



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

WARNING LETTER

September 6, 2001

Via Federal Express

Our Reference: 2952023

MQSA Facility ID: 174813  
Inspection ID: 1478130009

E. James McLaughlin, M.D.  
Medical Director Radiology  
Sierra Kings District Hospital  
Radiology Department  
372 W. Cypress Avenue  
Reedley, CA 93654

Dear Dr. McLaughlin:

We are writing to you because on August 20, 2001, 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:

- Phantom QC records were missing for 5 weeks for unit 1, [REDACTED] room mammography.

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, it represents 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 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, your corrective actions should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 finding is:

- 1 of 6 random reports reviewed did not contain an assessment category for site Sierra Kings District Hospital.

We acknowledge receipt of Joe Torres', R.T. Supervisor, letter dated August 29, 2001 responding to the Level 1 and Level 2 findings discussed above. Mr. Torres' response appears to adequately address both the Level 1 and Level 2 findings. 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, Compliance Officer, at 510-337-6861.

Sincerely yours,

  
Dennis K. Linsley  
District Director