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APPENDIX A

NOTICE OF VIOLATION

Cambridge Medical Diagnostics, Inc.  
Billerica, Massachusetts 01865

Docket No. 30-04659  
License No. 20-06799-02

As a result of the inspection conducted on December 13-14, 1982, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

- A. 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 the above, as of December 14, 1982, no surveys were made to assure compliance with 10 CFR 20.106, which limits the release of radioactivity to unrestricted areas. Surveys intended to meet this requirement were made, but were inadequate, in that they were not complete. Specifically, they did not include the efficiency of the air filtration system for iodine, nor did they relate the air monitoring and bioassay data to the requirements in 10 CFR 20.106.

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

- B. Condition 16 of License No. 20-06799-02 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated August 18, 1977.

1. Item 14 of this application refers to the Safety Manual.

Sections III.A.3. -a and -b of this manual require that all seams in the radioiodine and radioactive particulate ventilation systems be galvanized welded.

Contrary to the above, as of December 14, 1982, the seams in that part of the radioiodine and radioactive particulate ventilation systems that are below the roof were not welded.

2. Item 5 of this application specifies that certain named individuals act as your Radiation Safety Officers.

Contrary to the above, as of December 14, 1982, the individuals designated as your Radiation Safety Officer were changed and you failed to amend your license to reflect the change.

These items are Severity Level IV violations. (Supplement VI)

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Pursuant to the provisions of 10 CFR 2.201, Cambridge Medical Diagnostics, Inc. 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.