



DEPARTMENT OF HEALTH AND HUMAN SERVICES

92039d

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

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

December 13, 2001

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Reference: Warning Letter SEA 02-18
Inspection ID: 1317970007

Ms. Mary Savage, Regional Director of Diagnostic Imaging
Providence Milwaukie Hospital
10150 S.E. 32nd Avenue
Milwaukie, Oregon 97222

WARNING LETTER

Dear Ms. Savage:

We are writing to you because on December 6, 2001, your facility was inspected by J. Robert Rapcinski, a representative of the State of Oregon, acting on 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 (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. The inspection revealed the following level 1 findings at your facility:

1. Phantom QC records were missing for at least 4 weeks for unit 3, Lorad Medical Systems Inc., MIV, room 1.
2. Phantom QC records were missing for at least 4 weeks for unit 4, Lorad Medical Systems Inc., MIV, room 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 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 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 Level 2 findings are:

1. The facility does not have adequate procedures to be followed for infection control or either did not follow them when required. The written policies and procedures currently in place appear to address general cleaning but not disinfection. Additionally, the current procedure does not adhere to the instructions on the product used, "Hospit All III", which is to permit it to remain wet on the applied surface for at least ten minutes.
2. The facility does not have adequate written procedures for collecting and resolving consumer complaints or either did not follow them when required. The current procedures fail to include all the elements required by the MQSA. Specifically, the procedures do not indicate that the facility will maintain records of serious complaints for at least three years; and, indicate that the facility will notify its accrediting body concerning unresolved, serious complaints. Your procedure should include a definition of "serious complaint" (serious adverse event) as defined by the MQSA.

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 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.

Ms. Mary Savage, Regional Director of Diagnostic Imaging
Providence Milwaukie Hospital, Milwaukie, Oregon
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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,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

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

CC:

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

J. Robert Rapcinski
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