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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
FACSIMILE: 214-655-8130

WARNING LETTER

July 27, 1997

**Certified Mail
Return Receipt Requested**

John M. Schmidt
Region Compliance Engineer
General Electric Medical System
1425 Greenway Suite 150
Irving, TX 75038

Re: Field Test No. GI50756
Mineral Area Hospital
Potosi, MO
Room No. Radiology
Manufacturer: General Electric
Control Serial No. 329572
Model No. 46-178450G1

Dear Mr. Schmidt:

On May 28, 1997, a representative from the Food and Drug Administration conducted a field test on the above referenced x-ray equipment. This system, installed by your firm on April 14, 1997 as reported by Form FDA 2579, D321288, was tested to determine its compliance with applicable portions of the Performance Standards for Diagnostic X-ray Equipment, Title, 21, Code of Federal Regulations (CFR), Part 1020. Analysis of the data obtained indicates that the following item was not in compliance with the standard as follows:

Fluoroscopic Portion:

X-Ray production was possible with the primary protective barrier in the park position (outside of the primary x-ray beam). This is in violation of 21 CFR 1020.32(a)(1).

In addition to the problem mentioned above, we consider the compliance status on the following items to be suspect. Please verify the compliance status of these items when you correct the previously cited problem.

Radiographic Portion:

The actual vs. the indicated SID (source-to-image-receptor-distance) differs by 3.7%. This exceeds the allowed limit of up to 2% of the SID, as specified by 21 CFR 1020.31(e)(1).

The actual x-ray field size deviates from the indicated size by 3.2% of the SID for width when the collimator settings are adjusted manually. This exceeds the limit of 2 % as specified by 21 CFR 1020.31(e)(3).

In accordance with provisions of 21 CFR, Parts 1003 and 1004, as the responsible manufacturer/assembler, it is requested that you investigate the cause of this noncompliance as soon as possible. If it is due to improper assembly or installation, or caused in any way by the factory based manufacturer, the regulations require that the noncompliance be corrected without charge to the user by either repairing the system, replacing it, or refunding the cost (if caused by the factory based manufacturer, you should notify him of the noncompliance) and arrange for corrective action at no cost to the owner.

If the noncompliance is due to normal wear and tear, unwarranted user abuse, improper maintenance by the user, or improper repair, and if you can clearly explain and provide evidence which demonstrates the validity of this conclusion, then you are not required to correct the noncompliance at no charge to the owner.

Please report to this office within 15 days of receipt of this letter the causes for noncompliant performance and corrective actions taken. The corrective action should be submitted as a VOLUNTARY CORRECTIVE ACTION PLAN (CAP) that you followed to make the corrections. Any documentation, such as service order, etc., should include at least the following: date of service, type of service, and model and serial number of the certified components which required service in order to bring the system into compliance. Your CAP should also include formulas and calculations, or a copy of the manufacturer's installation procedure for the certified component corrected.

If special parts are required to be ordered, thus delaying completion of your planned corrective action beyond 15 days, you should submit a copy of the parts supplier's invoice verifying that the order has been accepted and the projected date for delivery of parts to you. In this case, your corrective actions are expected within 30 days of receipt of this letter unless otherwise precluded by parts delivery.

As you are probably aware, under Federal Law, an assembler is a manufacturer of diagnostic x-ray systems. The installation of a noncompliant x-ray system is a violation of the Food, Drug, and Cosmetic Act. An assembler who installs a noncompliant x-ray system may, therefore, be liable to civil penalty enumerated in the Act. In order to protect yourself from the penalties, your firm should make every effort to assure that every installation results in performance which complies with all requirements of the diagnostic x-ray performance standard.

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Your response to this letter may be directed to Deborah M. McGee, Radiation Specialist, at Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, TX 75247. If you have any questions regarding results of the referenced field test, or related to technical matters, you may contact Ms. McGee by telephoning (214) 655-8100 x138.

Sincerely,



B. Belinda Collins
Regional Radiological
Health Representative

cc: Mineral Area Hospital
600 Purcell Drive
Potosi, MO 63664

General Electric Company
Medical System Division
P.O. box 414
Milwaukee, WI 53201

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