



DEPARTMENT OF HEALTH & HUMAN SERVICES

m4197n

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

**WARNING LETTER**

September 14, 2000

via Federal Express 4165 0459 5702

MQSA Facility ID: 180299  
Inspection ID: 1802990013  
FDA Reference #: 2952048

Lana Smallwood  
Fairmount Hospital  
Radiology Department  
15400 Foothill Blvd.  
San Leandro, CA 94578

Dear Lana Smallwood:

We are writing to you because on 05/03/2000, your facility was inspected by a representative of the State of CA, 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 significant MQSA requirements.

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, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, the inspection revealed the following Level 2 findings that were listed on the inspection report provided to you at the close of the inspection:

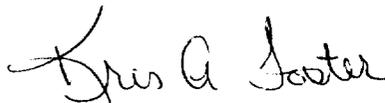
- Processor QC records were missing 2 out of 20 days of operation in month 12/1999. Processor QC records missing 10%, for processor 1, [REDACTED] room General at site Fairmount Hospital
- Processor QC records were missing 2 consecutive days for processor 1, [REDACTED] room General at site Fairmount Hospital

We acknowledge receipt of your letter dated May 11, 2000. Your response appears to adequately address the Level 1 and Level 2 findings 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,



Kris A. Foster  
Acting District Director