Materials and Equipment are electronic products that are listed in the Code of Federal Regulations (21 CFR, Part 820).

During an inspection of your firm located in Palm Harbor, Florida, on April 20 and May 5-7, 1998, Investigator Christine M. Humphrey determined that your firm manufactures diagnostic x-ray systems. Diagnostic x-ray systems are devices as defined by Section 201(h) of the Food, Drug, and Cosmetic Act (Act) and are electronic products as defined by Title 21, Code of Federal Regulations (21 CFR), Section 1000.3(j).

Several violations of Section 518 of Subchapter C - Electronic Product Radiation Control (EPRC) [formerly the Radiation Control for Health and Safety Act (RCHSA) of 1968] of Chapter V of the Act and 21 CFR, Part 820, were documented. Some of the EPRC violations were listed on the FDA 483 Inspectional Observations, which was presented to and discussed with you at the conclusion of the inspection.

A separate Warning Letter will be issued to you by the Food and Drug Administration's (FDA) Florida District Office citing violations of the Quality System (QS) Regulation noted on the FDA 483. Because of the technical merit of EPRC violations and the impact these violations present to your certification and testing program, we believe that it is in your firm's best interest that we address the EPRC violations under separate cover from the QS Regulation violations.

Our review of the items listed on the FDA 483 and the Establishment Inspection Report (EIR) disclosed significant violations of the EPRC. The following is a list of the more significant EPRC violations. This list is not an all-inclusive list of EPRC violations that may exist at your facility.
Section 538(a)(1): Your firm has manufactured and distributed Visualizer 2000 c-arm videofluoroscopic units which do not comply with the Federal performance standard for diagnostic x-ray equipment (21 CFR 1020.30, 1020.31, and 1020.32).

Section 538(a)(3): Your firm failed to establish and maintain finished device testing records for Visualizer 2000 units, as required by 21 CFR 1002.30(a).

Section 538(a)(4): Your firm failed to submit a product (initial) report (including a complete description of the product as well as a description of the quality control and testing program used by your firm to certify that any distributed products are fully compliant with all requirements applicable to the particular product) prior to the introduction of products into interstate commerce and annual reports (summarizing of certification testing and quality control procedures) for the Visualizer 2000 system to comply with the reporting requirements of 21 CFR 1002.10 and 1002.13, respectively. In addition, your firm failed to file a "Report of Assembly of a Diagnostic X-Ray System" (form FDA 2579) to FDA for the installation of the Visualizer 2000 system at user sites within 15 days after assembly of the products, as required by 21 CFR 1020.36(d)(1).

Section 538(a)(5): Your firm failed to establish an adequate certification testing program in accordance with the standard or which is in accordance with the Current Good Manufacturing Practices Requirements of the QS Regulation, as required by 21 CFR 1010.2(c).

Based on the violations listed above, FDA's Center for Devices and Radiological Health (Center) is disapproving your testing and quality control program for certification of the Visualizer 2000 system manufactured by your firm. Until this disapproval is lifted, you may not legally introduce any of your products into commerce. When you have provided all the required reports and test records as indicated above, and the Center concurs that it is adequate to certify your product, a revision letter will be issued notifying you that you may legally begin marketing again.

Because your firm is marketing the components as a complete system, compatibility among all components must be addressed. When assembled, the system must comply with all applicable requirements of the Federal performance standard for diagnostic x-ray systems and their major components. Although each component has been certified by each of their respective manufacturers, your firm, by marketing and assembling the components into a system, is ultimately responsible for compliance.
You must respond in writing within 15 working days of receipt of this letter to one of the options listed below:

1. **Refutation** - You may submit your views and evidence in accordance with 21 CFR 1003.11 to establish that the alleged noncompliances do not exist, do not relate to the safety of the product, or are directly attributable to user abuse or lack of maintenance.

2. **Exemption Request** - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. You must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31). Also, indicate all models and brands that are to be covered by the exemption along with the number produced and dates of production.

3. **Purchaser Notification and Corrective Action** - If you neither refute the noncompliances 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 at no charge to the user.

   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 this office. It is recommended that you submit a draft of any letters to us for review and concurrence prior to mailing.

   b. **Corrective Action Plan** - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, and 1004.4. In accordance with 21 CFR 1003.11(b), you must also notify us of the total number and location of units produced (including identification of all models and brands involved) and the approximate number 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.
Failure to respond to this letter or to correct these products in a timely manner can result in regulatory action being initiated by the FDA without further notice. These actions may include, but are not limited to, an injunction and/or imposition of civil penalties as provided for in Section 539 of the Act. Persons failing to correct violations are subject to civil penalties of up to $1,000 per violation and up to a maximum of $300,000.

If you request additional time to investigate the extent of the problem or 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 by 21 CFR 1003.11(c) and 1003.21 to proceed with interim notification to affected persons. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

Your response should reference II-1798 and be sent to the attention of Ms. Xuan T. Vo or the Diagnostic Devices Branch, Division of Enforcement I at the above letterhead address, with a copy to the Florida District Office, Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and Radiological Health