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San Francisco District  
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Telephone: 510/337-6700

## WARNING LETTER

November 27, 2000

via Federal Express

MQSA Facility ID: 122408

Inspection ID: 1224080006

FDA Reference #: 2951754

Mike Stemen  
Sutter North Medical Foundation  
800 Third Street  
Marysville, CA 95901

Dear Mike Stemen:

We are writing to you because on June 13, 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 finding at your facility:

- Level 1: Mammograms were processed in processor 1, Kodak, Other, room MAMMO at site Sutter North Medical Foundation, when it was out of limits on 5 days

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 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

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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, the inspection revealed the following Level 2 finding that was listed on the inspection report provided to you at the close of the inspection:

- Level 2: Corrective action for a failing image score (before further exams) was not documented for unit 3, room Mammo

We acknowledge receipt of your letter dated August 10, 2000. Your response appears to adequately address the Level 1 and Level 2 findings discussed above. Your corrective actions will be verified during the next inspection.

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