DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

936926

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone. 612-334-4100

November 13, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 – 05

John Kosanovich
President and Chief Executive Officer
Watertown Memorial Hospital
125 Hospital Drive
Watertown, Wisconsin 53098

Dear Mr. Kosanovich:

On October 15, 2002, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your facility, Center for Women's Health Imaging Department, located at 128 Hospital Drive, Watertown, WI 53098 (FDA certificate #227695). This inspection revealed serious regulatory problems involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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. Based on the documentation your site presented at the time of the inspection, the following Level 1 and Level 2 findings were documented at your facility:

Level 1 Non-Compliance:

1. The system to communicate results for the Center for Women's Health Imaging Department site is inadequate because there is no system in place to provide timely lay summaries for all patients within 30 days of their examination. Patient notification must be in writing.

   Title 21, Code of Federal Regulations, Part 900.12(c)(2) [(21 CFR 900.12(c)(2)] states:

   > Communication of mammography results to the patients. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic

examination. If assessments are 'Suspicious' or 'Highly suggestive of malignancy,' the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

Note: Employees told the inspector that patients with positive findings were telephoned, and in those cases, the written lay summary was not distributed.

Level 2 Non-Compliances:

2. The mammography equipment evaluation (by a medical physicist) was not done following a major repair ([redacted], Room 134 Mammography 2, ACR unit designation = 2).

   900.12(e)(10) states:

   > Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired.

3. Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for the following mammography systems:

   [redacted], Room 130 Mammography 1, ACR unit designation = 1.

   [redacted], Room 134 Mammography 2, ACR unit designation = 2.

   These are required weekly tests under 21 CFR 900.12(e)(2). 21 CFR 900.12(e)(8)(ii)(A) requires that the failing test condition be corrected before resuming clinical practice. Note: Acceptable practice includes written documentation of what corrective action was taken and the performance of a re-test that indicates that the failed parameter is in compliance, prior to producing clinical images. Re-establishing the control chart's "aim values" to mask an out-of-control condition is not an acceptable corrective action.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because these conditions may be 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 FDA taking 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 up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA standards, seeking a suspension or revocation of your facility's FDA certificate, or seeking 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 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;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (include technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

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/index.html.*

If you have specific questions about mammography facility requirements, or about the content of this letter, please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

Sincerely,

Annette Byrne
Acting Director
Minneapolis District

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