



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

m4921n

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

**WARNING LETTER**

November 27, 2000

via Federal Express

FDA Reference #: 2954124

MQSA Facility ID: 212068  
Inspection ID: 2120680005

Mike Steman  
Sutter North Medical Foundation  
480 Plumas Blvd.  
Yuba City, CA 95991

Dear Mike Steman:

We are writing to you because on September 20, 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 at your facility.

Under a United States Federal law, the Mammography Quality Standards Act 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 findings at your facility:

- Level 1: Phantom QC records were missing for 4 weeks for unit 1, [REDACTED], room Mammography
- Level 1: The interpreting physician 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: [REDACTED]

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 a significant MQSA requirement.

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: The interpreting physician did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography: [REDACTED]
- Level 2: The interpreting physician did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period): [REDACTED]

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;
- 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:

Russell A. Campbell, Compliance Officer  
San Francisco District  
U. S. Food and Drug Administration  
1431 Harbor Bay Parkway  
Alameda, CA 94502

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 Russell A. Campbell, Compliance Officer, at 510-337-6861.

Sincerely yours,



Roger L. Lowell  
Acting District Director