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

**WARNING LETTER**

September 29, 2000

via Federal Express

MQSA Facility ID: 190587  
Inspection ID: 1905870007  
FDA Reference #: 2952123

Patricia Carpenter  
Kaiser Permanente - Mountain View  
555 Castro Street  
Mountain View, CA 94041

Dear Patricia Carpenter:

We are writing to you because on 06/21/2000, 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 [REDACTED], room Darkroom at site Kaiser Permanente - Mountain View, when it was out of limits on 8 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, they represent 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

Letter to Patricia Carpenter  
Page 2

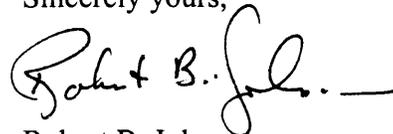
Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

We acknowledge receipt of your letter dated August 25, 2000. Your response appears to adequately address the Level 1 finding 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 at (510) 337-6861.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert B. Johnson", followed by a horizontal line.

Robert B. Johnson  
Acting District Director