



1/27/98

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
98-DT-02

January 5, 1998

Jerrold Weiss, M.D.
Radiologist
Delta Medical Center
1107 East Miller Rd.
Lansing, MI 48911

Dear Dr. Weiss:

Your facility was inspected on December 15, 1997 by a representative of the State of Michigan, acting in behalf of the Food and Drug Administration (FDA). The inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

1. The interpreting physician, [REDACTED], did not meet the requirement of being licensed by the State of Michigan to practice medicine.

The specific deficiency noted above appears under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. The deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- **impose civil money penalties** on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.
- **suspend or revoke a facility's FDA certificate** for failure to comply with the Standards.

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- **seek an injunction in federal court** to prohibit any mammography activity that constitutes a serious risk to human health.

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 action (s), therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify the FDA in writing of:

- the specific steps you have taken to **correct** all of the violations noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations;
- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

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

1. The interpreting physician, [REDACTED] did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months.

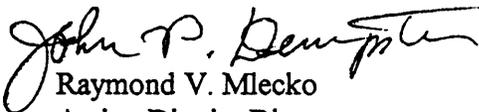
Please send the original copy of your response to Mr. David M. Kaszubski, Compliance Officer, U.S. Food & Drug Administration,, 1560 East Jefferson Ave., Detroit, MI 48207. Also, send a copy to Mr. James Camburn, Chief, Michigan Dept. Of Consumer & Industry Services, Radiation Safety Section, P.O. Box 30664, Lansing, MI 48909. You may choose to address both FDA and State requirements in your response.

I have enclosed a copy of the MQSA Facility Inspection Report that was previously provided to your facility by the State of Michigan representative.

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If you have any questions regarding this letter or how to ensure that you are meeting the MQSA Standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,


for Raymond V. Mlecko
Acting District Director
Detroit District Office

Enclosures: a/s