



DEPARTMENT OF HEALTH & HUMAN SERVICES

LF 35 (Page 2)  
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

April 8, 1998

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Howard C. Thomas  
President  
Applied X-ray Technologies, Inc.  
2727 West 92nd Avenue, Suite 10  
Denver, CO 80221

**PURGED**

Ref. # DEN-98-10

Dear Mr. Thomas:

During an inspection of Applied X-ray Technologies, Inc. (AXT), Denver, Colorado, conducted February 24, 1998 through March 5, 1998, by Investigator Lynnette I. Riggio and Radiation Specialist Robert G. Antonson, it was determined that your firm manufactures an X-ray multi-format spotfilm device, the AXT 1400 Spotfilm device. This product is a medical device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that the device is adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure to establish procedures and conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22.
2. Failure to maintain a complete device master record (DMR) which includes, or refers to the location of, all device specifications, production process specifications; quality assurance procedures and specifications; packaging and labeling specifications; and installation, maintenance, and servicing procedures and methods, as required by 21 CFR 820.181. For example, the firm has some records, such as the AXT Configuration/Tracking Report and specification drawings, but these and other necessary records have not been assembled into a DMR.

3. Failure to maintain a complete device history record (DHR) which includes, or refers to the location of, the dates of manufacture, quantity manufactured, quantity released for distribution, acceptance records, and the primary identification label and labeling used for each production unit, as required by 21 CFR 820.184(a) through (e). For example, the DHR used consists of an AXT Configuration/Tracking report which includes the name of the customer, the date the device is shipped, the device configuration, and the device serial number. Copies of labels are maintained which do not include the serial number of the device.
4. Failure to document the inspection and acceptance or rejection of incoming product, as required by 21 CFR 820.80(b); and failure to document the final acceptance of each finished device, as required by 21 CFR 820.80(d).
5. Failure to document the evaluation of complaints for Medical Device Reporting (MDR) and for determining whether an investigation is necessary; and a failure to document the reason no investigation is made or, if an investigation is made, the results of any investigation and any corrective actions taken, as required by 21 CFR 820.198. For example, the firm received two complaints involving loose set screws which resulted in corrective action; however, a record was not made of the complaints' applicability to the MDR, the investigation, and the corrective action.
6. Failure to document in the DHR the retesting and reevaluation of rework of nonconforming product, as required by 21 CFR 820.90(b)(2). For example, when the AXT 1400 spotfilm device was built and tested, component failures were diagnosed, fixed, and retested; however, documentation of these activities was not made.
7. Failure to include on documents the date and signature of the approving individual, as required by 21 CFR 820.40(a). For example, ~~the~~ master part drawing for the AXT 1400 spotfilm device were reviewed; however, only ~~it~~ had a date and signature of an approving individual.

It should be noted that items 1, 3, and 7 above were also observed during the previous inspection of your facility on April 18 through 25, 1995.

Our inspection also disclosed violations of Subchapter C of the Act - Electronic Product Radiation Control (formerly the Radiation Control for Health and Safety Act of 1968). The Center for Devices and Radiological Health (CDRH) will review these deviations separately and any further correspondence in regards to these matters will issue from that office.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all Warning Letters regarding medical devices so they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

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.

Your reply should be sent to the Food and Drug Administration, Denver District Office, to the attention of Russell W. Gripp, Compliance Officer, at the above address.

Sincerely,

*for*   
Gary C. Dean  
District Director

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