

DEPARTMENT OF HEALTH & HUMAN SERVICES

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PUBLIC HEALTH SERVICE



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Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
Telephone 303-236-3000

March 19, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Morgan W. Niels
Chairman and CEO
Fischer Imaging Corporation
12300 North Grant Street
Denver, Colorado 80241

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Ref. # - DEN-97-15

Dear Mr. Niels,

During an inspection of your firm, Fischer Imaging Corporation, on November 5 through December 19, 1996, Investigators Michael R. Goga, Thomas B. Dowell, and Nicholas R. Nance, and Radiation Specialist Robert G. Antonsen determined that your firm manufactures diagnostic X-ray and mammography systems. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Good Manufacturing Practice Regulations (GMP) for Medical Devices specified in Title 21, Code of Federal Regulations, part 820 (21 CFR 820), as follows:

1. The quality assurance program did not always consist of procedures adequate to assure that solutions to quality assurance problems were identified, recommended, or provided and that implementation of solutions were verified, in that procedure " " which defines the policy requirements for statistical techniques did not cover all products manufactured by Fischer Imaging, indicate what data to collect, indicate how to evaluate the data, and define action levels. For example:
 - (a) Data entered on " " and " " form was used in trending; however, (i) no written procedures were found for the conduct of inspections and (ii) how the data representing failures from the inspections was to be investigated.
 - (b) Data for trending was not collected for " " or other contract products.

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- (c) Data for trending was not included for returned/failed components, field service reports, and in-process failures such as " " in-process failures. Documentation of the investigation of PCB failures was not found.
 - (d) Procedure " " which defines the policy requirements for corrective and preventive action was not fully implemented in that it was only observed in use for internal quality assurance audits and observed in use for corrective action requests (CAR) number concerning missing transformer serial numbers; concerning items for shipment not properly segregated and identified; and concerning missing computer boards.
 - (e) Installation reports selected for investigation were not always reviewed, conclusions drawn, solutions identified where appropriate, and the investigation closed. For example:
 - (1) Site Installation Problem Reports # (oil leak), (no vertical brake), (compression issue), and (mis-assembly).
 - (2) Site Installation Problem Reports # (intermittent compression drive), (compression issue), fit issue), and (compression issue).
2. Formalized assessment methods and procedures for the inspection, testing, or verification of component and finished device quality were not applied adequately. For example: a review of approximately DHR for diagnostic x-ray and mammography systems manufactured and released in 1996, revealed:
- (a) At least systems observed with in-process component and system mis-assemblies such as miswired parts; incorrect or defective printed circuit boards (PCB); missing hardware; defective computer or monitor; incorrect labeling; and defective components such as hand switches, foot switches, collimators, radiation detectors, x-ray tubes, cables, a bucky, a consoles, and a power supply. Some of these systems later were found to have defects during installation at the user facility, such as missing hardware, incorrect or defective PCB's, incorrect software version, miswired parts, and radiation leakage. These systems included, but were not limited to:
 - (b) DHR's lacked required or correct data, or contained unexplained data changes. For example:
 - (i) a lack of correction and/or retest of in-process discrepancies ()
 - (ii) unexplained test result changes such as the change of an out of specification auto compression force to an acceptable force () and an inapplicable test of paddle release compression at end of exposure was changed to pass
 - (iii) missing quality audit checks such as a check for compression paddle fit into holders, paddle frame fit into compression carriage, and manuals present ()
 - (iv) correction of imaging problems which are not explained in specific terms such as "problems with imaging" and "problem corrected" ()

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3. All information relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of devices was not evaluated for complaint and MDR applicability, such as reports from the field of system malfunctions and/or failures, and reports of returns of defective components. The following are examples of reports from the field and reports of returns:
- (a) Field Service Logs indicating: "unit over exposing" (5/17/96), "double exposure ..." (7/30/96), "long exposure" (8/21/96), "flunked state insp - both rooms" (6/5/96), "radiologist displeased" (8/8/96), "failed physicist report" (9/11/96), "Down! Not terminating exposure!" (6/27/96), and "terrible burning smell" (10/29/96).
 - (b) Field Service Reports indicating: "inter. Irratic exposures" (5/23/96), "intermittent or no exposures" (7/31/96), "unit makes exposure but time too long" (9/96), "intermittent E-51" (6/96), "compression paddle slips" (5/96), and "tube on table leaking oil" (9/96).
 - (c) Return Authorization (RA) indicating: "Detector would never cause termination of exposure" (10/23/96), "generator locks up" (10/96), and "intermittent short exp" (9/96).
4. Procedure " ", states " "... " It was observed that PCB's returned from the field identified as unused and still in the pouch were returned to stock without testing or evaluation.
5. Failures of components, which were part of distributed finished devices, to meet performance specifications were not always investigated and/or documented. For example, Return Authorization (RA) indicating: "Detector would never cause termination of exposure" (10/23/96), "generator locks up" (10/96), and "intermittent short exp" (9/96).
6. Formal approval procedures for any changes to the manufacturing process of a device were not adequate, and when approved were not communicated to appropriate personnel in a timely manner. For example,
- (a) Document No. "Product Change Request/Order" establishes the procedure for generating, evaluating, authorizing, and processing Product Change Requests (PCR), and Product Change Orders(PCO).
 - (i) The procedure indicated that validation references will only be required for software changes, but does not assure a documented hazard analysis that provides the rationale for validation, or the decision to not validate.
 - (ii) The procedure does not assure that validation protocols were generated defining the extent and scope of the validation, including the degree of testing necessary to assure proper function of the system following the change.
 - (b) The Procedure provides a tool to obtain and show authorization to temporarily deviate from the Device Master Record (DMR). The procedure states that a "

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1996 over [redacted] were issued; however, some were part of a permanent deviation from the DMR. For example:

- (i) [redacted] and [redacted] extended a test change from 10/95 to 12/96
- (ii) [redacted] and [redacted] extended the use of an unvalidated test procedure from 11/95 to 12/96

(c) The [redacted] Procedure [redacted] pertains to a printed circuit assembly in-circuit (ICT) tester to test components on a circuit board for proper placement. Changes made to the [redacted] System were not always authorized, documented, validated, or dated. For example, handwritten changes were made to the procedure such as:

- (i) In the sentence, "[redacted] ... [redacted] ...", the "[redacted] ..." was changed to "[redacted] ..."

(ii) A sentence indicated that the [redacted] file can be periodically deleted "[redacted]". The "[redacted]" was changed to "[redacted]".

(iii) The [redacted] procedure [redacted] pertains to validation of new or a major revision of an in-circuit test fixture or program, i.e., the [redacted] and includes validation specifically intended to be used when software changes are made. However, these forms are not always used. For example, they were not used for the following changes which were recorded in a [redacted] Log:

- (1) January 12 - Program [redacted] test values were changed on [redacted] and [redacted]
- (2) December 2 - [redacted] included adjustments of [redacted]

7. The [redacted] Procedure [redacted] included maintenance and calibration procedures which were not always followed, in that records did not always indicate the performance of required daily, weekly, monthly maintenance and operational checks, and corrective actions taken when software or system failures occurred.

8. The procedures for the inspection, sampling, and testing of components did not always prevent the release and use of defective components, in that:

(a) miswired, mis-assembled and/or defective components were found during manufacture as well as during system installation in the field. For example, [redacted] and [redacted]

(b) PCB's were stored in the stock room, manufacturing, and test areas without any identification as to their status as accepted or rejected.

(c) returned PCB's in the logistics areas were not handled with [redacted] controls.

(d) PCB's testing procedures did not assure that boards were tested properly in accordance with one or more test databases, i.e., [redacted] and/or [redacted] in that, procedures did not indicate which boards required which test or tests. For example:

- (i) PCB's [redacted] were tested with [redacted]
- (ii) PCB's [redacted] were tested with [redacted]. Some of these PCB's later failed during system manufacture. For example, on 9-14-96 some PCB's were missing components [redacted]
- (iii) PCB's [redacted] were tested with [redacted]

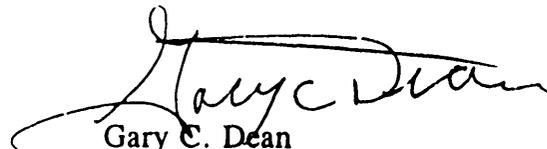
Please notify this office in writing, within fifteen (15) working days of receipt of this letter, regarding the specific steps you have taken to correct the above violations, including an explanation of each step being taken to prevent the recurrence of similar violations and any documentation necessary to show that correction has been achieved. 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.

We acknowledge receipt of your response of January 13, 1997, to the Form FDA-483 issued at the close of the inspection. Your response is under review. Corrective actions addressed in your previous letter may be referenced in your response to this letter.

Your response should be sent to the Food and Drug Administration, Denver District Office, Attention: Russell W. Gripp, Compliance Officer, at the above address.

Sincerely,

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Gary C. Dean
District Director