DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
9-42859
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER

August 25, 2003

VIA FEDEX

Re: MQSA Inspection ID # 2019880008

Robert Filpi, M.D.
Medical Director
Community Hospital & Rehabilitation Center of Los Gatos
815 Pollard Road
Los Gatos, CA 95032

Dear Dr. Filpi:

On June 23, 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: The system to communicate results is not adequate for site Community Hospital & Rehabilitation Center of Los Gatos because:

- There is no system in place to provide timely medical reports. [21 CFR 900.12(c)]
- There is no system in place to provide timely lay summaries. [21 CFR 900.12(c)(2)]
- There is no system in place to communicate serious or highly suggestive cases as soon as possible. [21 CFR 900.12(c)(2) and 900.12(c)(3)(ii)]

Level 1: Phantom QC records were missing for at least 4 weeks for unit 3, [redacted] room Mammography Room. For example: Phantom QC records were missing for the weeks of 3/24/2003, 3/31/2003, 4/7/2003, 4/14/2003, and 4/21/2003. [21 CFR 900.12(c)(2) and 21

CFR 900.12(d)(2)]

Level 1: Processor QC records in the month of October 2002 were missing for at least 30% of operating days, for processor [redacted] room Darkroom at site Community Hospital & Rehabilitation Center of Los Gatos. [21 CFR 900.12(e)(1) and 21 CFR 900.12(d)(2)]

Level 1: Processor QC records were missing at least 5 consecutive days for processor [redacted] room Darkroom at site Community Hospital & Rehabilitation Center of Los Gatos. For example: Processor QC records were missing from February 10 through 17, 2003. [21 CFR 900.12(e)(1) and 21 CFR 900.12(d)(2)]

Level 1: Mammograms were processed in processor [redacted] room Darkroom at site Community Hospital & Rehabilitation Center of Los Gatos, when it was out of limits on at least 5 days. For example the mid-density was out of limits from January 27, 2003 through January 31, 2003. [21 CFR 900.12(e)(1)]

Level 2 (Repeat): Medical audit and outcome analysis was not done separately for each individual at site Community Hospital & Rehabilitation Center of Los Gatos. [21 CFR 900.12(f)(1)]

Level 2: Failed to produce documents verifying that the radiologic technologist [redacted] met the continuing experience requirement of having performed 200 mammography examinations. [21 CFR 900.12(a)(2)(iv) and 21 CFR 900.12(d)(2)]

Level 2: Failed to produce documents verifying that the radiologic technologist [redacted] (9 CEU's in 36 months) met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in 36 months. [21 CFR 900.12(a)(2)(iii) and 21 CFR 900.12(d)(2)]

Level 2: Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit [redacted], room Mammography Room. [21 CFR 900.12(e)(8)(ii)]

These violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility. FDA may take additional actions, which may include, but are 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; and
- Seeking a court injunction enjoining further mammography.

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

Please explain to this office in writing, within fifteen (15) working days after receiving this letter:

1. The specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;
2. The specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementing those steps; and
3. Sample records that demonstrate proper record keeping procedures. (Note: Patient names or identification should be deleted from any copies submitted.)

The other items identified as Level 3 Noncompliance on the facility inspection report from June 23, 2003, should also be corrected.

If your facility is unable to complete corrective action with 15 working days, you should state the reason for the delay and provide a timeframe within which corrections will be completed. Please submit your response to this letter to:

Russell A. Campbell, Compliance Officer
United States Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

Finally, you should understand that there are many requirements pertaining to mammography. This pertains only to violations related to the recent inspection 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