



WARNING LETTER

April 21, 1998

CIN 98-260

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

James V. Zelch, M.D.
Medical Director
Grace Hospital
2307 West 14th Street
Cleveland, OH 44113

Facility I.D.# 180265

Dear Dr. Zelch:

Your facility was inspected on April 9, 1998, by a representative from the State of Ohio radiation control program acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, Mammography Quality Standards Act of 1992, your facility must comply with specific requirements for mammography. These requirements enhance the protection of the health of women by assuring that a facility can perform quality mammography.

The April 9, 1998 inspection revealed the following Level 1 finding at your facility:

Your records indicate that there was no medical physicist survey performed on your facility's mammography operation, in the past fourteen (14) months.

The specific noncompliance issue noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

In addition, your response should address the Level 2 Repeats, Level 2 and Level 3 Repeats noncompliance items that were listed on the same inspection report provided to you. These Level 2 Repeats, Level 2 and Level 3 Repeats noncompliance items are:

- Level 2 Repeats

1. Your facility lacks records demonstrating that the following interpreting physicians meet the initial training requirement of having forty (40) hours of continuing medical education in mammography. (██████████) and (██████████)

2. Your facility lacks records demonstrating that the following interpreting physicians meet the initial experience requirement of having read and interpreted mammograms from the examinations of at 240 patients in six (6) months. ([REDACTED] and [REDACTED]

- Level 2

1. A reaccreditation application had not been submitted to the American College of Radiology for the mammography x-ray system.

2. There were no records demonstrating that the interpreting physician, [REDACTED] meets the continuing education requirements of having completed a minimum of 15 credits in mammography over a three (3) year period (an average of five (5) credits/year).

- Level 3 Repeats

There was lack of documentation as part of your facility's quality assurance program covering personnel responsibilities.

These deficiencies noted above appeared under the Level 2 Repeats and Level 3 Repeats heading on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These deficiencies were also observed in the previous inspection dated March 31, 1997. Your facility did not contact this office or submit a written response to the previous Level 2 noncompliance items found in the March 31, 1997 inspection. The lack of attention to the matter is symptomatic of serious underlying problems that compromise the quality of mammography at your facility.

Because these conditions are symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in the 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 the 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, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

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

- the specific steps you have taken to **correct** all of the violations noted in this letter;
- in particular, 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 (including submitting a copy of the medical physicist survey report);

and

- sample records that demonstrate proper record keeping procedures, if the findings found 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 Radiological Health Officer
Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202.
FAX: 513-684-3780

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>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please contact Mr. R. Terry Bolen at (513)684-3501, extension 138.

Sincerely yours,



Henry L. Fielden
Acting District Director
Cincinnati District Office