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

93284d

May 16, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 32

David B. Kellen, M.D.
President
Krohn Clinic
610 West Adams Street
Black River Falls, Wisconsin 54615

Dear Dr. Kellen:

On April 16, 2002, a representative of the State of Wisconsin acting in behalf of the Food and Drug Administration (FDA), inspected your mammography facility (FDA Certificate # 186304). 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 non-compliances were documented at your facility:

Repeat Level 2 Non-Compliance

1. Four of 8 random reports reviewed did not contain an acceptable final assessment of findings.

   All mammography reports must contain a single final assessment for the exam, classified in one of the categories listed in Title 21, Code of Federal Regulations, Sections 900.12(c)(1)(iv) - (v). Each of the four non-compliant mammography reports reviewed during the inspection improperly contained more than one final assessment. When more than one abnormality is found during an exam, and each one is given a separate assessment in the mammography report, the report must still contain one final assessment for

the exam overall, based on the most suspicious lesion or finding. That final assessment must use either (a) the precise wording of one of the final assessment categories listed in Title 21, Code of Federal Regulations, Sections 900.12(c)(1)(iv) - (v); or (b) approved alternate wording established in published FDA policy. For the list of such permitted alternative wording, see *http://www.fda.gov/cdrh/mammography/robohelp/personnel/contents_of_records_and_reports.htm* (answer to Question 5).

The specific problems noted above appeared on your MQSA *Post 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 imposing statutory sanctions. These sanctions 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, federal mammography standards, or suspending or revoking your facility's FDA certificate.

It is necessary for you to act on this matter immediately. Please explain 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 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, FDA, 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 certain findings of your inspection and does not necessarily address other obligations you have under the law, including, but not limited to, correcting the other violation cited on your MQSA *Post Inspection Report*. 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

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xc:

Lead Interpreting Radiologist
Krohn Clinic
610 W. Adams Street
Black River Falls, WI 54615

Paul Schmidt
Chief, Radiation Protection Unit
State of Wisconsin
P.O. Box 2659
Madison, WI 53701-2659

Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 20191