receptacle. Specifically, an ordinary waste receptacle (i.e., not designated, labelled, and properly shielded) located in the Nuclear Medicine Hot Lab was found to contain a piece of gauze reading approximately 2 millirem/hour.

   This is Severity Level IV violation. (Supplement VI)

2. Item 2 of Appendix R requires, in part, that prior to transfer of a waste storage container to the decay-in-storage area, a tag be affixed to the container which identifies the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container.

   Contrary to the above, on June 26, 1990, the inspector noted that four waste storage containers were transferred to the decay-in-storage area without a tag which identified the date sealed, the longest-lived radioisotope in the container, and the initials of the person sealing the container.

This is a Severity Level IV violation. (Supplement VI)

B. 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.

Contrary to the above, all individuals working in a restricted area were not instructed in the precautions and procedures to minimize exposure to radioactive materials. Specifically, during non-routine working hours (Saturday evening), an untrained, unescorted painter was permitted to work in the Nuclear Medicine hot lab.

This is a Severity Level IV violation. (Supplement VI)

C. 10 CFR 35.70(e) requires that licensees survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, from February 9 through June 26, 1990, the licensee did not survey for removable contamination once each week where radiopharmaceuticals are routinely prepared for use, administered, or stored.

This is a Severity Level IV violation. (Supplement VI)

D. 10 CFR 35.22(a)(3) requires that a quorum of at least half of the members of the Radiation Safety Committee, including the Radiation Safety Officer and management's representative, be present for the Committee to conduct business.

Contrary to the above, on February 20, 1990, the Radiation Safety Committee met to conduct business and management's representative was not present.

This is a Severity Level IV violation. (Supplement VI)

E. 10 CFR 35.205(d) requires, in part, that the licensee post, in the area of radioactive aerosol or gas use, the spilled gas clearance time and safety measures to be instituted in the event of a spill.

Contrary to the above, as of June 27, 1990, the licensee had not posted in the area of radioactive aerosol or gas use, the spilled gas clearance time and safety measures to be instituted in the event of a spill.

This is a Severity Level IV violation. (Supplement VI)

F. 10 CFR 35.50(b)(3) requires, in part, that the dose calibrator linearity test be performed over the range of its use between the highest dosage that would be administered to a patient and 10 microcuries.

Contrary to the above, as of June 26, 1990, dose calibrator linearity tests were not performed over the range of its use between the highest dosage that would be administered to a patient and 10 microcuries. Specifically, on June 13, 1989 and December 12, 1989, quarterly dose calibrator linearity tests were performed to a minimum of 400 microcuries and on September 11, 1989 and March 22, 1990, quarterly dose calibrator linearity tests were performed to a minimum of 380 microcuries.

This is a Severity Level IV violation. (Supplement VI)

G. 10 CFR 35.50(e)(3) requires, in part, that records of quarterly dose calibrator linearity tests include the model and serial number of the dose calibrator, the calculated activities, and the signature of the Radiation Safety Officer.

Contrary to the above, as of June 26, 1990, records of quarterly linearity tests did not include the model and serial number of the dose calibrator, the calculated activities, and the signature of the Radiation Safety Officer.

This is a Severity Level V violation. (Supplement VI)

H. 10 CFR 35.92(a)(3) requires that all radiation labels be removed or obliterated before disposal in ordinary trash.

Contrary to the above, on June 26, 1990, all radiation labels were not removed or obliterated before disposal in ordinary trash. Specifically, two unobliterated radiation labels were found in the ordinary trash located in the licensee's hot lab.

This is a Severity Level V violation. (Supplement VI)

I. 10 CFR 35.406 requires, in part, that a licensee make a record of brachytherapy source use, including: the number of sources removed from storage; the number and activity of the sources in storage after the removal; the number of sources returned to storage; and the number of sources in storage after the return.

Contrary to the above, as of June 26, 1990, the licensee's record of brachytherapy source use did not include the number of sources removed from storage, the number and activity of the sources in storage after the removal, the number of sources returned to storage, and the number of sources in storage after the return.

This is a Severity Level V violation. (Supplement VI)

J. 10 CFR 35.59(g) requires, in part, that quarterly inventory records of brachytherapy sources contain the model number of each source, the nominal activity of each source, and the signature of the Radiation Safety Officer.

Contrary to the above, as of June 26, 1990, quarterly inventory records of brachytherapy sources did not contain the model number of each source, the nominal activity of each source, and the signature of the Radiation Safety Officer.

This is a Severity Level V violation. (Supplement VI)

K. 10 CFR 35.92(b) requires, in part, that records of disposal of byproduct material held for decay-in-storage include the survey instrument used, the background dose rate, and the name of the individual who performed the disposal.

Contrary to the above, as of June 26, 1990, records of disposal of byproduct material held for decay-in-storage did not include the survey instrument used, the background dose rate, and the name of the individual who performed the disposal.

This is a Severity Level V violation. (Supplement VI)

Pursuant to the provisions of 10 CFR 2.201, Holy Family Hospital and Medical Center is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

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