Appendix A

NOTICE OF VIOLATION

Hackley Hospital License No. 21-04125-01

As a result of the inspection conducted on August 5, 1982, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

1. 10 CFR 35.14(b)(5)(v) requires that sealed sources possessed and used pursuant to Group VI of Schedule A of 10 CFR 35.100 be physically inventoried quarterly to account for all the sources received and possessed.

   Contrary to this requirement, as of the day of the inspection, you failed to perform the required quarterly inventories. Specifically, Group VI sealed sources are inventoried for source accountability only upon removal from a patient.

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

2. 10 CFR 30.34(c) requires that you confine your possession and use of byproduct materials to the locations and purposes authorized by your license. Condition 23 of your license requires that licensed material be used in the areas of your hospital specified in your letter dated March 27, 1978 (with supplements).

   Contrary to this requirement, you have used byproduct materials in your hospital at locations not authorized by your license. Specifically, you relocated your nuclear medicine department in April of 1981 without amending your license to account for this change.

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

3. 10 CFR 20.201(b) requires that you make such surveys as may be necessary for you to comply with all sections of Part 20. 20.201(a), "Survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to this requirement, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.105(b), "Permissible levels of radiation in unrestricted areas." Specifically, in April of 1981, you failed to survey your old nuclear medicine department prior to releasing it as an unrestricted area.

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

4. 10 CFR 20.201(b) requires that you make such surveys as may be necessary for you to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "Survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive material or other sources of radiation under a specific set of conditions.

Contrary to this requirement, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.105(b), "Permissible levels of radiation in unrestricted areas." Specifically, you failed to perform surveys of the radiation levels in the surrounding corridors and adjacent rooms to the room of a patient containing radioactive implants since this requirement began on September 7, 1978.

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

5. License Condition No. 23 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The above referenced letter dated October 24, 1977, Section entitled "Technologist Procedures for Iridium-192," states that the patient's room and the room used for removal of the Ir-192 seeds shall be monitored with a survey instrument to assure that no seeds are inadvertently left in the area, and the results of this survey shall be recorded.

Contrary to this requirement, you failed to record the results of the above referenced surveys since the requirement began on September 7, 1978.

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

6. License Condition No. 23 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced letter dated October 24, 1977, Section entitled "Standardization of Dose Calibrator" requires: (a) in Item I(g) that annual linearity tests be repeated the following week or the instrument repaired when the number of data points exceeding a ±10% deviation is in excess of ¼ of the total number of points; (b) in Item III(d) that accuracy tests be performed semiannually; and (c) in Item V(d) that daily constancy checks be performed.

Contrary to the above requirements: (a) your last linearity test done on July 27, 1981, exceeded the ±10% deviation and was not repeated nor was the instrument repaired; (b) you failed to perform semiannual accuracy tests from September 10, 1980, to the date of inspection; and (c) you failed to perform daily constancy checks from April 4 to May 3, 1982, July 7 to July 19, 1982, and on several other occasions.

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.

8/24/82
Dated

J. R. Miller, Chief
Technical Inspection Branch

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.