



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

114873  
 Food and Drug Administration  
 Cincinnati District Office  
 6751 Steger Drive  
 Cincinnati, OH 45237-3097  
 Telephone: (513) 679-2700  
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**WARNING LETTER**

Cin WL -5347-0  
 November 20, 2000

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

Mr. Michael Roe  
 Radiology Technical Director  
 Holzer Medical Center  
 100 Jackson Pike  
 Gallipolis, OH 45631

Facility I.D.#: 116954

Dear Mr. Roe:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on November 7, 2000. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

**Quality Assurance – Equipment - 21 CFR 900.12(e)(1)(i)-(iii)**

Your records showed that your facility processed mammograms when the processor quality control records were missing three of seven days or 43% of total days of operation in September 2000. This specific deficiency is noted in your MQSA Facility Inspection Report, which your facility received at the close of the inspection. The deficiency is identified as repeat Level 1 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of the problem found during your previous inspection.

**Quality Assurance – Equipment - 21 CFR 900.12(e)(2)(i)-(iv)**

Your records revealed that your facility phantom quality control records for the mammography unit were missing for seven weeks. The MQSA regulation requires the mammography unit be evaluated by performing at least weekly the image quality evaluation test. The inspection found that your facility failed to perform this quality control test during the weeks of August 1-4, 7-11, 14-18, 21-25, 28-31, September 1, 5-8, 11-14.

Because these conditions may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, they represent violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

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

**Quality Assurance – Equipment - 21 CFR 900.12(e)(1)(i)-(iii)**

Your records revealed that your facility processed mammograms when the processor quality control records were missing for two (2) consecutive days in the month of September 2000.

The specific problem noted above appeared in your MQSA Facility Inspection Report, which your facility received at the close of the inspection. The problem is identified as **repeat** Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement **permanent correction of the problem** found during your previous inspection.

The other items listed in your November 7, 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.

You must act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date of receipt of this letter:

- the specific steps you have taken or plan to take to correct all of the violations noted in this letter;
- each step your facility is taking **to prevent the recurrence of similar violations**; and
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate.

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen  
MQSA Compliance Officer  
Food & Drug Administration  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
FAX: 513-679-2772

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

Ms. Stacey Melick  
Ohio Department of Health  
Radiologic Technology Section  
P.O. Box 118  
Columbus, OH 43266-0118

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,



Henry L. Fielden  
District Director  
Cincinnati District Office

c.  
OH/SMelick

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