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

WARNING LETTER

February 17, 2000

via Federal Express

MQSA Facility ID: 126102
Inspection ID: 1261020006
FDA Reference #: 2951771

Harry C. Claybough, III, M.D.
Chief Radiologist
Modesto Imaging Center, Inc.
157 East Coolidge Avenue
Modesto, California 95350

Dear Dr. Claybough:

We are writing to you because on January 25, 2000, your facility was inspected by a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious problem involving the mammography procedures performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), 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 and level 2 findings at your facility, which represent departures from Title 21, Code of Federal Regulations (CFR), Part 900.

Level 1: Phantom quality control records were missing for four weeks of operation in month November 1999 for units one and two, [REDACTED] ([REDACTED]), located in Mammo Room 1 and [REDACTED], located in Mammo Room 2, respectively. {21CFR§900.12(e)(2)}

Level 2: The interpreting physician, [REDACTED] did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a twenty-four month period. {21CFR§900.12(a)(1)(ii)(A)}

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

These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and they represent serious violations 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.

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:

John M. Doucette, MQSA Inspector/Program Monitor
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, California 94502-7070
510-337-6793 (tel) / 510-337-6702 (fax)

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 Mr. John M. Doucette at 510-337-6793.

Sincerely yours,



Darrell T. Lee
Acting Director
San Francisco District