



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

1135631

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

## WARNING LETTER

**MAR 15 2000**

Certified Mail  
Return Receipt Requested

Rebecca Bittner, M.D.  
Peninsula Diagnostic Center  
1360 West 6<sup>th</sup> Street  
North Building 100  
San Pedro, CA 90732

**W/L 42-00**  
**Inspection ID: 1302940005**

Dear Dr. Bittner:

We are writing to you because on 12/15/1999, your facility was inspected by a representative of the state of California, 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 (MQSA) 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. **Phantom QC records were missing for 10 weeks for unit 1, Lorad Medical Systems Inc., D450, room Room 1**
2. **Phantom QC records were missing for 10 weeks for unit 2, Lorad Medical Systems Inc., MII, room Room 2**
3. **The system to communicate results is not adequate for site Peninsula Diagnostic Center because:**
  - **There is no system in place to provide timely lay summaries**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which your facility received 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 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 performing 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 x-ray system for unit 1, Lorad Medical Systems Inc., D450, room Room 1 does not include the following:**
  - **Image receptors for 2 sizes**
  - **Moving grids for 2 sizes**
- 2. There is no written procedure for handling consumer complaints at site Peninsula Diagnostic Center**
- 3. Corrective actions for processor QC failures were not documented at least once for processor 0000000001, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Daylight at site Peninsula Diagnostic Center**
- 4. Mammograms were processed in processor 0000000001, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Daylight at site Peninsula Diagnostic Center, when it was out of limits on 2 days**
- 5. 5 of 5 random reports reviewed did not contain an assessment category for site Peninsula Diagnostic Center**
- 6. There was no designated reviewing interpreting physician for site Peninsula Diagnostic Center**

It is necessary for you to act on this matter immediately. Please explain the following elements 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.
- 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**).\*

\*this note is not applicable for letters which also address patient notification.

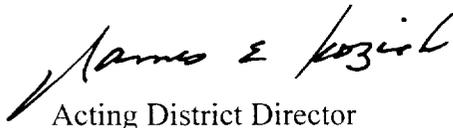
Please submit your response to:

Thomas L. Sawyer  
Director, Compliance Branch  
Food and Drug Administration  
19900 MacArthur Boulevard, Suite 300  
Irvine, CA 92612-2445

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 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/dmgrp.html> <<http://www.fda.gov/cdrh/dmgrp.html>>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas at (949) 798-7708 or Minh Phan at (949) 798-7711.

Sincerely yours,

  
Acting District Director