



WARNING LETTER

Cin WL -7051-01
March 28, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Michael Rowan,
Chief Operating Officer
St. Elizabeth Health Center
1044 Belmont
Youngstown, OH 44501

Re: MQSA Facility I.D.#: 222683
St. Joseph Health Care Center
476 South Main St., Andover, OH 44003

Dear Mr. Rowan:

On March 14, 2001, a representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected St. Joseph Health Care Center, 476 South Main St., Andover, OH 44003. 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 finding at your facility:

Medical Records and Mammography Reports – *Communication of Mammography Results to the Patients* – 21 CFR 900.12(c)(2)(i)&(ii)

Your facility's system is inadequate in communicating to the patients the results of their mammograms. Your facility's system fails to indicate that the mammography results will be provided to each of the patients in a lay summary report within 30 days of the mammography examinations. Verbal communication must be supplemented with written communication (lay summary letter). This requirement includes mammograms result assessment of "Category 0 – Needs additional imaging evaluation."

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, this represent a violation of the law which may result in FDA

taking regulatory actions 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 noncompliance item that was listed on the inspection report provided to you at the close of the inspection. This **repeat** Level 2 noncompliance item is:

Medical Records and Mammography Reports- 21 CFR 900.12(c)(1)(iv)(A)-(E) &(v)

Two of seven random interpreting physician mammography reports did not contain the required overall final assessment of findings.

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.**

You must 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 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

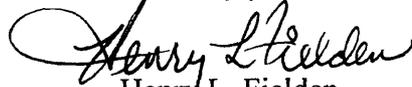
Also, please send a copy to the State radiation control office:

Ms. Terri Eckert
Ohio Department of Health
Radiologic Technology Section
161 South High St., Suite 400
Akron, OH 44308-1616

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 Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,



Henry L. Fielden
District Director
Cincinnati District Office

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OH/TEckert

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