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

## WARNING LETTER

February 28, 2000

Cin WL 1939-0

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

Ms. Barbara M. King  
Radiology Supervisor  
Community Memorial Hospital  
208 North Columbus St.  
Hicksville, OH 43526

Facility I.D.#:168278

Dear Ms. King:

A representative from the State of Ohio radiation control program under contract to the Food and Drug Administration inspected your facility on February 15, 2000. This inspection revealed that your facility 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. 21 CFR 900.12 (a)(1)(i) or (iii)

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

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

1. There were inadequate records regarding the initial training of 40 hours of continuing medical education in mammography for the interpreting physician: [REDACTED]  
21 CFR 900.12 (a)(1)(i) or (iii)

2. There were inadequate records regarding the interpreting physician's initial experience reading and interpreting mammograms of at least 240 patients in 6 months for of the interpreting physician: [REDACTED] 21 CFR 900.12 (a)(1)(i) or (iii)

3. There were inadequate records that the interpreting physician, [REDACTED] meets the continuing experience requirement in reading and interpreting 960 patient mammograms in a 24 month period preceding the current inspection. 21 CFR 900.12 (a)(1)(ii)(A)

4. There were inadequate records that the interpreting physician, [REDACTED] meets the continuing education of completed a minimum of 15 hours of CME credit in a 36 month period. 21 CFR 900.12 (a)(1)(ii)(B)

5. There were inadequate records that the radiologic technologist, [REDACTED] meets the continuing education of completed a minimum of 15 hours of CME credit in a 36 month period. 21 CFR 900.12 (a)(2)(iii)

The other item listed in your February 15, 2000 inspection report identified, as Level 3 should also be corrected. We will verify correction of this item during our next inspection. You are not required to address the Level 3 item in your written response.

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.

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;

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.

Please send the original copy of your response to:

R. Terry Bolen  
MQSA Compliance Officer  
Food and Drug Administration  
6751 Steger Dr.  
Cincinnati, OH 45237-3097

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

Ms. Cindy Grant  
Ohio Department of Health  
Government Center  
Suite 1320  
Toledo, OH 43406

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,



Henry L. Fielden  
District Director  
Cincinnati District Office

c.  
OH/CGrant

Director, Breast Imaging Accreditation Program  
American College of Radiology  
1891 Preston White Dr.  
Reston, VA 20191