DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administratio

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

WARNING LETTER

July 29, 2003

VIA FEDEX

Re: MQSA Inspection ID # 2249070002

Mr. Brian Bidwell
Director of Diagnostic Imaging Services
Sutter Warrack Hospital
2449 Summerfield Road
Santa Rosa, CA 95405

Dear Mr. Bidwell:

On May 28, 2003, a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. This inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA") which is codified in Section 263b of Title 42 of the United States Code (USC), your facility must meet specific requirements to practice mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed the following violations of the MQSA at your facility:

Level 1 (Repeat): Phantom QC records were missing for at least 4 weeks for unit 1, [redacted], room Mammography Room. Specifically, the phantom QC records were missing from May 2, 2002, through November 10, 2002. The previous inspection conducted April 30, 2002 found the Phantom QC records were missing for at least two weeks, but less than four weeks for unit 1, [redacted], room Mammography Room. See 21 CFR 900.12(e)(2).

Level 2: Medical audit and outcome analysis was not performed annually, as required by 21 CFR 900.12(f)(2). Specifically, the last medical audit and outcome analysis was performed April 18, 2002.

Level 2: Processor QC records in the month of July, 2002 were missing for at least 10% but less than 30% of operating days, for processor [redacted]

[redacted], room DARKROOM. See 21 CFR 900.12(e)(1).

Level 3 (Repeat): The fixer retention QC is not adequate for processor [redacted]. Specifically, the fixer retention QC tests were not done at the required frequency. See 21 CFR 900.12(e)(3).

On July 10, 2003, we received your response to the MQSA Facility Inspection Report. Your response describes measures that, if implemented, appear adequate to address these violations. FDA will need to perform a Compliance Follow-up Inspection to verify that the corrective actions described in your response have been taken.

A continued failure to resolve these violations could be indicative of serious underlying problems that could compromise the quality of mammography at your facility. Consequently, if these violations are not resolved, FDA may take additional actions, including, but not limited to, the following:

- Requiring your facility to undergo an Additional Mammography Review
- Placing your facility under a Directed Plan of Correction
- Charging your facility for the cost of on-site monitoring
- Seeking 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
- Seeking to suspend or revoke your facility's FDA certificate

FDA may also take the following actions with respect to unresolved MQSA violations, depending on the circumstances:

- Requiring a facility to notify patients who received mammograms at your facility, and their referring physicians, of the deficiencies, the potential harm resulting from such deficiencies, appropriate remedial measures, and other relevant information
- Seeking a court injunction against a facility

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to violations related to the two most recent MQSA inspections of your facility 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/cdrh/mammography/index.html.

If you have additional or more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Russell A. Campbell at (510) 337-6861.

Sincerely yours,

Dennis K. Linsley
District Director

cc:

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