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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

T1396M

Refer to: CFN 1124363
98-BLT-32

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4099

January 16, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Cindy Almony
Vice President of Human Resources
American Radiology Services, Inc. at Essex
404 Eastern Boulevard
Baltimore, Maryland 21221

Inspection ID #1654800009

Dear Ms. Almony:

Your facility was inspected on November 12, 1997 by a representative of the Maryland Department of the Environment, Radiological Health Program, under contract to the Food and Drug Administration (FDA). 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, Part 900.12, as follows:

Records indicate that there was no medical physicist survey done for the x-ray system. The inspector's report indicates that the last physicist's survey was conducted on July 19, 1996. Physicist's surveys should be performed at least annually and shall be retained by the facility until the next annual survey is satisfactorily completed.

[REDACTED] did not meet the requirement of being licensed by the State of Maryland to practice medicine. [REDACTED] should immediately discontinue performing mammography until we have proof of a valid medical license. All personnel records should be available at the time of the inspection for review. Please provide documentation showing that [REDACTED] was licensed to practice medicine during the period of November 12, 1996 to November 12, 1997.

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. Also, the following Level 2 findings have not been satisfactorily addressed by your facility:

75% data points for either Medium Density, Density Difference, or Base Plus Fog were missing for the processor. Adequate documentation must be provided to ensure that daily Quality Control will be conducted on the processor prior to processing patient films and that patient films will not be processed when the processor is out of specifications. A standard operating procedure should be implemented so this does not recur.

██████████ did not meet the initial training requirement of having 40 hours of continuing medical education (CME) in mammography. ██████████ must discontinue performing mammography until proper documentation of 40 CMEs, specifically in mammography, is documented. Interpreting physicians shall have 40 hours of documented CME specifically in mammography. Time spent in residency specifically devoted to mammography will be accepted if the following criteria is met:

- 1) If ██████████ mammography medical education was completed prior to October 1, 1994, an attestation will be accepted as documentation.
- 2) If ██████████ mammography medical education was completed after October 1, 1994, a letter from his residency program will be accepted as documentation.

The documentation of 40 CMEs in mammography should be forwarded for our review prior to allowing ██████████ to perform independent mammography.

██████████ did not meet the requirement of having read and interpreted mammograms for the examinations of at least 240 patients in a 6-month period. ██████████ should discontinue performing mammography until documentation can be provided showing he interpreted 240 patients in a 6-month period. Documentation should be forwarded for our review.

██████████ did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months. The inspector's report indicates that ██████████ averaged 30 patients per month over 24 months. ██████████ should discontinue performing independent mammography until one of the following criteria is met:

- 1) Interpret mammograms under the direct supervision of a qualified radiologist to increase to 240 patients in a 6-month period,

or

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- 2) Interpret mammograms under the direct supervision of a qualified radiologist so that [REDACTED] average patient exams are at the minimum of 40 per month.

[REDACTED] the interpreting physicians, did not meet the continuing education requirement of having completed a minimum of 15 credits in mammography over a 3-year period. [REDACTED] must acquire 15 credits in mammography within 90 days from the date of the inspection to continue to perform independent mammography. All CME documentation should be forwarded for our review. If 15 CMEs are not met within this time period, further regulatory action will be considered.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identified and promptly initiating permanent corrective action.

If you fail to do so, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards;
- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards;
- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action, therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

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- Sample records that demonstrate proper record keeping procedures, if the noncompliances found relate to quality control or other records. (Note: Patient names or identification should be deleted from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of William Bargo, acting Compliance Officer. Also, send a copy 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.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, you may contact Lori A. Holmquist at (410) 962-3591, Ext.175.

Sincerely yours,



Elaine Knowles Cole
District Director

cc: Maryland Department of the Environment
Radiological Health Program
2500 Broening Highway
Baltimore, Maryland 21224

Mr. Jim Potter, Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091