



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

January 14, 2003
NWE-01-03

VIA FEDEX

Mr. Lars Peterson
Manager QA and Compliance
Siemens Medical Solutions USA, Inc.
186 Wood Avenue South
Iselin, NJ 08830

Dear Mr. Peterson:

On December 4, 2002, an inspector from the Commonwealth of Massachusetts (under agreement with the U.S. Food and Drug Administration (FDA)) performed a field test of a certified diagnostic x-ray system (GI70151) at:

[REDACTED]
[REDACTED]
[REDACTED]
X-Ray Control Manufactured [REDACTED]
X-Ray Control Model # [REDACTED]
Serial Number [REDACTED]
Room # : Room R138

Our records indicate that your firm assembled this system (FDA-2579; #D943964) on June 29, 2002, and we tested this system to determine its compliance with portions of the Performance Standard for Diagnostic X-Ray Equipment (21 CFR 1020.30-32). Diagnostic x-ray equipment are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our analysis of the field test data indicates that the system does not comply with the following item of the Performance Standard:

X-ray production was not prevented when the conditions for positive beam limitation (PBL) were met, but the length and width of the x-ray field in the plane of

the image receptor exceeded the corresponding image receptor dimension by more than 3 percent of the source to image distance (SID).

The Federal Performance Standard requires that when a PBL system is provided, it shall prevent x-ray production when either the length or width of the x-ray field in the plane of the image receptor differs from the corresponding image receptor dimension by more than 3 percent of the SID. 21 CFR 1020.31(g)(1)

We request that you, as the responsible assembler, immediately investigate the deviations from the performance standard cited above in accordance with 21 CFR 1003 and 1004, as follows:

1. If you determine that the noncompliance and/or defect is caused by improper assembly or installation, you must correct the noncompliance and/or defect at no charge to the user by either repairing the system, replacing it, or refunding the cost.
2. If you determine that the noncompliance and/or defect is caused by the factory-based manufacturer, you must notify him of the noncompliance and/or defect and send documentation of such notification to this office.
3. If you can establish that the system is compliant, that the alleged defect does not exist or does not relate to the safety of the product, or is directly attributable to user abuse or lack of maintenance, you may submit such evidence in accordance with 21 CFR 1003.11(a)(3) within thirty (30) working days of receipt of this letter.

You are requested to report the results of your investigation and follow-up action to this office within thirty (30) working days of receipt of this letter. Your response should include the date that the corrective action was completed and copies of service records and/or other supportive documents. If you do not respond within thirty (30) working days, the FDA may consider you to be in violation of the Act, Sections 538(a)(2) and 538(a)(4) of Subchapter C – Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Please note that improper installation, including failure to follow installation instructions which cause the system to be noncompliant with the Performance Standard may cause the system to be adulterated. Under Section 501(c) of the Act the system would not be of a quality represented by the labeling (including the certification statement).

You should notify this office, in writing, within (30) working days of receipt of this letter, of the specific steps you have taken to correct the noted violation, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within thirty (30) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to M. Patricia Murphy, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, MA 02180. If you have any questions, please contact Michael Leal, X-ray Auditor, at 508-793-0422.

Sincerely yours,



Gail T. Costello
District Director
New England District Office

cc:



cc: Robert Walker
Director
Radiation Control Program
Department of Health
174 Portland St., 5th Floor
Boston, MA 02114