Appendix A

NOTICE OF VIOLATION

Hackley Hospital License No. 21-04125-01

As a result of the inspection conducted on July 17 and 18, 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 24 requires that all licensed material be possessed and used in accordance with statements, representations, and procedures contained in letter dated December 29, 1983 (with attachments) and letters dated June 1, 1978 and January 7, 1983.

   Letter dated December 29, 1983 (with attachments) designates James Carlson, M.S., as the Radiation Protection Officer.

   Contrary to this requirement, an individual other than James Carlson is the Radiation Protection Officer. Specifically, it was learned from statements of licensee representatives, and a review of records, that James Carlson resigned as Radiation Protection Officer on April 3, 1985, and Lawrence Kirshner, an individual not authorized by the license, was appointed Radiation Protection Officer.

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

2. License Condition 12 states that licensed material listed in Group VI of 10 CFR Part 35, Schedule A, shall be used by or under the supervision of Richard R. Oslund, M.D., Everett H. Johnston, M.D., or Donald P. Stratton, M.D. Group VI authorizes the use of iridium-192 as seeds for interstitial treatment of cancer.

   Contrary to this requirement, licensed material listed in Group VI of Schedule A in 10 CFR Part 35 was not used by or under the supervision of the physicians authorized by the license. Specifically, iridium-192 seeds were used for interstitial treatment of cancer on April 29, 1985, and May 15, 1985 by individuals not authorized by the license.

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

3. License Condition 21 states that the licensee shall calibrate the dose calibrator in accordance with the procedures contained in Section 2 of Regulatory Guide 10.8, October 1980. Section 2 states that daily constancy checks of the dose calibrator shall include the measurement of a long lived standard (such as cesium-137) on commonly used settings.

Contrary to this requirement, daily constancy checks of the dose calibrator did not include the measurement of a long lived standard on the commonly used settings. Specifically, daily constancy checks did not include the molybdenum-99, technetium-99m, iodine-131, and xenon-133 settings since the date of license issuance. As an example, the molybdenum-99 and technetium-99m settings were used on May 20, 24, 29, and 30, 1985, and June 5, 6, 7, 13, 14, and 15, 1985; the iodine-131 setting was used on April 23, 25, and 26, 1985 and May 30, 1985; the xenon-133 setting was used on July 1 and 8, 1985, and the settings were not checked for constancy.

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

4. License Condition 24 requires that all licensed material be possessed and used in accordance with statements, representations, and procedures contained in letter dated December 29, 1983 (with attachments).

Letter dated December 29, 1983 (with attachments) states that the procedure for receipt of radioactive materials shall include a measurement of the exposure rate at the surface of the package and at 3 feet from the surface of the package.

Contrary to this requirement, it was learned from statements of licensee representatives that the exposure rate at the package surface and 3 feet from the package surface was not always measured for packages containing radioactive materials. Specifically, the exposure rate was not measured for shipments of iridium-192 seeds received in April 1985 and May 1985.

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

5. License Condition 22 states the licensee shall wipe test the final source container of all licensed material received and maintain records of the results.

Contrary to this requirement, wipe tests of the final source container of all licensed material received were not always performed. Specifically, wipe tests of the final source container were not performed on packages containing radioactive materials since the date of license issuance, April 19, 1985. As an example, wipe tests of the final source container were not performed on molybdenum-99/technetium-99m generators and xenon-133 vials received on July 1 and 15, 1985.

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

6. 10 CFR 71.5 states that no licensee shall transport licensed material out of his facility unless the licensee complies with 49 CFR Parts 170-189.

49 CFR 173.475 states that before each shipment of any radioactive materials package, the shipper shall ensure by examination or appropriate tests that:

"External radiation and contamination levels are within the allowable limits specified in this chapter."

Contrary to this requirement, the licensee failed to ensure that the contamination levels were within allowable limits for packages containing molybdenum/technetium generators returned to the manufacturer for disposal. Specifically, the licensee failed to perform wipe tests for removable contamination on packages returned to the manufacturer since February 1985.

As an example, molybdenum-99/technetium-99m generators were shipped to the manufacturer on May 28 and 31, 1985; June 14 and 28, 1985; and July 5 and 12, 1985 and wipe tests for removable contamination were not performed.

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

7. License Condition 24 requires that all licensed material be possessed and used in accordance with statements, representations, and procedures contained in letter dated December 29, 1983 (with attachments).

Letter dated December 19, 1983 (with attachments) states that daily G-M or Cutie Pie surveys shall be performed in the isotope preparation area, storage area, and the injection room. Weekly wipe tests shall be performed at the injection station, counter top (camera room), pharmatopes delivery area, drawing station and counter top (cardiac room).

Contrary to this requirement, G-M or Cutie Pie surveys of the isotope preparation area, storage area and injection room were not always performed daily. Wipe tests at the injection station, counter top (camera room) pharmatopes delivery area, drawing station and counter top (cardiac room) were not always performed weekly.

Specifically, daily G-M or Cutie Pie surveys were not performed on May 20, 24, 29, and 30, 1985 and June 5, 6, 7, 13, 14, and 15, 1985. Wipe tests were not performed on four occasions between April 29 and June 24, 1985.

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

8. Item 8B of the License states that 2 curies of each byproduct material authorized in Subitem 6B, is the maximum amount that the licensee may possess at any one time under the license. Subitem 6B states the licensee is authorized to use any byproduct material listed in Group III of 10 CFR 35.100, Schedule A. Group III authorizes the use of molydenum-99/technetium-99m generators.

Contrary to this requirement, it was learned from statements of licensee representatives and a review of records that the licensee exceeded the maximum amount of byproduct material listed in the license for molybdenum-99/technetium-99m generators. Specifically, the licensee has received a 2.5 curie molybdenum-99/technetium-99m generator weekly since April 1984.

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

9. 10 CFR 35.14(b)(5)(v) states that the licensee shall conduct a quarterly physical inventory to account for all Group VI sources and devices received and possessed.

Contrary to this requirement, the licensee failed to conduct a quarterly physical inventory to account for all Group VI sources and devices received and possessed.

Specifically, the nominal 100 millicurie, Tracer Lab strontium-90 eye applicator was not inventoried quarterly. The last inventory was performed during the last leak test performed on March 21, 1985. The source was inventoried every 6 months when the leak test was due rather than quarterly.

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

10. 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 April 19, 1985.

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

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 violation: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further violation; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

8-19-85
Dated

J. 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.