



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 28, 2001

Via FEDEX

MQSA Facility ID: 183442  
Inspection ID: 1834420005

FDA Reference #: 2952068

Walter C. Perez, President  
Doctors' Clinic Imaging Center  
851 Gov. Charles Camacho Rd.  
Tamuning, GU 96911

Dear Walter C. Perez,

We are writing to you because on August 7, 2001, your facility was inspected by a representative 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:

1. The system to communicate results is not adequate for site Doctors' Clinic Imaging Center because:
  - There is no system in place to provide timely medical reports;
  - there is no system in place to provide timely lay summaries; and
  - there is no system in place to communicate serious or highly suggestive cases as soon as possible.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. These problems are identified as Level 1, because they identify a failure to meet a significant MQSA requirement.

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 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 response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

1. Failed to produce documents verifying that the interpreting physician [REDACTED] met the initial requirement of having 40 hours of medical education in mammography prior to 4/28/99.
2. Failed to produce documents verifying that the interpreting physician [REDACTED] met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months.
3. Failed to produce documents verifying that the interpreting physician [REDACTED] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.
4. Failed to produce documents verifying that the interpreting physician [REDACTED] (0 CME's in 36 months) met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months.
5. Failed to produce documents verifying that the interpreting physician [REDACTED] met the initial requirement of having 40 hours of medical education in mammography prior to 4/28/99.
6. Failed to produce documents verifying that the interpreting physician [REDACTED] met the initial experience requirement of having interpreted or multi-read 240 mammograms in 6 months.
7. Failed to produce documents verifying that the interpreting physician [REDACTED] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.

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).\*

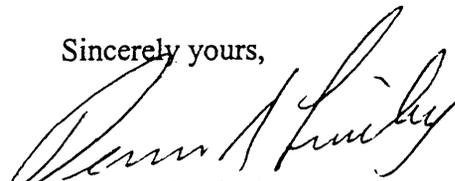
Please submit your response to:

Russell A. Campbell, Compliance Officer  
San Francisco District  
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/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 Russell A. Campbell at 510-337-6861.

Sincerely yours,



Dennis K. Linsley  
District Director

\*This note is not applicable for letters which also address patient notification.