



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m4939 n

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

WARNING LETTER

Certified Mail
Return Receipt Requested

November 13, 2000

Ms Pat Wolfram, Chief Executive Officer
San Clemente Hospital
(fka: Samaritan Medical Center)
654 Camino De Los Mares
San Clemente, CA 92673

W/L #01-01

Inspection ID #1639070007
CFN: 20-29,850
FEI #: 1000519005

Dear Ms Wolfram,

We are writing to you because on October 13, 2000, 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 problems 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 findings at your facility:

- Level 1: Phantom QC records were missing for 12 weeks for unit #2 located in the Mammo Room.
- Level 1: Processor QC records were missing 6 out of 18 days of operation (33%) in the month February 2000 for processor #1 (a [REDACTED] machine, model [REDACTED]) located in the darkroom.
- Level 1: The interpreting physician, [REDACTED], 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.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent 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 Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: There is no written procedure for infection control.
- Level 2: 3 of 5 random reports reviewed did not contain an assessment category.
- Level 2: The interpreting physician, [REDACTED], did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.
- Level 2: The interpreting physician, [REDACTED], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period.
- Level 2: The interpreting physician, [REDACTED], did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.
- Level 2: The interpreting physician, [REDACTED], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period.
- Level 2: The radiologic technologist, [REDACTED], did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36 month period. She had zero CEU's in 36 months.
- Level 2: The radiologic technologist, [REDACTED], did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36 month period. She had 7 CEU's in 36 months.
- Level 2: The radiologic technologist, [REDACTED], did not meet the continuing education requirement of having completed a minimum of 15 CEUs in mammography in a 36 month period. She had 13 CEU's in 36 months.
- Level 2: The interpreting physician, [REDACTED], did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period).
- Level 2: The interpreting physician, [REDACTED], did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.
- Level 2: The interpreting physician, [REDACTED], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period.
- Level 2: The interpreting physician, [REDACTED], did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period).
- Level 2: The interpreting physician, [REDACTED], did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36 month period. He had 12 CME's in 36 months.

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re: San Clemente Hospital
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- Level 2: The interpreting physician, [REDACTED], did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period).
- Level 2: There were no examples of nor attempts to get biopsy results.
- Level 2: There is no written procedure for handling consumer complaints.

The Agency acknowledges receipt of your letter (dated October 26, 2000) explaining your responses to the inspection of October 13, 2000. We will review said letter and determine if the responses are adequate based upon the following elements:

- the specific steps you have taken to correct all of the violations noted in this Warning Letter;
- each step your facility is taking to prevent the recurrence of similar violations; 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).

If you feel that your letter did not address all of the above shown elements, please feel free to submit additional information and/or documents to support your responses.

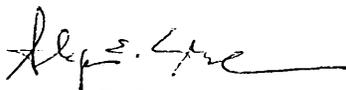
Any additional responses should be submitted to:

Mr. 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 (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 [REDACTED] (MQSA Auditor) at telephone number (949) 798-[REDACTED]

Sincerely,



Alonza E. Cruse
District Director