



WARNING LETTER

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

APR 21 2000

Certified Mail
Return Receipt Requested

Edmee Miura, CRT
Mobile Breast Care Services
316 East Live Oak Street
San Gabriel, CA 91776

WL- 49-00
Inspection ID: 1909830004

Dear Ms. Miura:

We are writing to you because on 3/22/2000, 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 device 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 finding at your facility:

1. **The system to communicate results is not adequate for site Mobile Breast Care Services because:**
 - **There is no system in place to provide timely medical reports,**
 - **There is no system in place to provide timely lay summaries,**
 - **There is no system in place to communicate serious or highly suggestive cases ASAP.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received 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 this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents 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. The following Level-2 findings were disclosed.

- 2. There is no written procedure for handling consumer complaints at site Mobile Breast Care Services.**
- 3. There is no written procedure for infection control at site Mobile Breast Care Services.**
- 4. Not all positive mammograms were entered in the tracking system for site Mobile Breast Care Services.**
- 5. There were no examples of or nor attempts to get biopsy results for site Mobile Breast Care Services.**

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:

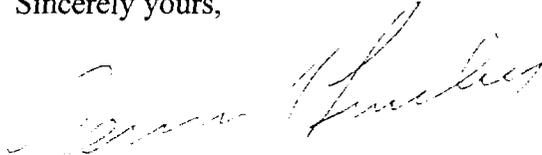
Thomas L. Sawyer, Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

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

cc: County of Los Angeles
Department of Health Services
Radiation Management
550 South Vermont Avenue, Room 600
Los Angeles, CA 90020

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American College of Radiology
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