



CERTIFIED MAIL
RETRUN RECEIPT REQUESTED

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

WARNING LETTER
2001-DT-04

November 30, 2000

Renee Hlavaty
Vice President & CEO
St. Margaret Mercy Healthcare Center-North
5454 Hohman Ave., North Campus
Hammond, IN 46320

Dear Ms. Hlavaty:

We are writing you because on November 14, 2000, your facility was inspected by a representative 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 findings at your facility:

1. There was no mammography equipment evaluation of the [REDACTED] X-ray machine in Room 1 conducted after the system was relocated and returned to service.
2. A random review of medical reports revealed that [REDACTED] of [REDACTED] reports reviewed did not have an assessment category as required by the Quality Standards.

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 Repeat Level 2 because they identify a failure to meet a significant MQSA requirement and indicate failure by your facility to implement permanent correction of problems found during your previous inspection.

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11/30/00

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of 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 onsite monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with MQSA 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 additional Level 2 and Repeat Level 3 findings that were listed on the inspection report provided to your staff at the close of the inspection. These Level 2 and Repeat Level 3 findings are:

1. Corrective actions for the mammography processor QC test failures were not documented for failures occurring on 12/10/99, 1/21/00, 2/29/00 and 5/12/00.
2. Corrective actions for a failing phantom image due to failing image score or a phantom background optical density or density difference outside of allowable regulatory limits, was not documented for the [REDACTED] X-ray system in Room 1.
3. The medical physicist's survey for the [REDACTED] mammography x-ray system in Room 2 was incomplete in that the report did not indicate that the following tests were conducted nor were there numerical results.
 - a) Focal spot size/resolution
 - b) Automatic Exposure Control (AEC)-Reproducibility
 - c) AEC – Performance capability
4. Documentation was not available at the time of the inspection to show that personnel providing mammography services at your facility were qualified. Specifically, there was no documentation available at the time of the inspection to show that Dr. Ericka Ugianskis met the requirement for Initial Experience.

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, Level 2 and Repeat Level 3 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).

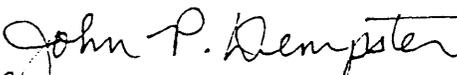
Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207-3179

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. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should also send a copy to the State of Indiana radiation control office.

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,


for Raymond V. Mlecko
District Director
Detroit District

Enclosures: a/s