



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1647d

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

**WARNING LETTER**

**Certified Mail**  
**Return Receipt Requested**

August 17, 2001

Lisa Marie Weiler, M.D.  
Radiologist  
University of California, Irvine Medical Center  
101 City Drive South; Rt. #146  
Orange, CA 92868

W/L Number: 72 - 01  
Inspection ID: 1445500008  
CFN: 2029727  
FEI: 1000519428

Dear Dr. Weiler:

We are writing to you because on August 8, 2001 your facility was inspected by a representative of the State of California acting in behalf of the U. S. 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 finding at your facility:

- Level 1: Phantom quality control (QC) records were missing for the weeks of October 30<sup>th</sup> and December 20<sup>th</sup> of the year 2000 and the weeks of January 1<sup>st</sup> and January 8<sup>th</sup> of the year 2001 for unit #3 (a [REDACTED] machine, model [REDACTED], serial number [REDACTED]) which is located in room PV-1.

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, it represents 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, MQSA 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 **repeated** Level 2, Level 2, and **repeated** Level 3 findings that were listed on the inspection report provided to you at the close of the inspection. These **repeated** Level 2, Level 2, and **repeated** Level 3 findings are:

- Level 2: 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 #3 (a [REDACTED] machine, model [REDACTED], serial number [REDACTED]) which is located in room PV-1. This is a **REPEAT** violation.

- Level 2: 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 #4 (a [REDACTED] machine, model [REDACTED], serial number [REDACTED]) which is located in room BR - 2. This is a **REPEAT** violation.

-- Level 2: 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 #5 (a [REDACTED] machine, model [REDACTED], serial number [REDACTED]) which is located in room BC - 1. This is a **REPEAT** violation.

- Level 2: 1 of 9 random reports reviewed did not contain an acceptable assessment category.

- Level 2: Mammograms were processed in processor #2 (a [REDACTED] machine, model [REDACTED]), which is located in room BC, when it was out of limits on July 25<sup>th</sup> and July 28<sup>th</sup> of the year 2000.

- Level 2: There were no examples of, nor attempts, to get biopsy results.

- Level 2: Medical audit and outcome analysis was not done separately for each individual.

- Level 2: Medical audit and outcome analysis was not done for the facility as a whole.

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- Level 2: Medical audit and outcome analysis was not performed annually.
- Level 2: Corrective actions for processor QC failures were not documented at least once for processor #2 (a [REDACTED] machine, model [REDACTED] which is located in room BC.
- Level 2: Mammograms were processed in processor #1 (a [REDACTED] machine, model [REDACTED]), which is located in the darkroom, when it was out of limits on at least 2 but less than 5 days.
- Level 3: The quality assurance (QA) program is inadequate due to missing or incomplete items in the current technique tables/charts. This is a **REPEAT** violation.
- Level 3: The fixer retention QC is not adequate for processor #2 (a [REDACTED] machine, model [REDACTED]) because the fixer retention QC tests were not done at the required frequency. This is a **REPEAT** violation.

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;
- in reference to the repeated violations, address why weren't these problems corrected after your previous inspection in the year 2000; who was responsible (by name and title for having the responsibility, authority, and capability) of correcting these previous violations and, apparently, failed to do so.
- 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
- please provide 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).

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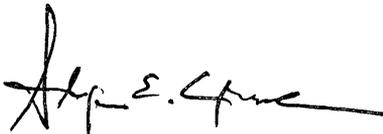
Please submit your response to:

Thomas L. Sawyer  
Director, Compliance Branch  
U.S. Food & Drug Administration  
19900 MacArthur Blvd.; Suite #300  
Irvine, CA 92612-2445  
Phone: (949) 798-7600

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

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

Sincerely,



Alonza E. Cruse  
District Director

cc:

Priscilla F. Butler  
Director, Breast Imaging Accreditation Programs  
Standards and Accreditation Department  
American College of Radiology  
1891 Preston White Drive  
Reston, Virginia 20191