



g198/d

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (714) 798-7600

## WARNING LETTER

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

November 19, 2001

Judy C. Dean, M.D.  
Radiologist  
2428 Castillo Street, Suite B  
Santa Barbara, CA 93105-4349

W/L Number: 14 - 02  
Inspection ID: 2212120003  
CFN: 20-32,170  
FEI: 3003146922

Dear Dr. Dean:

We are writing to you because on October 24, 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 records were missing for the weeks of August 28<sup>th</sup>, October 23<sup>rd</sup>, December 18<sup>th</sup>, of the year 2000 plus February 19<sup>th</sup> and August 8<sup>th</sup> of the year 2001 for unit #2 (an [REDACTED] machine, model [REDACTED], serial number [REDACTED]) which is located in mammography room #2.

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 this condition 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

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Plan of Correction (DPC), 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.

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; 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).

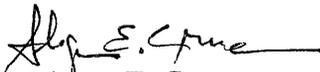
Please submit your response to:

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: 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 Scott Goff (the Compliance Officer assigned to this case) at telephone number 949-798-7644.

Sincerely,

  
Alonza E. Cruse  
District Director

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re: W/L Number 14 - 02

cc:

State of California  
Department of Health Services  
Radiological Health Branch  
10605 Balboa Blvd.; Suite #315  
Granada Hills, CA 91344-6342