



10/27/97

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-86

September 30, 1997

Raul R. Martin, Manager
CT Imaging, Inc.
395 West 10th Street
Hialeah, Florida 33010

Dear Mr. Martin:

We are writing to you because on July 2, 1997 FDA Investigator Carlos I. Medina collected information that revealed a serious regulatory problem involving the mammography at your facility.

Under a Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility is required to have a valid FDA MQSA certificate to perform mammography. Only facilities that have applied to an approved accreditation body and either (1) are being evaluated for accreditation by that body, or (2) have been accredited by that body are entitled to a certificate. The accreditation process is a necessary requirement of the law for every facility that performs mammography. This process helps to protect the health of women by ensuring that a facility can perform quality mammography. The evidence collected by the FDA shows that your facility performed mammography without a valid FDA MQSA certificate. During a period beginning April 2, 1996 through October 26, 1996, your facility performed mammography on 58 different patients.

Performing mammography without a valid certificate is a violation of the law which may result in regulatory action being initiated by the Food and Drug Administration without further notice. A facility may be subject to civil money penalties up to \$10,000 for each failure to substantially comply with, or each day on which a facility fails to substantially comply with the Standards. A facility may also have its certificate suspended or revoked for failure to comply with the Standards. Continuation or any activity related to the provision of mammography by a facility that constitutes a serious risk to human health may result in injunction.

You should be advised that FDA regulations do not preclude enforcement of requirements under State laws and regulations. In some cases, State requirements may be more stringent than requirements under FDA regulation. You may receive a letter or notification from the State advising you of this fact. When conducting corrective actions, you should take into

consideration the more stringent State requirements. A copy of your response to the FDA should always be sent to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be completed.

The original copy of your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809. Also send a copy to the Florida Department of Health, Bureau of Radiation Control, Radiation Machine Program, P.O. Box 210, Jacksonville, FL 32231.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Thomas R. Trout, FDA, Southeast Regional Radiologic Health Representative, at (404) 347-3576.

Sincerely yours,



Douglas D. Tolen
Director, Florida District