



DEPARTMENT OF HEALTH & HUMAN SERVICES

3660d

New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

November 1, 2002

WARNING LETTER NYK 2003-04

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Donald Gearing, Operations Leader  
Diagnostic Imaging, Inc.  
13 Corporate Drive  
Clifton Park, NY 12065

Dear Mr. Gearing:

On September 23, 2002, an inspector from the State of New York Department of Health, acting on behalf of the U.S. Food and Drug Administration (FDA), performed a field test of a certified diagnostic x-ray system which your firm assembled on March 28, 2002, according to Report of Assembly of a Diagnostic X-ray System, Form FDA 2579 (D388793). This system was tested to determine its compliance with portions of the Performance Standard for Diagnostic X-ray Equipment (Title 21, *Code of Federal Regulations* (CFR), Sections 1020.30-32). Diagnostic x-ray systems are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The field test, Test ID #GI66276, was performed at:

[REDACTED]  
[REDACTED]  
[REDACTED]  
X-Ray Control Manufacturer: [REDACTED]  
X-Ray Control Model No.: [REDACTED]  
Serial No.: [REDACTED]  
Room No.: X-ray

Our analysis of the field test data indicated the system does not comply with the following items of the Performance Standard:

- We measured the entrance exposure rate in the manual mode of the fluoroscopic system to be 27 roentgens per minute at the point where the center of the useful beam enters the patient. This condition is a serious radiation health hazard and warrants your immediate attention.
- We measured the entrance exposure rate in the Automatic mode of the fluoroscopic system to be 18.3 roentgens per minute at the point where the center of the useful beam enters the patient.

21 CFR 1020.32(d)(3) limits the entrance exposure rate to 10 roentgens per minute for systems with both an automatic exposure rate control and a manual mode.

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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 15 working days.

You must submit the results of your investigation and follow-up actions to this office within 15 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 15 working days, the Agency 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).

Failure to promptly correct this violation can result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include seizure and/or injunction and/or the imposition of civil penalties as provided for in section 539 of the Act. Persons violating section 538 of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum of \$300,000.

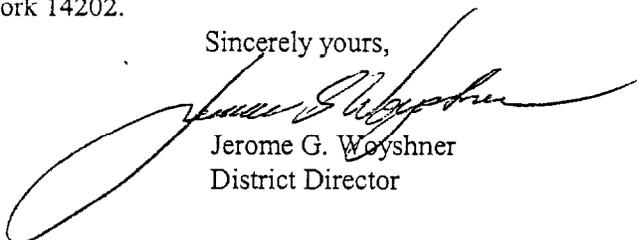
In addition to the problems listed above, we consider the compliance status on the following items to be suspect. Please verify the compliance status of these items when you correct the previously cited problem:

- **The measured source to image distance (SID) differs from the indicated 40 inch SID by 4.6 percent. 21 CFR 1020.31(e)(1) requires means be provided to indicate the SID to within 2 percent.**
- **The average illuminance of the x-ray light localizer measured 146 lux at 100 centimeters. 21 CFR 1020.31(d)(2)(ii) requires the light localizer provide an average illuminance of not less than 160 lux (15 foot candles) at 100 centimeters.**

You should notify this office, in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Lisa M. Utz, Compliance Officer, Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, New York 14202.

Sincerely yours,



Jerome G. Woyshner  
District Director