DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

933280

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

June 6, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 34

Ronald J. Peterson, M.D.
President
John A. Haugen Associates, P.A.
3250 W. 66th Street, Suite 200
Edina, Minnesota 55435

Dear Dr. Peterson:

On May 8, 2002, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your mammography facility (FDA certificate #200162). This inspection revealed a serious regulatory problem 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. The inspection revealed the following Level 1 and Level 2 findings at your facility:

Level 1 Non-Compliance:

1. On at least five days mammograms were processed in the mammography film processor ([redacted], room = Darkroom) when it was out of limits (Repeat).

   Title 21, Code of Federal Regulations, Part 900.12(e)(8) requires that out of limit condition(s) be resolved before mammography is allowed to resume.

Level 2 Non-Compliance:

2. Corrective actions for processor QC failures were not documented at least once for the mammography film processor ([redacted] room = Darkroom (Repeat).

Title 21, Code of Federal Regulations, Part 900.12(e)(8)(ii) requires that the source of the problem be identified. Acceptable practice requires documentation of the problem and that retest be performed (which documents that the QC parameter is now in control) before allowing mammography to resume.

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 mammography system (~~~~ room = Mammography, ACR unit designation = 1) (Repeat).

   Title 21, Code of Federal Regulations, Part 900.12(e)(8) requires that out of limit condition(s) be resolved before mammography is allowed to resume.

A non-compliance is annotated as "Repeat" if it was also cited during the prior inspection.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. A Level 1 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

These conditions represent a serious violation of the law which may result in FDA taking regulatory action against you including, but 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 mammography quality standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography [see Sections 354(h) through (j) of the MQSA].

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:

1. the specific steps you have taken or will take to **correct** all of the violations noted in this letter, any reason that corrective action has not been taken, and the time within which any steps not yet taken will be complete;

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

3. equipment settings (including technique factors), raw test data, and calculated

4. final results, where appropriate; and

4. documentation showing that correction is complete including, if the findings relate to quality control or other records, sample records that demonstrate proper record keeping procedures, (**Note: Patient names or identification should be deleted from any copies submitted**).

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 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/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

TWG/ccl

xc:

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