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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL 2102-0

March 15, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gerald Valle, M.D.
Staff Physician in Charge
Medical Associates of Gallipolis, Inc.
936 State Route 160
Gallipolis, OH 45631

Facility I.D.#: 123042

Dear Dr.Valle:

We are writing to you because on February 25, 2000, your facility was inspected by a representative of the State of Ohio, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography 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 health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 finding at your facility:

Your records revealed that your facility processed mammograms when the processor quality control records were missing or the processing activities were uncharted for all of 22 days in the month of August 1999. Also, your facility performed mammography from August 2 to December 16,1999 without charting the daily processor quality control activities.

21 CFR 900.12 (e)(1)

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because the problem identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, the condition represents a serious 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, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

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

1. Your facility has no written procedure for handling consumer complaints.
21 CFR 900.12 (h)
2. Your facility has no written procedure for infection control.
21 CFR 900.12 (e)(13)
3. Your medical physicist survey report for the mammography unit at your facility is incomplete because the following tests were not performed with the Rhodium target and/or Rhodium filter in the mammography unit:
 - a. AEC Performance – Reproducibility
 - b. Artifact evaluation
 - c. Collimation:
 - 1) X-ray field – light field alignment
 - 2) X-ray field – image receptor alignment
 - 3) Compression device edge alignment
 - d. Beam quality (HVL) measurement

21 CFR 900.12 (e)(9) as required by 21 CFR 900.12 (e)(5)

3. Five of five random interpreting physician mammography reports did not contain the required overall final assessment of findings.
21 CFR 900.12 (c)(1)(iv)(A)-(E) &(v)

The other item listed in your February 25, 2000 inspection report identified, as "List of Claimed Items" was corrected by your facility's submission of the appropriate documents to the inspector. However, the inspector did not cite a Level 3 noncompliance, which should read: "Required documents were not available at time of inspection." This item should also be corrected. We will verify correction of this item during our next inspection. You are not required to address this Level 3 item in your written response.

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 received this letter:

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

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Ms. Allison Sincek
Ohio Department of Health
Radiologic Technology Section
P.O. Box 118
Columbus, OH 43266-0118

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you 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, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen at 513-679-2700 extension 138.

Sincerely yours,



Henry L. Fielden
District Director
Cincinnati District

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OH/ASincek

Priscilla F. Butler, M.S.
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