



NOV 30 2000

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

WARNING LETTER

Ref:OC:II-1879

via FEDERAL EXPRESS

Stephen P. DeFalco  
President  
Perkin Elmer Instruments  
Detection Systems  
4031 Via Oro Avenue  
Long Beach, California 90801-5709

Dear Mr. DeFalco:

This letter is written to advise you of items of noncompliance with model Linescan 222 cabinet x-ray systems encountered during a field test at Yankton Federal Prison and with a model Sys 107 at Oxford Federal Correctional Institution.

The Linescan 222 was noncompliant with:

21 CFR 1020.40(c)(3)(i), Ports and apertures. The system fails to meet this requirement because it is possible to insert a part of the human body, a hand, into the area where the primary beam is located during the generation of x-radiation.

The field test also identified that the system can emit radiation at a rate of 0.5 milliRoentgen per hour when a long object (over two feet), which holds the lead curtains open, is being inspected. This data is not sufficient to support a noncompliance with the performance standard. However, it is appropriate for you to investigate worst case scenarios to determine if it is possible for this model to fail to meet emission limit requirements of the standard as stated in 21 CFR 1020.40(c)(1).

The Sys 107 was noncompliant with:

21 CFR 1020.40(c)(10), Additional requirements for x-ray baggage inspection systems. The system fails to meet this requirement because the footpad provided to assure operator presence allows x-ray exposures to continue when the operator has removed his weight from the footpad.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce cabinet x-ray products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to

invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failures to comply do not exist.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.
  - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.
  - b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

The following failure to comply with the regulations regarding reports and record keeping was observed:

1. 21 CFR 1002.13, Annual Reports. A review of our database revealed that we have not received your annual report for cabinet x-rays systems covering July 1, 1999 through June 30, 2000. This report was due on September 1, 2000.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Your response should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a copy of your response to: Director, Compliance Branch, Los Angeles District Office, Food and Drug Administration, Los Angeles District, 19900 Mac Arthur Blvd, Ste 300, Irvine, CA 92715. If you have further questions on these requirements, please contact Daniel Kassiday of the Electronic Products Branch at (301) 594-4654.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Larry D. Spears".

Larry D. Spears  
Acting Director  
Office of Compliance  
Center for Devices and  
Radiological Health