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PURGED *BAK*

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

February 25, 2000

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 22

James E. Raney
Chief Executive Officer
Appleton Medical Center
5 Innovation Court
Appleton, Wisconsin 54914

Dear Mr. Raney:

On February 24, 2000, a representative of the State of Minnesota acting on behalf of the Food and Drug Administration (FDA) inspected your facility, Appleton Medical Center, 1818 North Meade, Appleton, WI (Identification # 101220). 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-Compliances:

1. Phantom QC records were missing for four weeks for the mammography unit (~~~~~) located in Room 1.
2. Phantom QC records were missing for four weeks for the mammography unit (~~~~~) located in Room 2.

A weekly phantom became a mandatory requirement on April 28, 1999.
Evaluation criteria: number of weeks missing within worst 12-week period.

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Level 2 Non-Compliances:

3. Corrective actions for processor QC failures were not documented at least once for the film processor (M35 or M35A-M) located in the mammography darkroom.
4. Corrective action for a failing phantom image score (before further exams) was not documented for the mammography unit located in Room 1.
5. Corrective action for a failing phantom image score (before further exam) was not documented for the mammography unit located in Room 2.

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 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 Thomas W. Garvin, Radiological Health Specialist, FDA, 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

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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 though 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,



Albert H. Schwab
Acting Director
Minneapolis District

TWG/ccl

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