



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 27, 2001

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-49

JoEllen Callahan, Manager
Breast Care Screening Program
Group Health Cooperative-Eastside Hospital
2700 152nd Avenue, NE
Redmond, Washington 98052

WARNING LETTER

Dear Ms. Callahan:

We are writing to you because on April 11, 2001, a representative of the State of Washington, Bill Van Pelt, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. 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. The inspection revealed the following level 1 findings at your facility:

1. Processor QC records were missing at least 5 consecutive days for processor 0000000001, [REDACTED] Other, room Mam Dark1.
2. Processor QC records were missing at least 5 consecutive days for processor 0000000002, [REDACTED] Other, room Mam Dark2.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1, because they identify a failure to meet a significant MQSA requirement.

In addition, repeat level 2 findings were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

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1. Mammograms were processed in processor 0000000002, [REDACTED] Other, room Mam Dark2 when it was out of limits on at least 2, but less than 5 days.
2. Corrective actions for processor QC failures were not documented at least once for processor 0000000001, [REDACTED] Other, room Mam Dark1.
3. Corrective actions for processor QC failures were not documented at least once for processor 0000000002, [REDACTED] Other, room Mam Dark2.

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 fifteen (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 (Note: patient names or identification should be deleted from any copies submitted).*

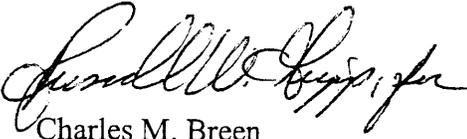
Please submit your response to U.S. Food and Drug Administration, Attention Thomas S. Piekarski, Compliance Officer, 22201 23rd Drive, SE, Bothell, Washington 98021-4421.

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.

JoEllen Callahan, Manager, Breast Care Screening Program
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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, Maryland 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

Sincerely,



Charles M. Breen
District Director

*This note is not applicable for letters that also address patient notification.

CC: Priscilla F. Butler, M.S.
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