



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  
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November 20, 2000

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 01-06

Michelle Murray, M.D.  
Prosser Memorial Hospital  
Radiology Department  
723 Memorial Street  
Prosser, Washington 99350

Re: Inspection # 1819170006

WARNING LETTER

Dear Dr. Murray:

We are writing to you because on November 2, 2000, a representative of the State of Washington, Kelly Cameron, acting in 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 four level 1 findings at your facility:

1. Phantom QC records were missing for 7 weeks for unit 1, [REDACTED] room Mammo;
2. Processor QC records were missing 5 out of 8 days of operation in month 08/2000. Processor QC records missing 62%, for processor 0000000001, [REDACTED] room Mammo;
3. Processor QC records were missing 5 consecutive days for processor 0000000001, [REDACTED] room Mammo;
4. Mammograms were processed in processor 0000000001, [REDACTED] room Mammo when it was out of limits on 6 days.

Michelle Murray, M.D.  
Prosser Memorial Hospital, Prosser, Washington  
Re: Warning Letter SEA 01-06  
Page 2

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 one 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 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.

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 two Level 2 findings are:

1. Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit 1, [REDACTED] room Mammo;
2. Corrective actions for processor QC failures were not documented at least once for processor 0000000001, [REDACTED] room Mammo.

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 & Drug Administration, Attention Thomas S. Piekarski, Compliance Officer, 22201 23<sup>rd</sup> 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.

Michelle Murray, M.D.  
Prosser Memorial Hospital, Prosser, Washington  
Re: Warning Letter SEA 01-06  
Page 3

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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