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

93722

December 17, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 – 08

Scott R. Schultz, M.D.
President
Minneapolis Radiology Associates, Ltd.
3366 Oakdale Avenue North, Suite 604
Minneapolis, Minnesota 55422

Dear Dr. Schultz:

On November 18, 2002, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your mammography facility (FDA certificate #170753). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States law, 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. Mammograms were processed in the film processor ([redacted], room = darkroom) when it was out of limits on at least 5 days.

Title 21, Code of Federal Regulations, Sections 900.12(e)(1)(i), (ii), and (iii) specify the control limits for performing mammography. If the film processor is not within these control limits, then mammography can not be performed.

Level 2 Non-Compliance:

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

Title 21, Code of Federal Regulations, Section 900.12(e)(8)(ii) with reference to Sections 900.12(e)(1)(i), (ii), and (iii) requires that the QC failures be **identified** and **corrected**. Documentation of what corrective actions were taken and the performance of a retest verifying that the corrective actions were successful need to be completed. For the daily processor QC test, these operations must be completed before resuming clinical mammography.

During the previous (2001) inspection, your facility was cited for failing to perform the mandatory daily QC test. The current inspection documented that the required daily test is now being performed, but your facility is failing to take appropriate steps when the test results are beyond regulatory limits.

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 (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, Wisconsin 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

TWG/ccl

xc:

Lead Interpreting Physician
c/o Minneapolis Radiology Associates, Ltd.
3366 Oakdale Avenue North, Suite 604
Minneapolis, MN 55422

Sue McClanahan
Supervisor, Radiation Unit
Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, MN 55108-2970

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