DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service 9420d

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

**WARNING LETTER**
**2003-DT-19**

**August 8, 2003**

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

Re: MQSA Inspection ID #1957010010

Mr. Patrick Feyen, CEO
Winona Memorial Hospital
3232 N. Meridian Street
Indianapolis, IN 46208

Dear Mr. Feyen:

On July 10, 2003, a representative of the State of Indiana, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 (MQSA), which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report and the document "*Important Information about Your MQSA Inspection*" that the inspector left at your facility at the close of the inspection. The violations are again identified below.

Repeat Level 2 findings:

1. Your facility failed to produce documentation to verify that your technologist [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in the previous 36 month period. This is in violation of 21 C.F.R. § 900.12(a)(2)(iii)(A). See also 21 C. F. R. § 900.12 (a)(4).

2. Your facility failed to produce documentation that your technologist [redacted] met the continuing experience requirement of having performed 200 mammography examinations in the previous 24 month period. This is in violation of 21 C.F.R. § 900.12(a)(2)(iv)(A). See also 21 C.F.R. § 900.12 (a)(4).

These problems are identified as Repeat Level 2 because they identify a failure to meet significant MQSA requirements and indicate a failure by your facility to implement permanent correction of problems found during your previous inspection.

In addition, you should also address the following Level 2 and Repeat Level 3 findings that were listed on the inspection report provided to you at the close of the inspection.

1. Your facility failed to produce documentation that your interpreting physician, [redacted] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in the previous 24 month period. This is in violation of 21 C.F.R. § 900.12 (a)(1)(ii)(A). See also 21 C.F.R. § 900.12 (a)(4).

2. The fixer retention quality control testing for the mammography film processor was inadequate because the test was not conducted at the required frequency of at least quarterly. This is in violation of 21 C.F.R. § 900.12 (e)(3)(i).

Because the continued failure to resolve these violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- placing your facility under a Directed Plan of Correction
- charging your facility for the cost of on-site monitoring
- seeking 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
- seeking to suspend or revoke your facility's FDA certificate
- seeking a court injunction against your facility

See 42 USC 263b(h)-(j) and 21 C.F.R. 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

If you choose to respond to the above violations, your response should include:

- the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

- the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps;

- sample records that demonstrate proper record keeping procedures (Note: Patient names or other information that would likely reveal the patient's identity should be deleted from any copies of records you submit).

Please submit your response to this letter to:

Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
300 River Place, Suite 5900
Detroit, MI 48207

Please send a copy of your response to:

Indiana State Department of Health
Indoor and Radiology Health
2 North Meridian Street
Indianapolis, IN 46204

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You may choose to address both the FDA and any additional State requirements in your response.

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the recent inspection of your facility 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/index.html.

If you have additional or more specific about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Dennis E. Swartz, Radiological Health Specialist, at 313-393-8156.

Sincerely yours,

Joann M. Givens
District Director
Detroit District Office

Enclosure (MQSA Facility Inspection Report)