



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MIN 99-44



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

August 30, 1999

cc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 44

David Wessner
Chief Executive Officer
Park Nicollet Medical Center
3900 Park Nicollet Boulevard
St. Louis Park, Minnesota 55416

Dear Mr. Wessner:

On August 3, 1999, a representative of the State of Minnesota acting on behalf of the Food and Drug Administration (FDA) inspected your Bloomington Clinic located at 5320 Hylands Greens Drive, Bloomington, MN 55437. This inspection (inspection ID: 1664210006) revealed a serious regulatory problem involving the 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:

Quality Control (sensitometric) records for the x-ray film processor were missing for 33% of the days your site processed mammographic films in July 1999 (three of nine days). Quality Standards required that this QC

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test be completed prior to processing clinical films; it verifies that the processor is operating within recognized control limits.

Level 2 Non-Compliance:

The above noted days were consecutive.

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: This report also listed three additional Level-3 non-compliances involving lapses in performing other required QC tests.

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.

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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/dmgrp.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 ext. 12.

Sincerely,



Cheryl A. Bigham
Acting Director
Minneapolis District

HEM/ccl

xc: Sue McClanahan
Supervisor, Section of Radiation Control
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