



M34521

PURGED *rt*

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

January 25, 2000

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 15

Jeannine Schlottmann
Administrator
Fridley Medical Center
Multicare Association of the Twin Cities
7675 Madison Street NE
Fridley, Minnesota 55432

Dear Ms. Schlottmann:

On January 14, 2000, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA) inspected your facility (FDA certification # 113431). This inspection revealed a serious regulatory problem involving the performance of mammography at your facility.

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

Radiologic Technologist *~~~~~* did not meet the requirement of being licensed by a State or certified by a FDA-recognized board. Her American Registry of Radiologic Technologists (ARRT) certification expired in March 1999. Reportedly your site's management was aware of this lapse in certification but allowed her to continue to perform mammography.

Page Two

Jeannine Schlottmann
January 25, 2000

Level 2 Non-Compliances:

Radiologic Technologist  did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36-month period.

There is no written procedure for handling mammography related consumer complaints in accordance with the MQSA regulation, 21 CFR 900.12(h)(1), (2), (3) and (4).

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

Note: Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography. Procedures to re-establish continuing education qualifications may be found in 21 CFR 900.12(a)(2)(iii)(D).

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 without further notice to you. 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 Radiological Health Specialist Thomas W. Garvin, FDA, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Page Three

Jeannine Schlottmann
January 25, 2000

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 call Mr. Garvin at (414) 771-7167 x12.

Sincerely,



Edwin S. Dee
Acting Director
Minneapolis District

TWG/ccl

xc: Sue McClanahan
Supervisor, Section of Radiation Control
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975

Pamela A. Wilcox-Buchalla, R.N., M.B.A.
Director, Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, VA 22091