



DEPARTMENT OF HEALTH & HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

Public Health Service

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**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

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

**WARNING LETTER**  
**2002-DT-11**

November 20, 2001

Michael T. Sunday, M.D.  
Medical Director  
Community Memorial Hospital  
748 S. Main Street  
Cheboygan, MI 49721

Dear Dr. Sunday:

We are writing you because on November 13, 2001, your facility was inspected by a representative of the State of Michigan acting in behalf of the Food & Drug Administration (FDA). The 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 (MQSA), 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 Repeat Level 2 finding at your facility:

1. Corrective action, before further exams, for a failing phantom image background density (BD) was not documented for your [REDACTED] mammography unit. This failure occurred on seven (7) different weeks during September and October, 2001.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which your facility received at the close of the inspection. This problem is identified as a Repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of problems found during your previous inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent 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 performing further mammography.

In addition, your response should address the Level 2 finding that was also listed on the inspection report that was provided to you at the close of the inspection. This Level 2 finding is:

1. There was no designated audit (reviewing) interpreting physician for your certified mammography facility.

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 Repeat Level 2 and Level 2 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).

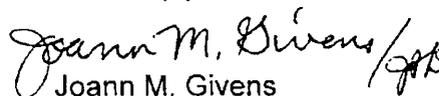
Please submit your response to: Mr. David M. Kaszubski  
Director Compliance Branch  
U. S. Food & Drug Administration  
1560 East Jefferson Ave.  
Detroit, MI 48207-3179

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.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under 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 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: a/s