



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

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

July 11, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-55

Paul Conklin, Director of Radiology  
St. Mary Medical Center  
401 West Poplar  
Diagnostic Imaging Department  
Walla Walla, Washington 99362

**WARNING LETTER**

Re: Inspection ID - 1398320008

Dear Mr. Conklin:

We are writing to you because on June 27, 2000, your facility was inspected by a representative of the State of Washington, acting in behalf of the Food and Drug Administration (FDA). 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:

Mammograms were processed in processor 0000000001, [REDACTED]  
[REDACTED] room darkroom, when it was out of limits on 6 days.

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.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a

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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, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Corrective actions for processor QC failures were not documented at least once for processor 0000000001, [REDACTED], room darkroom at site St. Mary Medical Center.
- Corrective action for a failing image score (before further exams) was not documented for unit 2, [REDACTED] OTH, room Mammo.
- The time period between the previous and current surveys for x-ray unit 2, [REDACTED] OTH, exceeds 14 months.
- The radiologic technologist did not meet the continuing education requirements of having completed a minimum of 15 CEUs in mammography in a 36 month period: [REDACTED] 10 CEUs in 36 months).
- Three of 5 random reports reviewed did not contain an assessment category at site St. Mary Medical Center.

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:

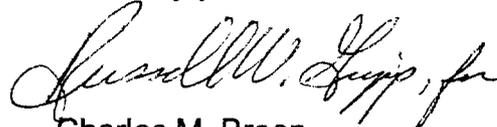
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample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

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Please submit your response to Thomas S. Piekarski, Compliance Officer, at the above mailing address.

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 (800-838-7715) or through the Internet at <http://www/fda.gov>.

Sincerely yours,



Charles M. Breen  
District Director

Copy: Kelly Cameron  
State of Washington  
2409 West Albany  
Kennewick, Washington 99336

Priscilla F. Butler, M.S.  
Director, Breast Imaging Accreditation Programs  
Standards and Accreditation Department  
American College of Radiology  
1891 Preston White Drive  
Reston, Virginia 20191