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

November 1, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 - 03

David Wessner
Chief Executive Officer
Park Nicollet Health Systems
5600 Excelsior Boulevard
St. Louis Park, Minnesota 55426

Dear Mr. Wessner:

On October 10, 2002, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your mammography facility at Park Nicollet Medical Center—Bloomington Clinic, 5320 Hyland Greens Drive, Bloomington, MN (FDA Certificate #166421). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under 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 that your site presented at the time of the inspection, the following repeat non-compliance was noted at your facility:

Repeat Level 2 Non-Compliance:

1. Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for the mammography unit ([redacted], Mammography room, ACR unit designation = 2).

   This is a required weekly test under Title 21, Code of Federal Regulations, Section 900.12(e)(2). Title 21, Code of Federal Regulations, Section 900.12(e)(8)(ii)(A) requires that the failing test condition be corrected before

resuming clinical practice. Note: Acceptable practice includes written documentation of corrective action and the performance of a re-test that indicates that the failed parameter is in compliance, prior to producing clinical images.

A non-compliance is designated a "repeat" if it was also cited during the prior inspection.

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

Because this violation may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions including, but 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 of 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.

You should respond in writing to FDA within 15 working days from the date you received this letter. Your response should include:

- 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 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography facilities. This letter pertains only to findings related to the recent inspection of your facility 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: [redacted]
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