

FEB 1 1983

Docket Nos.: 30-04659
30-11473
30-11391

License Nos.: 20-06799-02
20-06799-03MD
20-06799-04G

Cambridge Medical Diagnostics, Inc.
ATTN: Joseph J. Fitzgerald, Ph.D.
President
575 Middlesex Turnpike
Billerica, Massachusetts 01865

Gentlemen:

Subject: Inspection No. 82-02

This refers to the special safety inspection conducted by Dr. Lawrence F. Friedman of this office on December 13-14, 1982 of activities by NRC License Nos. 20-06799-02, -03MD and -04G and to the discussions of our findings held by Dr. Friedman with yourself and other members of your staff at the conclusion of the inspection, and to a subsequent telephone discussion between Edward Fitzgerald of your staff and Dr. Friedman on December 20, 1982.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and the conditions of your licenses. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, measurements made by the inspector, and observations by the inspector.

The inspector took air samples in your production and sales areas which were analyzed in our Regional Office Laboratory in King of Prussia, Pennsylvania. The results of our analyses indicate levels were below minimum detectable activities, and at least a factor of 100 below the concentration limit in 10 CFR Part 20, Appendix B, Table II, Column 1.

Based on the results of this inspection, it appears that certain of your activities were not conducted in full compliance with NRC requirements, as set forth in the Notice of Violation, enclosed herewith as Appendix A. This violation has been categorized by severity level in accordance with the NRC Enforcement policy (10 CFR 2, Appendix C) published in the Federal Register Notice (47 FR 9987) dated March 9, 1982. You are required to respond to this letter and in preparing your response, you should follow the instructions in Appendix A.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

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Your cooperation with us in this matter is appreciated.

Sincerely,

Original Signed By:

for JOHN E GLENN
Thomas T. Martin, Director
Division of Engineering and
Technical Programs

Enclosure: Appendix A, Notice of Violation

cc w/o encl:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts (2)

bcc w/o encl:
Region I Docket Room (with concurrences)
Senior Operations Officer (w/o encl.)

for RI:DETP
Friedman/nm 1/26/83
RI:DETP
Glenn 1/27/83

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