



**WARNING LETTER**

Cin WL - 5258-0  
November 13, 2000

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

Adele M. Lipari, M.D.  
Director of Mammography Services  
Northside Medical Center - Beeghly Medical Park  
6505 Market St.  
Youngstown, OH 44512

Facility I.D.#: 202291

Dear Dr. Lipari:

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 **repeat** Level 2 finding at your facility:

**Quality Assurance - Equipment [21 CFR 900.12(e)(2)(i)-(iv), as required by 21 CFR 900.12(e)(8)(ii)]- Level 2 Finding**

Your records showed that no corrective actions were documented for phantom image quality control failures that occurred on June 12, 26, September 25, and October 2, 2000.

The specific problem noted above appeared on 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.

Because the condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a 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.

The other items listed in your November 7, 2000 inspection report identified, as Level 3 should also be corrected. We will verify corrections on these items during our next inspection. You are not required to address the Level 3 items in your written response.

It is necessary for you to act on these matters immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct all of the violations noted in this letter; and
- Each step your facility is taking to prevent the recurrence of similar violations.

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:

Mr. Dwight W. Leeseberg  
Ohio Department of Health  
Radiologic Technology Section  
161 South High St., Suite 400  
Akron, OH 44308

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 E. Fielden  
District Director  
Cincinnati District Office

c.  
OH/DWLeeseberg

Priscilla F. Butler, M.S.  
Director, Breast Imaging Accreditation Program  
American College of Radiology  
1891 Preston White Dr.  
Reston, VA 20191