DEPARTMENT OF HEALTH & HUMAN SERVICES

94942d

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

WARNING LETTER

August 27, 2004

VIA FEDEX

Re: MQSA Inspection ID # 1457630010

Raju Thiara, Technical Manager
Washington Township Hospital
2000 Mowry Avenue
Fremont, CA 94538

Dear Raju Thiara,

On June 28, 2004, a representative of the State of California, acting in 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 for 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: Processor QC records in the month of 08/2003 were missing for 80% of the operating days, for processor [redacted], at site Washington Township Hospital. [21 CFR 900.12(e)(1)(i),(ii),(iii)]

Level 1: Processor QC records were missing for 25 consecutive days for processor [redacted] room Hospital at site: Washington Township Hospital. [21 CFR 900.12(e)(1)(i),(ii),(iii)]

Level 2: Processor QC records in the month of 07/2003 were missing for 18 % of the operating days, for processor [redacted] Outpatient Clinic at site: Washington Township Hospital. [21 CFR 900.12(e)(1)(i),(ii),(iii)]

Level 2: Processor QC records were missing for 3 consecutive days for processor [redacted] Outpatient Clinic at site: Washington Township Hospital. [21 CFR 900.12(e)(1)(i),(ii),(iii)]

Level 2 (REPEAT): Mammograms were processed in processor [redacted] Outpatient Clinic at site: Washington Township Hospital, when it was out of limits on 4 days. [21 CFR 900.12(e)(1)(i),(ii),(iii)]

Level 2 (REPEAT): Corrective actions for processor QC failures were not documented at least once for processor [redacted] Outpatient Clinic at site: Washington Township Hospital. [21 CFR 900.12(e)(1)(i),(ii),(iii)]

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 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 compliance for the level 2 non-compliances listed, if the

findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

If your facility is unable to complete corrective action within 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:

Don A. Leeseberg, Jr., Radiological Health Specialist
United States Food & Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502

Finally, you should understand that there are many requirements pertaining to mammography. This letter pertains only to non-compliances 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 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 more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Don A. Leeseberg, Jr., Radiological Health Specialist at 510-337-6877.

Sincerely yours,

Barbara J. Cassens
District Director

cc:

Mr. Ed Gloor, MQSA Inspections Monitor
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