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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

19900 MacArthur Blvd., Ste 300
Irvine, California 92715-2445
Telephone (714) 798-7600

WARNING LETTER

Nov 4, 1997

WL-3-8

Ms. Alicia Brow
Director of Operations
California Breastcare Centers - Mobile
3540 Wilshire Boulevard, Suite 701
Los Angeles, California 90010

Inspection ID: 186437

Dear Ms. Brow:

Your facility was inspected on September 22, 1997, by a California State representative from Los Angeles County, Department of Health Services, Radiation Management, under contract to the Food and Drug Administration (FDA). The inspection, as stated above, revealed that your facility failed to comply with the Quality Standards for Mammography (Standards), as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

1. The number of masses scored in the phantom image was 1.5 and did not meet the requirement number. The minimum number required for masses is 3: LORAD MEDICAL SYSTEMS, INC. TRANSP0 350; Mobile.

The specific deficiency noted above is a Level 1 noncompliance. In addition, your response should address the Level 2 noncompliance that is listed on the inspection report provided to you at the close of the inspection. The Level 2 noncompliance is:

2. The number of specs groups scored in the phantom image was 2.0 and did not meet the required number. The minimum number required for speck groups is 3: LORAD MEDICAL SYSTEMS, INC. TRANSP0 350; Mobile.

The specific deficiencies noted above appeared under the specific headings on your Mammography Quality Standards Act (MQSA) Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility. Be advised that these phantom deficiencies are of a category that may require a reinspection whose costs will be the responsibility of your facility.

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It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. These requirements should be evaluated when you plan your corrective action(s). Therefore, you should consider the more stringent State requirements, if any.

Within 15 working days of receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to correct all the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (include technique factors), raw test data, and calculated final results, where appropriate; and
- example records that demonstrate proper recordkeeping procedures, if the noncompliances were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

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Please send the original of your response to:

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

Also, send a copy to the California State radiation control office (Los Angeles County, Department of Health Services, Radiation Management) that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response. If you have any questions in regards to this letter, Compliance Officer Nicol can be reached at (714) 798-7668.

Sincerely yours,



Elaine C. Messa
District Director

cc: Mrs. Jeanne Crosby, MQSA Supervisor
County of Los Angeles
Department of Health Services
Radiation Management
550 South Vermont Avenue, Room 601
Los Angeles, CA 90020