



932521

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

May 9, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 02 - 31

Michael T. Decker
President and Chief Executive Officer
Divine Savior Healthcare
1015 W. Pleasant Street
Portage, Wisconsin 53901

Dear Mr. Decker:

On April 17, 2002, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA) inspected your mammography facility (FDA Certificate #110197). This inspection 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 non-compliances were documented at your facility:

Repeat Level 2 Non-Compliance:

1. Eight of 8 random mammography reports reviewed did not contain an acceptable assessment category for Divine Savior Healthcare site.

All mammography reports must contain a single assessment category for the exam. Wording of the assessment must conform to Title 21, Code of Federal Regulations, Part 900.12(c)(1) [21 CFR 900.12(c)(1)] or approved alternate wording established in published FDA policy.

Level 2 Non-Compliance:

2. Failure to produce documents verifying that the interpreting physician mm met the initial requirement of 40 hours of medical education in mammography prior to April 28, 1999.

Page Two

Michael T. Decker
May 9, 2002

21 CFR 900(a)(1) specifies personnel requirements for Interpreting Physicians.

FDA acknowledges an April 24, 2002, letter from your Director of Diagnostic Imaging, [REDACTED]. An attachment to [REDACTED] letter (S. [REDACTED] dated April 30, 1990) references Dr. [REDACTED] residency program. However, it is non-specific on the extent of his mammography training. Provided he received at least 40 hours of mammography training (prior to 10/1/94) it is acceptable that Dr. [REDACTED] supply a signed attestation to document his initial training in mammography.

The specific problems noted above appeared on your MQSA Post 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, Food and Drug Administration, 2675 No. 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

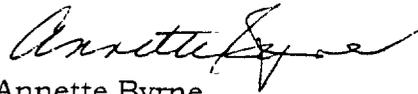
Page Three

Michael T. Decker
May 9, 2002

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: 

