



Revised by S. Rice 6/10/88
Public Health Service
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5/18/88

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-09

April 30, 1998

Michael LaLa, M.D.
South-Allen Radiology
5518 Allen Rd.
Allen Park, MI 48101

Dear Dr. LaLa:

Your facility was inspected on April 16, 1998 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 measured darkroom fog was **0.12** O.D. which exceeds the allowable level of 0.05 O.D.

The specific deficiency noted above appears under the Level 2 Repeats 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.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

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South-Allen Radiology
Allen Park, MI 48011

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:

- each step your facility is taking to **prevent the recurrence** of this or similar violations;

We acknowledge the letter of Ms. ██████████, RT(R)(M) of your office dated April 17, 1998 which indicates that a bulb in your darkroom had been changed and other white light leaks were sealed. However, the letter was silent on what procedures will be implemented to prevent the recurrence of this problem.

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.

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,

E.A. Williams/for
Raymond V. Mlecko
Acting District Director
Detroit District Office

Enclosures: a/s