APPENDIX A

NOTICE OF VIOLATION

Radiological Diagnostic Center of Englewood — Docket No. 30-17239

Englewood, New Jersey 07631 — License No. 29-19?65-01

As a result of the inspection conducted on March 9, 1982, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, as of March 9, 1982, deliveries containing licensed materials were routinely left unlocked and unsecured in the parking lot outside of your office, which is an unrestricted area, and were neither under constant surveillance nor under your immediate control.

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

B. 10 CFR 20.201(b) requires that each license make adequate surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means as 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.

1. Contrary to the above, no surveys were performed to assure compliance with 10 CFR 20.301, a regulation that describes authorized means of disposing of licensed material contained in waste. Specifically, on March 9, 1982, no surveys were performed for contamination on absorbent materials containing measurable amounts of licensed material prior to disposing of the materials in the normal trash.

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

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2. Contrary to the above, as of March 9, 1982, no surveys (evaluations) were made to assure compliance with 10 CFR 20.101, a regulation limiting the exposure of individuals to radiation in restricted areas. Specifically, the necessary personnel monitoring to evaluate the dose to the extremities and whole body of a nuclear medicine technologist who began employment on January 11, 1982 was not provided.

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

C. 10 CFR 19.12 requires that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

   Contrary to the above, as of March 9, 1982, an individual working in the restricted area had not been instructed in the applicable provisions of the regulations and conditions of the license.

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

D. Condition 15 of License No. 29-19265-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in an application dated November 30, 1979.

   1. Block 10 of this application requires that the dose calibrator be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8.

      a. Item A.3 of Appendix D, Section 2, requires that the linearity of the dose calibrator be determined at installation and quarterly thereafter.

         Contrary to the above, as of March 9, 1982, dose calibrator linearity had not been determined at installation or quarterly, as required.

      b. Items A.1 and C of Appendix D, Section 2, require that constancy checks be performed daily on the dose calibrator with at least two reference sources and that variations greater than ±5 percent from the predicted activity indicate the need for instrument repair on adjustment.

         Contrary to the above, as of March 9, 1982, constancy checks were not performed daily. Further, when the cesium-137 source was assayed, it varied by -18.9% from the predicted value and no instrument adjustment or repair was performed.

c. Items A.2 and 4 of Appendix D, Section 2, require that accuracy tests of the dose calibrator be performed at installation and annually thereafter and that geometrical variation test be performed at installation on the dose calibrator.

Contrary to the above, as of March 9, 1982, no accuracy or geometrical variation tests had been performed on the dose calibrator.

These are Severity Level IV violations (Supplement VII).

2. Item 10 of this application requires that the "Area Survey Procedures" contained in Appendix I of Regulatory Guide 10.8 be followed.

Item 1 of Appendix I requires daily surveys of all preparation and injection areas. Item 4.b of this Appendix requires that weekly surveys include wipes.

Contrary to the above, as of March 9, 1982, preparation and injection areas were not surveyed on a daily basis, and no wipe tests were performed.

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

3. Item 10 of this application requires that survey instruments be calibrated in accordance with the procedures in Appendix D, Section 1, of Regulatory Guide 10.8, Revision 1.

Item A.3 of Appendix D, Section 1 requires that survey meters be calibrated at least annually and after servicing.

Contrary to the above, as of March 9, 1982, a survey meter had not been calibrated since it was purchased in December 1980, a period of more than one year and the low level instrument was inoperable on the day of the inspection.

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

4. Block 15 of this application requires that the "General Rules for Safe Use of Radioactive Materials," contained in Appendix G of Regulatory Guide 10.8 be followed.

a. Item 4 of Appendix G requires that syringe shields be used for the preparation and administration of patient doses.

Contrary to the above, as of March 9, 1982, personnel handling radiopharmaceuticals failed to use syringe shields in the administration of patient doses.

b. Item 2 of Appendix G requires that gloves be worn at all times while handling materials.

Contrary to the above, as of March 9, 1982, gloves were not worn while opening packages, nor during assaying or administering of the radiopharmaceuticals.

c. Item 3 of Appendix G requires that hands and clothing be monitored for contamination after each procedure on before leaving the area.

Contrary to the above, as of March 9, 1982, no monitoring for contamination of hands and clothing was performed.

These are Severity Level IV violations (Supplement VI).

5. 10 CFR 35.14(b)(5)(i) requires that each source or device possessed and used pursuant to Group VI of Schedule A of 10 CFR 35.100 be tested for contamination and/or leakage at intervals not to exceed six months.

Contrary to the above, as of March 9, 1982, no tests for leakage contamination had been performed on a 203 microcurie cesium 137 source since it was purchased several years ago.

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

Pursuant to the provisions of 10 CFR 2.201, the Radiological Diagnostic Center of Englewood is hereby required to submit to this office within thirty days of the date of 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.

Date: 14 SEP 1982