



DEPARTMENT OF HEALTH & HUMAN SERVICES

WARNING LETTER
2002-DT-27

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 9, 2002

Michele Blair, DO
Lead Interpreting Physician
Mt. Clemens General Hospital
1000 Harrington
Mt. Clemens, MI 48043

Dear Dr. Blair:

We are writing you because on April 16, 2002, your facility was inspected by a representative of the State of Michigan acting on behalf of the Food & Drug Administration (FDA). The inspection revealed that your facility failed to comply with the Mammography Quality Standards Act of 1992 (MQSA) and certain Quality Standards for Mammography as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The recent inspection at your facility revealed the following Level 1 findings:

1. Processor Quality Control (QC) records were missing for at least 30% of the operating days during the month of July, 2001. This is in violation of Title 21 Code of Federal Regulations §900.12 (e) (1).
2. Phantom QC records were missing for at least four (4) weeks since your previous MQSA inspection. This is in violation of Title 21 Code of Federal Regulations § 900.12 (e) (2).
3. The system to communicate results of diagnostic mammograms was inadequate because:
 - a) There was no system in place to provide timely medical reports to the referring physicians.

- b) There was no system in place to provide timely lay summaries of the reports to the patients.
- c) There was no system in place to communicate serious or highly suggestive cases to the patients and referring physicians as soon as possible.

This is in violation of Title 21 Code of Federal Regulations § 900.12 (c).

The specific problems noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent 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, imposing civil money penalties, suspending or revoking your facility's FDA certificate, or obtaining a court injunction prohibiting any further mammography activity that constitutes a serious risk to human health.

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

1. Your facility has not specified adequate procedures to be followed for infection control including a system to record disinfection of equipment when such equipment may have come into contact with blood or other potentially infectious material. This is in violation of Title 21 Code of Federal Regulations § 900.12 (e) (13).
2. Your facility has not specified written procedures for the collection and resolution of consumer complaints. This is in violation of Title 21 Code of Federal Regulations § 900.12(h) (1).
3. There was no evidence of corrective actions for processor QC failures on at least one occasion. This is in violation of Title 21 Code of Federal Regulations § 900.12 (e) (8).
4. Processor QC records were missing on at least two, but less than five, consecutive days of operation. This is in violation of Title 21 Code of Federal Regulations § 900.12 (e) (1).

5. There was no evidence of corrective action, before further exams, when the phantom image failed either the image score or had a background density or density difference that was outside of regulatory limits. This is in violation of Title 21 Code of Federal Regulations § 900.12 (e) (8).
6. There is no system in place to track all positive diagnostic mammography exams, including the correlation of positive mammograms with biopsy results. This is in violation of Title 21 Code of Federal Regulations § 900.12 (f).
7. A medical audit and outcome analysis is not conducted on an annual basis to include data individually and collectively for all of the interpreting physicians at your facility. This is in violation of Title 21 Code of Federal Regulations § 900.12 (f).

It is necessary for you to act on this matter immediately. It is your responsibility to ensure adherence to each requirement of the MQSA and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiating permanent corrective actions.

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 Level 1 and 2 violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- the 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).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which corrections will be completed. Please submit your response to:

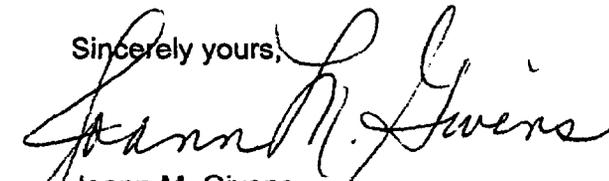
Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207-3179

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should also send a copy of your response to the State of Michigan radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

There are many FDA requirements pertaining to mammography. This letter only concerns the findings of your recent 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/cdrh/mammography>.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,



Joann M. Givens
District Director
Detroit District Office

Enclosures: MQSA Facility Inspection Report

CC:

