



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m2170n

CERTIFIED MAIL RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

October 9, 1998

WL-3-9

Ms. Nelquian Woods
Office Manager
Levin CGR Mobil Mammogram
231 S. Vernon, Suite 111
Los Angeles, California 90037

Inspection ID: 1963860001

Dear Ms. Woods:

We are writing you because on July 29, 1998, your facility was inspected by a representative of the Los County Health Department, acting on 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 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 and investigation revealed the following Level 1 findings at your facility:

1. Records indicate that there was no medical physicist survey done for the x-ray system: [REDACTED] Mammo.
[Note: This citation is when the medical health physicist survey report is not present, or if the frequency of the surveys exceed a foruteen month time period. The Performace Standards for Mammography state a medical health survey will be done annually.]

The specific deficiency 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 represent a 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 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.

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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 and investigation. These Level 2 findings are:

2. The medical physicist did not meet the continuing education requirement of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year): [REDACTED]
3. The radiologic technologist did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year): [REDACTED]

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:

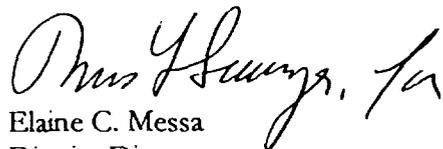
Robert W. Nicol
Compliance Officer
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

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>.

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If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Robert W. Nicol at (949) 798-7667

Sincerely yours,



Elaine C. Messa
District Director

cc: Ms. Joji Ortego, MQSA Inspector
County of Los Angeles
Department of Health Services
Radiation Management
550 South Vermont Avenue, Room 600
Los Angeles, CA 90020