



DEPARTMENT OF HEALTH AND HUMAN SERVICES

34171d
Food and Drug Administration
New Orleans District Office
Nashville Branch Office
297 Plus Park Blvd.
Nashville, TN 37217

Telephone: 615-781-5380
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July 31, 2003

VIA FEDERAL EXPRESS
NEXT DAY DELIVERY

Randolph D. McMoran, President
Precise Medical Imaging
101 Center Drive
White House, TN 37188

Warning Letter No. 03-NSV-21
Reference Field Test Number GI70306

Dear Mr. McMoran:

On June 30, 2003 a representative with the State of Mississippi X-Ray Branch, on contract to the Food and Drug Administration, field-tested this certified diagnostic x-ray system at the following facility:

Name of Facility: [REDACTED]
Address: [REDACTED]
City, State & Zip: [REDACTED]

X-Ray Control Manufacturer: [REDACTED]
X-Ray Control Model/Serial No.: MN: [REDACTED] SN: [REDACTED]

Our records indicate that your firm assembled this system (FDA-2579 #D921735) on or about December 1, 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).

This field test at this facility revealed the following Class A noncompliance finding:

Entrance Exposure Rate
21 CFR 1020.32(d)(3)

Entrance exposure rate = 97.8 R/min
Tube potential = 125 kVp
Tube current = 8.0 mA
Mode of operation = automatic or manual exposure rate control

The performance standard requires that, when the automatic or manual exposure rate control mode of operation is chosen and no high-level control is present, the fluoroscopic system shall not be operable at any

combination of tube potential and current which will result in an exposure rate in excess of 10 Roentgens (R) per minute at the point where the center of the useful beam enters the patient.

The facility was notified immediately after obtaining the test results by the state of Mississippi that this equipment is hazardous and should not be used. Additionally, FDA also contacted this facility on July 22, 2003, and spoke with [REDACTED] concerning the serious nature of this violation. [REDACTED] indicated that as of July 22, 2003 the facility will no longer use the fluoroscopic mode of this equipment until repaired or replaced. This finding is considered a serious noncompliance with the performance standard and we request that you immediately correct this violation.

The following Class B noncompliances were also noted:

Accuracy of Indicated Source-Image Receptor Distance (SID)

21 CFR 1020.31(e)(1)

Indicated SID = 32.0 IN
Measured SID = 92 CM (36.2 IN)
Difference = -13.2 %

The performance standard requires that the x-ray system indicate the SID to within 2 percent.

POSITIVE BEAM LIMITATION (PBL)

21 CFR 1020.31(g)

The Positive Beam Limitation of this unit failed to operate.

The collimator is designed for PBL operation; however, it fails to comply with the requirements of 21 CFR 1020.31(g)(1)-(2) for positive beam limitation (PBL). When a system is installed with a PBL type collimator it must meet the PBL requirements.

Primary Protective Barrier

21 CFR 1020.32(a)(1)

Primary protective barrier transmission = 14.2 (mR/hr)/(R/min)
Technique factors = 125 kVp, 1.2 mA
Entrance Exposure rate = 3.54 R/min

The primary protective barrier transmission shall not exceed 3.34×10^{-3} percent of entrance exposure rate (EER). In the case of your data this would be 7.08 mR/hr or 2.0 mR/min EER. The measured value of 14.2 mR/hr/R/min is more than 7 times larger than what is allowed.

Field Limitation and Alignment for Spot-Film Devices

21 CFR 1020.31(h)(2)

SID = 97.8 CM
Length plus width misalignment = 7.9 % of the SID

The performance standard requires that the total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor shall not exceed 3 percent of the SID when adjusted for

full coverage of the selected portion of the image receptor. The sum without regard to sign of the misalignment along any two orthogonal dimensions shall not exceed 4 percent of the SID.

Additionally, the following Class C deviations from the x-ray standard were also noted. Please verify the compliance status of these items when you correct the previously cited problems.

Actual versus Indicated Field Size

21 CFR 1020.31(e)(3)

SID = 40 IN

Percent difference (length) = 4.3 % of the SID

Percent difference (width) = 3.4 % of the SID

The performance standard requires that the aperture adjustments of the beam-limiting device result in x-ray field size dimensions which correspond to those indicated to within 2 percent of the SID.

Field Limitation and Alignment for Spot-Film Devices

21 CFR 1020.31(h)(2)

SID = 97.8 CM

Length (along-table) misalignment = 3.4 % of the SID

Width (across-table) misalignment = 4.5 % of the SID

The performance standard requires that the total misalignment of the edges of the x-ray field with the respective edges of the selected portion of the image receptor along the length or width dimensions of the x-ray field in the plane of the image receptor shall not exceed 3 percent of the SID when adjusted for full coverage of the selected portion of the image receptor. The sum without regard to sign of the misalignment along any two orthogonal dimensions shall not exceed 4 percent of the SID.

We request that you, as the responsible assembler, immediately investigate these deviations from the performance standard reported 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 assembler or installation, you must correct the noncompliance and/or defect at no charge to the user either by 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 fifteen (15) working days of the receipt of this letter.

You are requested to submit the results of your investigation and follow-up actions to this office within fifteen (15) working days of the receipt of this letter. Your response should include the date that the corrective action was completed, and copies of the service records and/or other supportive documents. If you do not respond within fifteen (15) working days, the Agency will consider you to be in violation

of the Federal Food, Drug, and Cosmetic Act (the Act), Sections 538(a)(2) and 538(a)(4) of Sub-chapter C - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968).

Your response should be sent to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217 as well as to the appropriate state agency. Questions in regard to this letter should be directed to Karen Smallwood, Radiation Specialist, 615/781-5380, extension 144.

Sincerely,



Carl E. Draper
Director, New Orleans District

CED:krs

Enclosures:

- CDRH Letter dated March 26, 1984
- 21 CFR 1020.31 - Radiographic Equipment
- 21 CFR 1020.32 - Fluoroscopic Equipment
- 21 CFR 1003 - Notification of Defects or Failure to Comply
- 21 CFR 1004 - Repurchase, Repair or Replacement of Electronic Products

cc: [REDACTED]
ATTN: [REDACTED]
[REDACTED]
[REDACTED]

Herman Gaines, Health Physicist Administrator
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