Appendix A

NOTICE OF VIOLATION

Schoolcraft Memorial Hospital License No. 21-16542-02

As a result of the inspection conducted on August 8, 1985, and in accordance with the General Policy and Procedures for NRC Enforcement Actions, (10 CFR Part 2, Appendix C), the following violations were identified:

1. License Condition 17 requires that all licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated November 30, 1981; and letter dated February 10, 1982.

   a. The letter dated February 10, 1982, states that the linearity checks of the dose calibrator will be performed quarterly.

   b. Letter dated February 10, 1982, also states that a 200 microcurie cesium-137 source will be used daily to check the constancy of the dose calibrator, and all dose calibrator channels will be checked at least once per year.

   c. Application dated November 30, 1981, states that the accuracy of the dose calibrator shall be checked annually.

   Contrary to these requirements:

   a. Linearity checks of the dose calibrator were not performed quarterly. Specifically, the dose calibrator was not checked for linearity during the first and second quarter of 1985.

      This is a repeat violation.

   b. The nominal 200 microcurie cesium-137 source was not used daily to check the constancy of the dose calibrator since the date of license issuance. As an example, the dose calibrator was used on July 10, 15, 16, 17, 1985, June 3, 4, 6, 11, 12, 20, 24, 26, 1985 and the nominal 200 microcurie cesium-137 source was not used to check the constancy of the dose calibrator. The licensee used a 10 microcurie cesium-137 button source rather than the 200 microcurie cesium-137 source to check the daily constancy of the dose calibrator. In addition, all dose calibrator channels were not checked yearly. Specifically, only the cesium-137 dose calibrator channels were checked since the date of the license issuance March 22, 1982.

   c. Accuracy of the dose calibrator was not performed annually. Specifically, accuracy checks of the dose calibrator were not performed in 1983, 1984, or 1985.

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

2. 10 CFR 35.14(b)(ii) states that before administration to patients, each elution or extraction of technetium-99m from a molybdenum-99/ technetium-99m generator shall be tested to determine either the total molybdenum-99 activity or the concentration of molybdenum-99.

   Contrary to this requirement, each elution of technetium-99m from a molybdenum-99/technetium-99m generator was not tested to determine the total molybdenum-99 activity or the concentration of molybdenum-99. Specifically, the total molybdenum-99 activity or the concentration of molybdenum-99 was not determined for technetium-99m administered to patients on January 2, 3, and 29, 1985, February 1, 12, and 21, 1985, March 6, 7, 13 and 27, 1985, April 3, 1985, May 6, 7, 10, 15, 28, and 30, 1985, June 3, 6, 11, 20, 24, 26, 1985, and July 10, 15 and 17, 1985.

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

3. License Condition 17 requires that all licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated November 30, 1981; letter dated February 10, 1982, and ALARA Program dated December 2, 1981.

   Application dated November 30, 1981, states that the procedures described in Appendix I of Regulatory Guide 10.8 will be followed for routine area surveys. Appendix I states that all elution, preparation, and injection areas will be surveyed daily, using a low range survey meter. Weekly G-M surveys will be performed of all waste storage areas and all other laboratory areas.

   Contrary to this requirement, daily G-M surveys were not performed of the elution, preparation, and injection areas; and weekly G-M surveys were not performed of all waste storage areas and all other laboratory areas, since the date of the license issuance.

   As an example, licensed material was used on July 10, 15, 16, 17, 1985, June 3, 4, 6, 11, 12, 20, 24, 26, 1985 and daily G-M surveys were not performed.

   Licensed material was used during the 2nd and 3rd week of July 1985; 1st, 2nd, 3rd and 4th week of June 1985, 2nd and last week of May 1985, and G-M surveys of the waste storage areas and other laboratory areas were not performed.

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

4. License Condition 17 requires that all licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated November 30, 1981; letter dated February 10, 1982; and ALARA Program dated December 2, 1981. Application dated November 30, 1981, states that the duties of the medical isotope committee shall be as described in Appendix B of NRC Guide 10.8. Appendix B states that the medical isotopes committee shall meet as often as necessary to conduct it business but not less than once in each calendar quarter.

Contrary to this requirement, the medical isotopes committee did not meet once in each calendar quarter. Specifically, the medical isotope committee did not meet during the first, second, or third quarter of 1983, the first, second or third quarter of 1984, or the first quarter of 1985.

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

5. License Condition 17 requires that all licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated November 30, 1981; letter dated February 10, 1982; and ALARA Program dated December 2, 1981. License application dated November 30, 1981, states that Appendix G of the NRC Guide 10.8 will be followed for safe use of radioactive material. Appendix G states that personnel shall monitor hands and clothing for contamination after each procedure or before leaving the area.

   Contrary to this requirement, it was learned from statements of licensee representatives that personnel did not monitor their hands and clothing for contamination after each procedure or before leaving the area. As an example, licensed material was used on July 10, 15, 16 and 17, 1985, and personnel did not monitor hands and clothing for contamination.

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

6. License Condition 17 requires that all licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated November 30, 1981; letter dated February 10, 1982; and ALARA Program dated December 2, 1981. Letter dated February 10, 1982, states that the package opening procedure will include measuring the exposure rate at one meter from the package surface.

   Contrary to this requirement, the exposure rate at one meter from the package surface was not measured. Specifically, the exposure rate at one meter from the package surface was not measured for packages containing radioactive material received on January 1 and 21, 1985, February 4 and 18, 1985, March 6 and 20, 1985, April 8 and 22, 1985, May 4 and 18, 1985, June 3 and 17, 1985 and July 8 and 22, 1985.

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

7. 10 CFR 20.401(b) requires that the licensee maintain records showing the results of surveys that were made to assure compliance with 10 CFR 20.201(b). 10 CFR 20.201(b) states that the licensee shall make such surveys as will be necessary to comply with the regulations in 10 CFR Part 20. 10 CFR 20.301 describes the authorized means of disposing of licensed material in waste.

   Contrary to this requirement, the licensee failed to maintain records of results of such surveys as were necessary to assure compliance with 10 CFR 20.301, a regulation that describes authorized means of disposing if licensed material contained in waste. Specifically, the licensee failed to maintain records of surveys of technetium-99m contaminated waste to assure that no measurable radiation above background was present

before disposal. Licensee has failed to keep records of survey results since the date of license issuance March 22, 1982.

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

8. License Condition 17 requires that all licensed material be possessed and used in accordance with statements, representations and procedures contained in letter dated February 10, 1982.

Letter dated February 10, 1982, states that the portable survey meter shall be calibrated annually.

Contrary to this requirement, the portable survey meter was not calibrated annually. Specifically, the Eberline and Victoreen survey meters were not calibrated in 1983, 1984 or 1985.

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

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

9-27-85
Dated

W D Shafer for
Jack A. Hind, Director
Division of Radiation Safety
and Safeguards

Appendix B

MANAGEMENT CONTROL

In order to provide you with some guidance in assessing the adequacy of your management control program, the NRC Region III office provides the following as the acceptance criteria for adequate management control for materials licensees. "Management Control" is a system instituted by management to assure that licensed activities are performed safely and in accordance with regulatory requirements (license conditions and applicable regulations).

This will include:

a. Delineation of duties and responsibilities of all persons involved in licensed activities.

b. Providing for indoctrination and training of all personnel performing licensed activities, specifically in those areas directly affecting compliance with NRC regulations and license conditions.

c. Verification, as by checking, auditing and inspecting, that activities affecting safety related functions have been correctly performed. The verifying process should be performed by individuals or groups other than those performing the safety related procedures.

d. Insuring continued compliance of licensed activities throughout periods during which routine activities may be interrupted, such as changes in equipment, personnel or facilities.

Because of the many variables involved, such as the number of personnel, type of activity being performed and the location or locations where activities are performed, the organizational structure for executing the management control program may take various forms; however, irrespective of the organizational structure, the individual or group responsible for this control should have the flexibility and authority to institute changes or corrections as required to maintain compliance with NRC regulations and license conditions.