



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m39017

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

JUN 7 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WL-57-00

Inspection ID: 1969980005

Carlisle Grey, M.D.
Palo Verde Hospital
250 North First Street
P.O. Box Z
Blythe, CA 92225

Dear Dr. Grey:

We are writing to you because on 5/23/2000, your facility was inspected by a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA) and 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. Processor QC records were missing 7 out of 19 days of operation in month 10/1999. Processor QC records missing 37%, for processor 0000000001, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Mammo at site Palo Verde Hospital.
2. Phantom QC records were missing for 12 weeks for unit 1, Lorad Medical Systems Inc., MIII, room Mammography.
3. The interpreting physician did not meet the requirement of being certified by an FDA-recognized board or having the alternative of 2 months training in the interpretation of mammograms: [REDACTED]

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. **Processor QC records were missing 3 consecutive days for processor 0000000001, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Mammo at site Palo Verde Hospital.**
2. **The phantom QC is not adequate for unit 1, Lorad Medical Systems Inc., MIII, room Mammography because:**
 - **The operating level for background density was < 1.20.**
3. **The interpreting physician did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period):** [REDACTED]
4. **The interpreting physician did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period:** [REDACTED]
5. **The interpreting physician did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period:** [REDACTED]
6. **Not all positive mammograms were entered in the tracking system for site Palo Verde Hospital.**

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, 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**).*

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

Please submit your response to:

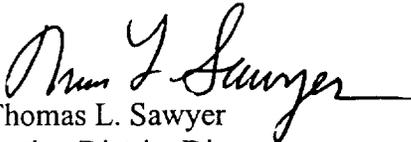
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

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>>.

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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,


Thomas L. Sawyer
Acting District Director

cc: California Department of Health Services
Radiologic Health Branch
1800 E. Lambert, Suite 125
Brea, CA 92821

Penny Butler, Director
Breast Imaging Accreditation
American College of Radiology
1891 Preston White Drive
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