



**WARNING LETTER**  
**2002-DT-37**

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

September 16, 2002

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

Joel Kimelman, D.O.  
Mammography Supervisor  
Midwest Health Center  
5050 Schaefer Road  
Dearborn, MI 48126

Dear Dr. Kimelman:

We are writing you because on July 31, 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 a serious compromise in the quality of the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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 recent inspection at your facility revealed the following Level 1 finding:

1. The phantom image score, using an FDA approved mammography phantom was less than 2 masses for your [REDACTED] mammography x-ray system.

This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement. This Level 1 finding is a violation of Title 21, Code of Federal Regulations § 900.12 (e)(2)(iii). The minimum acceptable score is 3.0 masses.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which your facility received at the close of the inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography 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, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing 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 Level 1 violation 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).

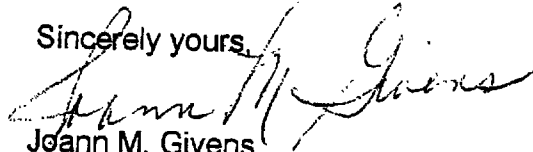
Please submit your response to: Mr. David M. Kaszubski  
Director Compliance Branch  
U. S. Food & Drug Administration  
1560 East Jefferson Ave.  
Detroit, MI 48207-3179

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

Enclosure (MQSA Facility Inspection Report)