DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

93635d

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

October 22, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03 – 01

John R. Landeck
Chief Executive Officer
Beaver Dam Community Hospital
707 S. University Avenue
Beaver Dam, Wisconsin 53916

Dear Mr. Landeck:

On October 1, 2002, a representative of the State of Wisconsin, acting on behalf of the Food and Drug Administration (FDA), inspected your mammography facility (FDA certificate #102848). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States law, the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 236b, 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:

1. The system to communicate results is not adequate because there is no system in place to provide timely lay summaries to all mammography patients within 30 days of their examination. Patient notification must be in writing.

   Your policy entitled "Mammography will be performed by self requesting and by physician referral (revision 9-99)" indicates on page 2, item 2, that the radiologist may choose to not send any letter to the patient. Title 21, Code of Federal Regulations, Part 900.12(c)(2): states:

Communication of mammography results to the patients. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility shall make reasonable attempt to ensure that the results are communicated to the patient as soon as possible.

Level 2 Non-Compliances:

2. The medical physicist's survey for x-ray unit 2 (~~~~~ model CONT, Mammo room), is incomplete because the following tests were inadequate or not done:

   No artifact evaluation.
   No recommendations for failed items were given.
   No evaluation of the Technologist's QC tests:
   - No processor QC.
   - No analysis of fixer retention.

   No uniformity of screen speed.
   - Numerical results were not given.

   Title 21, Code of Federal Regulations, Part 900.12(e)(5) details the required annual quality control tests. Note: All mammography processors must be evaluated. All film cassettes must be evaluated for artifacts during the Screen Uniformity test.

3. Failure to produce documents verifying that the medical physicist, ~~~ ~~~ met the continuing experience requirement of having surveyed at least two mammography facilities and a total of at least six mammography units in 24 months.

   Title 21, Code of Federal Regulations, Part 900.12(a)(3)(iv)(B) details the physicist's continuing experience requirement. Note: Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing surveys 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 FDA taking regulatory action. 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, seeking

civil money penalties 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.

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 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,

Cheryl A. Bigham
Acting Director
Minneapolis District

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