APPENDIX A

NOTICE OF VIOLATION

Berkshire Medical Center
725 North Street
Pittsfield, Massachusetts 01201

Docket Nos. 030-01942
030-00245
070-01450
License Nos. 20-12009-01
20-12009-03
SNM-1439

As a result of the inspection conducted on August 2, 1990, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1988), the following violations were identified:

A. Condition 17 of License No. 20-12009-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained, in part, in an application dated September 21, 1984.

1. Item No. 10 of this application requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Regulatory Guide 10.8, Revision 1.

a. Appendix D of Regulatory Guide 10.8, Revision 1, requires, in part, that linearity of a dose calibrator be ascertained over the entire range of activities administered.

Contrary to the above, as of August 2, 1990 dose calibrator linearity tests were not performed over the entire range of activities administered. Specifically, dosages of at least 100 millicuries were administered to patients, and dose calibrator linearity tests were performed only over a range of 40 millicuries to 100 microcuries.

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

b. Appendix D of Regulatory Guide 10.8, Revision 1, requires, in part, that dose calibrator constancy be verified before each day's use of the instrument.

Contrary to the above, as of August 2, 1990, dose calibrator constancy had not been verified before each day's use of the instrument. Specifically, dose calibrator constancy had not been performed since July 27, 1990, while byproduct material had been administered to patients on at least four days, July 30 through August 2, 1990.

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

2. Item No. 17 of this application requires that area surveys be performed in accordance with procedures contained in Appendix I, Regulatory Guide 10.8, Revision 1.

   a. Appendix I of Regulatory Guide 10.8, Revision 1, requires, in part, that all elution, preparation, and injection areas to be surveyed daily.

      Contrary to the above, as of August 2, 1990, daily surveys of elution, preparation, and injection areas had not been performed. Specifically, daily surveys had not bee performed since July 27, 1990, while byproduct material had been used at least four days, July 30 through August 2, 1990.

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

   b. Appendix I of Regulatory Guide 10.8, Revision 1, requires, in part, that wipe test results be evaluated is disintegrations per minute.

      Contrary to the above, as of August 2, 1990, wipe tests results were not evaluated in disintegrations per minute. Specifically, wipe test results were evaluated in counts per minute.

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

B. Condition 15 of License No. SNM-1439 requires that patients in whom pacemakers have been implanted be followed for the life of the patient.

   Contrary to the above, as of August 2, 1990, two patients whom pacemakers were implanted had not been followed. Specifically, the records indicated that no follow-up was performed since April, 1987 for one patient and since March 1988 for the other patient.

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

Pursuant to the provisions of 10 CFR 2.201, Berkshire 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.