DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

3465d

August 15, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 – 39

Lennie L. Libis
Chief Executive Officer
St. Croix Regional Medical Center
204 So. Adams Street
St. Croix Falls, Wisconsin 54024

Dear Mr. Libis:

On July 25, 2002, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your mammography facility (FDA Certificate #138156). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), 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:

The system to communicate results is not adequate to the St. Croix Regional Medical Center site because there is no system in place to provide timely lay summaries for all mammography patients within 30 days of their examination. Patient notification must be in writing.

Title 21, Code of Federal Regulations, section 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.

Level 2 Non-Compliance:

One of eight random reports reviewed did not contain an acceptable assessment category.

21 CFR 900.12(c)(1)(iv) specifies the exact wording for mammography assessment categories. Note: By policy, FDA has approved "equivalent" wordings; these equivalents may be found on the web site referenced below.

Medical audit and outcome analysis was not done for the facility as a whole.

21 CFR 900.12(f)(1): General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among patients imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of the malignancy.

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

These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and they represent a serious violation of the law that may result in FDA's taking regulatory action against your facility. 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, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining 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 (including 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,

James A. Rahto
Director
Minneapolis District

TSW/ccl

xc:

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