



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

M3499m

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

**WARNING LETTER**

Cin WL -1870-0  
February 22, 2000

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

Kathleen S. Alexander, M.D.  
Facility Supervisor  
St. Joseph Health Care Center  
476 South Main St.  
Andover, OH 44003

Facility I.D.#: 222683

Dear Dr. Alexander:

A representative from the State of Ohio radiation control program under contract to the Food and Drug Administration inspected your facility on February 17, 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 revealed that your facility processed mammograms when the processor quality control parameters were out of limits for seven days in the months of May, July and August 1999. Your records showed that on many occasions the staff of your facility incorrectly performed corrective action by reestablishing a new five-day average processor quality control chart reference points. **21 CFR 900.12 (e)(8)**

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. Your records did not demonstrate that your facility performed corrective actions for processor quality control failures. **21 CFR 900.12 (e)(8)(ii)(A)**
2. Your records showed that no corrective actions were conducted for the failed phantom image data. **21 CFR 900.12(e)(8)(ii)(A)**
3. Four of five random interpreting physician mammography reports did not contain the required overall final assessment of findings. **21 CFR 900.12 (c)(1)(iv)(A)-(E) &(v)**

The other items listed in your February 17, 2000 inspection report identified, as Level 3 should also be corrected. We will verify correction of these items during our next inspection. You are not required to address these Level 3 items 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;
- Sample records that demonstrate proper record keeping procedures related to quality control.

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:

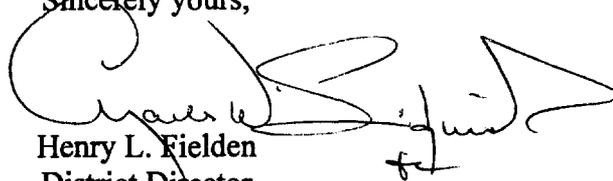
R. Terry Bolen  
MQSA Compliance Officer  
Food and Drug Administration  
6751 Steger Dr.  
Cincinnati, OH 45237-3097

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

Mr. Dwight W. Leeseberg  
Ohio Department of Health  
Northeast District Office  
Oliver R. Ocasek Government Office Building  
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,

A handwritten signature in black ink, appearing to read "Henry L. Fielden", written over a large, stylized circular flourish.

Henry L. Fielden  
District Director  
Cincinnati District Office

c.  
OH/DWLeeseberg

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