



M3725A

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

PURGED
April 28, 2000

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00-30

Ronald Harmon
Administrator
Albert Lea Medical Center
404 Fountain Street
Albert Lea, Minnesota 56007

Dear Mr. Harmon:

On April 10, 2000, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your facility (inspection ID - 1662310005). This inspection revealed a serious regulatory problem involving 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 document 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-Compliances:

1. Mammograms were processed in a film processor when it exceeded control limits on 44 days. (Processor = wavy line Darkroom; processor #2).
2. Phantom QC records were missing for 4 weeks for the mammography system located in mammography room #4. Evaluation Criteria = number of weeks missing in worst 12 week period.
3. Phantom QC records were missing for 4 weeks for the wavy line mammography system located in mammography room #4. Evaluation Criteria = number of weeks missing in worst 12 week period.

Page Two

Ronald Harmon
April 28, 2000

Level 2 Non-Compliances:

4. The measured fog density is equal to 0.1 for the mammography darkroom.
5. There is no written procedure for handling mammography consumer complaints in accordance with Title 21, Code of Federal Regulations, Part 900.12(h)(1)(2)(3)(4), [21CFR 900.12(h)(1)(2)(3)(4)].
6. Corrective actions for processor QC failures were not documented at least once for film processor #2.  , Darkroom; processor #2).
7. Five of 5 randomly selected mammography reports reviewed did not contain an assessment category in accordance with 21CFR 900.12(c)(1)(i), (ii), (iii) (A)(B)(C)(D)(E), (iv), (v), and (vi).
8. Based on the documentation that your site supplied, interpreting physician  did not meet the requirement of having a minimum of 40 CME credit hours of **initial** training in mammography.

Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography independently.

The specific problems noted above appeared on your MQSA Facility 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 the 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 of 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 reoccurrence of similar violations;

Page Three

Ronald Harmon
April 28, 2000

- 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 N. 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 the 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 x 12.

Sincerely,



Edwin S. Dee
Acting Director
Minneapolis District

TWG/ccl

xc: Dr. 
Interpreting Radiologist
Albert Lea Medical Center
404 Fountain Street
Albert Lea, MN 56007

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

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