



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

WARNING LETTER

FLA-97-18

January 22, 1997

Ezra M. Marshall, M.D.
Medical Director
2011 South 25th Street
Ft. Pierce, Florida 34947

Dear Dr. Marshall:

Your facility was inspected on January 16, 1997, by a representative of the State of Florida, State Department of Health and Rehabilitative Services, Office of Radiation Control, under contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

The phantom images failed to score at least the minimum required by the accrediting body for masses and fibrils. The number of masses scored in the phantom image was 1 (the minimum required for masses is 3) and the number of fibrils scored 1 (the minimum required for fibrils is 4).

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:

The phantom image failed to score at least the minimum required by the accrediting body for speck groups. The number of speck groups scored was 2 (the minimum required for speck groups is 3).

The film processor was deviating significantly from the expected performance measures. Your processing speed measured 31 for standard processing. The acceptable range for standard processing speed is 80 to 120.

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 Mammography Quality Standards

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Act of 1992 and regulations under the Act. The specific deficiencies noted in the letter and in the printed summary of test results listed under the Level 1 heading on your MQSA Facility Inspection Report, issued at the close of the inspection, may be symptomatic of serious underlying problems in your facility's quality assurance program for mammography.

You should take prompt action to correct these violations. Failure to promptly correct this violation 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 State Radiation Control Office at the Department of Health and Rehabilitative Services, Office of Radiation Control, P.O. Box 210, Jacksonville, FL 32231.

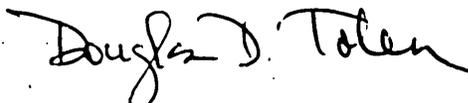
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If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Penny E. Glebowski, FDA Investigator, at (813) 228-2671 ext. 17.

Sincerely yours,

A handwritten signature in cursive script that reads "Douglas D. Tolen". The signature is written in dark ink and is positioned above the typed name.

Douglas D. Tolen
Director, Florida District