



DEPARTMENT OF HEALTH AND HUMAN SERVICES

AFI-35

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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

Cin WL - 4828-0
October 12, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Larry Bolgar
Business Manager
Northern Ohio Imaging Center
1900 West River Road, North
Elyria, OH 44035

Facility I.D.#: 128066

Dear Mr. Bolgar:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on October 4, 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:

Your facility records did not demonstrate that the interpreting physician, [REDACTED] meets the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period. **21CFR 900.12 (a)(1)(ii)(A)**

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.

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

Your facility did not perform and document corrective actions for failed phantom image quality control tests before conducting mammography exams. These deficiencies were noted for the mammography units located in rooms M1 and M2. 21 CFR 900.12 (e)(8)(A) & (e)(2)(i)&(ii)

The other items listed in your October 4, 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

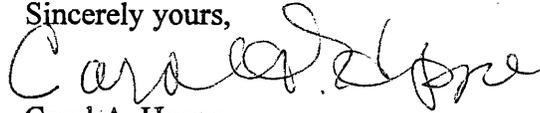
Also, please send a copy to the State radiation control office:

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,

A handwritten signature in cursive script, appearing to read "Carol A. Hepp".

Carol A. Hepp
Acting District Director
Cincinnati District Office

c.
OH/DWLeeseberg

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Program
American College of Radiology
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