



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M32260

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

via Federal Express

November 29, 1999

MQSA Facility ID: 135244
Inspection ID: 1352440005
FDA Reference #: 2951813

Tom Hart
Vice President
Santa Cruz Medical Clinic
2025 Soquel Avenue
Santa Cruz, California 95062

Dear Tom Hart:

We are writing to you because on October 14, 1999, your facility was inspected by a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious problems involving the mammography procedures performed 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 and level 2 findings at your facility, which represent departures from Title 21, Code of Federal Regulations (CFR), Part 900.

Level 1: Phantom quality control records were missing for seven weeks for unit 3, [REDACTED], located in Mammography Room 1. {21CFR§900.12(e)(2)}

Level 2: The radiologic technologist, [REDACTED] did not meet the continuing education requirement of having completed a minimum of fifteen Continuing Education Units (CEUs) in mammography in a thirty-six month period. {21CFR§900.12(a)(2)(iii)(A)}

Level 2: One out of five random reports reviewed did not contain an assessment category. {21CFR§900.12(c)(1)(iv)}

Level 2: Not all positive mammograms were entered in the tracking system.
{21CFR§900.12(f)(1)}

Additionally, the inspection revealed the following level 3 finding at your facility:

Level 3: The chest wall edge of the compression paddle is visible on the test image for unit 2, [REDACTED] located in Mammography Room 2. {21CFR§900.12(b)(8)(ii)(E)}

The specific problems noted above appeared on your initial MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and represent serious violations 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, the 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 or plan to take 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).

Please submit your response to:

John M. Doucette, MQSA Inspector/Program Monitor
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, California 94502-7070
510-337-6793 (tel)
510-337-6702 (fax)

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 Mr. John M. Doucette at 510-337-6793.

Sincerely yours,

Patricia C. Ziobro
Patricia C. Ziobro
Director
San Francisco District

cc:

Bonnie Bessemer, MQSA Inspection Program Monitor
Raisa Beezley, MQSA Inspector (2208)
Pamela A. Wilcox-Buchalla, R.N., M.B.A.