

HF1-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2141n

Refer to: CFN: 1124477
ID#194589

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

October 8, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Raymond E. Waters, III, President
Radiology: MRI Institute of Maryland
9602 F Martin Luther King, Jr. Highway
Landham, Maryland 20706

Dear Dr. Waters:

Your facility was inspected on September 10, 1998 by a representative from the Food and Drug Administration (FDA). Our inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

During your annual MQSA inspection, conducted March 27, 1998, [redacted] was cited for failing to complete a minimum of 15 credits in mammography over a 3-year period. He was given 90 days from the date of that inspection to meet this requirement while continuing to read mammograms independently. The 90-day period ended on June 25, 1998. [redacted] failed to earn the necessary credits by this date, but did complete the American College of Radiology's Breast Disease II Syllabus on July 17, 1998. Under MQSA, [redacted] was required to cease independent interpretation of mammograms at the end of the 90-day time period until he completed 15 credits in mammography. Records collected from your facility indicate that at least 37 patient examinations were interpreted by [redacted] during the 3-week period he was required to cease independent interpretation.

Dr. Raymond E. Waters, III

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Because this violation may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- ◆ The specific steps you have taken to correct the violation noted in this letter.
- ◆ Each step your facility is taking to prevent the recurrence of similar violations.

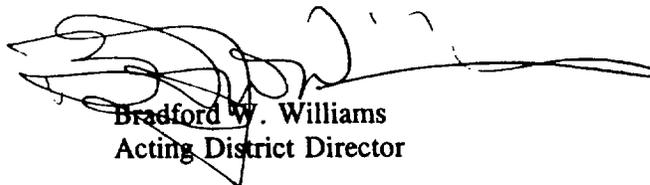
Please submit your response to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: Wiley T. Williamson, III
Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to deficiencies noted during our inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

If you have any specific questions about mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, Ext. 159.

Sincerely yours,



Bradford W. Williams
Acting District Director