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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

**WARNING LETTER**
**2003-DT-23**

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

September 25, 2003

Mr. William Miles
Radiology Manager
Ontonagon Memorial Hospital
601 S. Seventh Street
Ontonagon, MI 49953

Dear Mr. Miles:

We are writing you because on September 9, 2003, 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. Your facility failed to produce documentation to show that your radiologic technologist, [redacted] met the initial requirement of holding either a valid state license or a valid certificate from an FDA approved body. This is in violation of Title 21 Code of Federal Regulations (C.F.R.) § 900.12 (a)(4). See also 21 C.F.R. § 900.12 (a)(2)(i).

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 Level 1 because it identifies a failure to meet a significant MQSA requirement.

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, seeking civil money penalties, seeking to suspend or revoke your facility's FDA certificate, or seeking a court injunction against performing further mammography.

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;

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
300 River Place, Suite 5900
Detroit, MI 48207

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 Specialist at 313-393-8156.

Sincerely yours,

David M. Kaszubski

for Joann M. Givens
District Director
Detroit District Office

Enclosure (MQSA Facility Inspection Report)