DEPARTMENT OF HEALTH & HUMAN SERVICES

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WARNING LETTER
2003-DT-01

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

October 8, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Sheri Leaman- Case
Radiology Director
Saint Mary's Medical Imaging
4040 Euclid
Bay City, MI 48706

Dear Ms. Leaman-Case:

We are writing you because on September 20, 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 Repeat Level 2 finding:

1. Corrective action was not documented, before further exams, for a failing phantom image score, or a phantom background optical density or density difference outside of the allowable regulatory limits. This Repeat Level 2 finding is a violation of Title 21 Code of Federal Regulations § 900.12 (e)(8)(ii)(A).

The specific violation noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which your facility received at the close of the inspection. This violation 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 the same violation found during your previous inspection of September 26, 2001.

Since 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.

In addition, you should also address the following Level 2 finding that was listed on the inspection report provided to you at the close of the inspection:

1. One (1) of ten (10) medical reports, randomly reviewed, did not contain an acceptable assessment category. This is a violation of Title 21 Code of Federal Regulations § 900.12 (c)(1)(iv).

It is necessary for you to act on these matters 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;
- 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)