



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

January 8, 2001

Reference: Warning Letter SEA 01-18

James Barnhart  
Peace Harbor Hospital  
400 Ninth Street  
Florence, Oregon 97439

Inspection ID: 1846630006

**WARNING LETTER**

Dear Mr. Barnhart:

We are writing to you because on December 11, 2000, a representative from the State of Oregon, Mr. Robert Rapcinski, 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 finding at your facility:

Phantom QC records were missing for 4 weeks for unit 1, [REDACTED] OTH, room MAMMO.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because it identifies 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.

James Barnhart  
Peace Harbor Hospital, Florence, Oregon  
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Two level 2 deficiencies were found during this inspection one of which was a repeat finding from a previous inspection. These level 2 findings were:

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] OTH, room MAMMO;
2. Five of 5 random reports reviewed did not contain an assessment category for site Peace Harbor Hospital. *This observation is a repeat finding.*

We received a letter dated December 19, 2000, from Mr. Thomas J. Pummer, Imaging Director. Mr. Pummer responded only to the above mentioned level 2 findings and a level 3 finding. His corrective actions appear acceptable for those noncompliance levels.

It is necessary for you to act on the level 1 finding immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

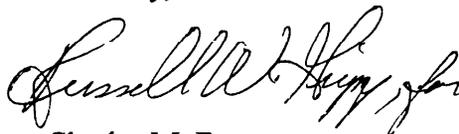
- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample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

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.