



M. 2075N

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-75

September 21, 1998

FACILITY ID# 103887

Mr. Mike Fencel
Chief Executive Officer
Brandon Regional Hospital
119 Oakfield Drive
Brandon Florida 33511

Dear Mr. Fencel:

Your facility was inspected on August 24, 1998, by a representative of the State of Florida, on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 1

Failure to have documentation that the following interpreting physicians, [REDACTED] and [REDACTED] have meet the requirement of being licensed by a State to practice medicine.

Level 2

Failure to have documentation that the following interpreting physicians, [REDACTED], [REDACTED], [REDACTED] and [REDACTED] meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per 24 months.

Failure to have documentation that the following interpreting physicians, [REDACTED], [REDACTED], [REDACTED] and [REDACTED] meet the continuing experience requirements of having completed a minimum of 15 credits in mammography over 3-year period.

Failure to have documentation that the following interpreting physicians, [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED] and [REDACTED] meet the initial training requirement of having 40 hours of continuing medical education in mammography.

Mr. Mike Fencel
Page 3
September 21, 1998

Your reply should be directed to Carlos I. Medina, Compliance Officer, U.S. Food and Drug Administration, P.O. Box 592256, Miami, FL 33159-2256, telephone (305) 526-2800, extension 921. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Mr. Medina.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, stylized initial "D".

Douglas D. Tolen
Director, Florida District

cc: State of Florida