



Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

January 26, 1999
Cin WL-1999-103 & 104

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gary E. Kaatz
President & CEO
Northside Medical Center
500 Gypsy Lane
Youngstown, OH 44501

Facilities ID#:128199 (Northside Medical Center)
and 202291 (Center for Breast BMP)

Dear Mr. Kaatz:

Your mammography facilities were inspected on December 10 and 21, 1998 by a representative from the State of Ohio radiation control program under contract to the Food and Drug Administration. These inspections revealed that your facilities failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Your records lack the required information that the interpreting physician, [REDACTED] is qualified to interpret mammograms: Your records did not demonstrate that [REDACTED] has either board certification from any of the approved boards or two months full-time training in the interpretation of mammograms.

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

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

There were no records or attestations regarding the initial training of 40 hours of continuing medical education in mammography for the interpreting physician, [REDACTED]

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:

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- **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.

Within 15 working days after receiving this letter, you should notify 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;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

If your facilities are 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.

Please send the original copy of your response to:

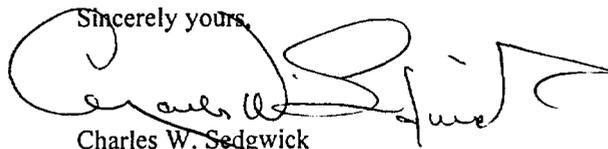
Mr. R. Terry Bolen
MQSA Radiological Health Officer
Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097.

Also, send a copy to the State radiation control office:

Ms. Neann Manubay
Ohio Department of Health
161 S. High St., Suite 400
Akron, OH 44308-1616

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513)679-2700, extension 138.

Sincerely yours,



Charles W. Sedgwick
Acting District Director
Cincinnati District Office

c.
OH/NManubay
Adele M. Lipari, Northside Medical Center, Director of Mammography Services