DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93672d

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

WARNING LETTER

November 6, 2002

Via Federal Express

MQSA Facility ID: 142794
CFN: 2951859

Inspection ID: 1427940009

John Ellis, Radiology Manager
Kaiser Permanente Hayward Medical Center
27400 Hesperian Boulevard
Hayward, CA 94545

Dear Mr. Ellis:

We are writing to you because on October 3, 2002, 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 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 repeat Level 2 violations at your facility:

1. 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 1, [redacted] room Mammography Room, as required by 21 CFR 900.12(e)(8)(ii)(A). For example: The density difference was out of specification on June 18, 2002, August 21 and 28, 2002 and September 4, 2002. In addition, the Spec. Groups fell below specification on October 3, 2001. There is no documentation that corrective actions were taken prior to performing exams.

2. Processor QC records were missing at least 2, but less than 5, consecutive days for processor 1, [redacted], room Process #4 at site Kaiser Permanente Hayward Medical Center. You are required to maintain

Quality Control records under 21 CFR 900.12(d)(2). Processor QC records were missing for April 10, 11, and 12, 2002.

A non-compliance is annotated as "REPEAT" if it was cited during the prior inspection.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

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 against 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, you should address these Level 2 findings that were listed on the inspection report provided to you at the close of the inspection:

1. Processor QC records in the month of April, 2002 were missing for at least 10% but less than 30% of operating days, for processor 1, [redacted], room Process #4 at site Kaiser Permanente Hayward Medical Center4. You are required to maintain Quality Control records under 21 CFR 900.12(d)(2). Our review of the records found that processor QC records were missing for 4 out of the 22 days (18.2%) that mammography was performed. Specifically, the records are missing for April 10, 11, 12, and 29, 2002.

2. You failed to maintain documents, as required by 21 CFR 900.12(a)(4), verifying that the radiologic technologist [redacted] (11 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, as required by 21 CFR 900.12(a)(2)(iii).

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).

Please submit your response to:

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

Sincerely yours,

Dennis K. Linsley
District Director