



g1283d

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

May 22, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 61

John T. Beecher, M.D.
Chief Executive Officer
Edina Family Physicians
5301 Vernon Avenue South
Edina, Minnesota 55436

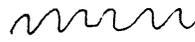
Dear Dr. Beecher:

On May 2, 2001, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your mammography facility (FDA Certificate #172874). 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 (MQSA), 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 was inadequate. The system in place did not provide written lay summaries to all patients regardless of their assessment category. Reportedly, your site was not sending lay summaries for mammography exams that were classified as "Incomplete—Need Additional Imaging Evaluation."

FDA acknowledges the May 3, 2001, letter from  R.T.(R)(M) of your staff. She indicated that beginning May 3, 2001, lay letters would be sent for all exams.

Page Two

John T. Beecher, M.D.
May 22, 2001

Note: If the results of the follow-up examination are available within 30 days of the initial examination, the facility has the option of combining the results into one lay summary (rather than providing two lay summaries). If one combined lay summary is provided, it must state specifically that it refers to both the initial and the follow-up examinations.

If the results of the follow-up examination are not available within 30 days of the initial examination, the facility must provide two lay summaries, one for the initial examination and one for the follow-up. Each must be provided within 30 days of the examination it covers.

Lay summaries are also required when the facility issues an "Addendum" or "Comparison" report.

Level 2 Non-Compliances:

2. A mammography equipment evaluation (by a medical physicist) was not done when a major component of either the mammography unit or processor equipment was changed or repaired (Unit 2 located in the mammography room).
3. The facility has not specified adequate written procedures for collecting and resolving mammography consumer complaints. The current general policy lacks specific elements required by MQSA regulation.

Note: Items 2 and 3 were not addressed in the May 3, 2001, letter from   referenced above.

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:

Page Three

John T. Beecher, M.D.
May 22, 2001

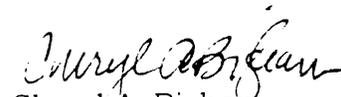
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample 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

TWG/ccl



xc: 
Lead Interpreting Radiologist
Edina Family Physicians
5301 Vernon Ave. So.
Edina, MN 55436

Sue McClanahan
Supervisor, Radiation Unit
Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, MN 55108-2970

Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, VA 20191