APPENDIX A

NOTICE OF VIOLATION

Dana-Farber Cancer Institute
Boston, MA 02115

Docket No. 030-20020
License No. 20-19761-02

As a result of the inspection conducted on March 28 and 29, 1985, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

A. License Condition No. 26 states that the licensee shall possess and use licensed material in accordance with statements, representations, and procedures contained in application dated January 14, 1984.

1. Item 7 of this application requires the Radiation Safety Committee to hold at least four meetings each year.

   Contrary to this requirement, since May 1984 when this license was issued, only two meetings of the Radiation Safety Committee were held during 1984. Meetings were held during September and October of 1984.

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

2. Item 21 of this application requires that the air flow in the xenon-133 storage and preparation room will be checked semi-annually with an anemometer.

   Contrary to this requirement, since this license was issued, the air flow in the xenon-133 storage and preparation room has not been checked.

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

3. Item 10 of this application requires that dose calibrators will be calibrated as specified in Appendix D, Regulatory Guide 10.8 (Revision 1) dated October 1980.

   Contrary to this requirement, since this license was issued, instrument linearity and accuracy tests have not been performed at the specified frequencies. The quarterly linearity tests were performed only during November 1984 and February 1985 and the annual accuracy test has not been performed to date.

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

4. Item 17 of this application requires that area survey procedures in Appendix I of the Radiation Manual will be followed. These procedures specify that weekly surveys must be performed when working with 5 mCi quantities or greater radioactive materials or with 100 uCi or more of radioiodine. In addition, Section 3.5 of the Radiation Manual specifies that the Harvard University Health Services (HUHS) will make monthly surveys of each laboratory using radionuclides.

   Contrary to these requirements, since this license was issued, weekly and monthly surveys have not always been performed in the Nuclear Medicine Department. During 1984 surveys were performed once each month in June, July, August, October, and December, three times during November and not at all during September.

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

B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary 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 materials or other sources of radiation under a specific set of conditions.

   Contrary to this requirement, as of the dates of this inspection, no surveys (evaluations) were performed to assure compliance with 10 CFR 20.101 for individuals who lost their extremity TLD ring badge for May 1984 and who lost their whole body film badge for June 1984.

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

C. License Condition No. 21 requires that the licensee conduct a physical inventory every six months to account for all sealed sources received and possessed under the license.

   Contrary to this requirement, as of the dates of this inspection, no physical inventories had been performed of Cs-137 and Ba-133 calibration check sources in excess of 100 uCi, used in the Nuclear Medicine Department.

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

Pursuant to the provisions of 10 CFR 2.201, the Dana-Farber Cancer Institute 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.