DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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–03-17193

April 28, 2003

Sent via FedEx

Mr. Steven Colecchi
President & CEO
Robinson Memorial Hospital
6847 North Chestnut St.
Ravenna, OH 44266

Facility I.D.#: 134221

Dear Mr. Colecchi:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on March 31, 2003. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act (MQSA) of 1992, 42 U.S.C. § 263b, and the regulations set forth in Title 21, Code of Federal Regulations (C.F.R.), Part 900, 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 (identified on your inspection report):

Medical records and mammography reports – *Communication of mammography results* (21 C.F.R. § 900.12(c)(2))

Your records revealed that your facility failed to provide lay summary letters to patients that included the results of each mammography examination written in lay terms within 30 days of the mammography examinations. When the mammography examination assessments are "Suspicious" or "Highly suggestive of malignancy", your facility failed to ensure that these results are communicated to the patients as soon as possible. According to your facility's records ("Patient Event List"), your facility on three occasions issued at greater than thirty days from the date of examinations, lay summary letters to patients whose mammography results were "Highly suggestive of malignancy".

The inspection also revealed the following issue (identified in the Inspector Remarks portion on your inspection report):

> **Medical records and mammography reports – *Communication of mammography results* (21 C.F.R. § 900.12(c)(1)(iv)**
>
> Your facility failed to report the overall final assessment of findings, classified in one of the required categories for patient reports.
>
> The inspector observed a mammography report containing an assessment for each of the right and left breast and there is no "overall" final assessment finding. The inspector received information from your staff that a particular radiologist has a practice of issuing an assessment for each breast and that radiologist does not provide an "overall assessment".

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent serious violations of the law that may result in FDA initiating regulatory action. 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; seeking civil money penalties of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA Standards; seeking suspension or revocation of your facility's FDA certificate; or seeking a court injunction against performing further mammography (see 42 USC §§ 263b(h) through (j) of the MQSA). Before initiating any enforcement action against you, FDA may need to perform a follow-up inspection of your facility to determine whether these problems have been corrected. FDA assesses fees for MQSA inspections, including follow-up inspections (42 USC 263b(r)).

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

1. The specific steps you have taken to correct the violations noted in this letter; and

2. Each step your facility is taking **to prevent the recurrence** of similar violations.

Please also provide the following in answering this letter: (Note: Patient names or patient social security numbers should be deleted from any copies submitted)

1. A copy of your corrected written procedure for communication of mammography results. The written procedures shall cover all mammography results for patients. The written procedure shall include assessments with "Suspicious" or "Highly suggestive of malignancy. Also, include a copy of sample lay summary letters for each final assessment categories.

2. A copy of your written procedure that all mammography reports will contain overall final assessment of findings. Also include copies of the corrected mammography report with the overall final assessment reported by Drs. [redacted] and others if applicable.

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 Leeseberg
Ohio Department of Health
Radiological 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 certain 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,

Carol A. Heppe
District Director
Cincinnati District Office

c.
OH/DWLeeseberg

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