



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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HFI-35

6/19/97  
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**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

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

**WARNING LETTER**

May 14, 1997

WL-23-7

Raymond Berke, MD  
Medical Director  
Anaheim Memorial Hospital  
1111 West La Palma Avenue  
Anaheim, California 92801

Inspection ID: 101014

Dear Dr. Berke:

Your facility was inspected on May 2, 1997, by a California State representative from Orange County Health Care Agency, Environmental Health Division, Public Health 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 interpreting physician is unqualified to interpret mammograms due to the lack of both board certification from any of the approved boards and two months full-time training in the interpretation of mammograms: [REDACTED]

The specific deficiency noted above appeared under the Level 1 heading on your Mammography Quality Standards Act (MQSA) Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

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 the violation noted in this letter; and
- each step your facility is taking to prevent the recurrence of similar violations;

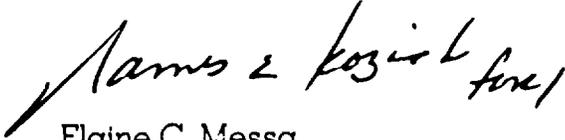
Please send the original of your response to:

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

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Also, send a copy to the California State Radiation Control Office (Orange County Health Care Agency, Environmental Health Division, Public Health) that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

Sincerely yours,

A handwritten signature in black ink that reads "Elaine C. Messa". The signature is written in a cursive style with a large initial 'E' and a long horizontal stroke extending to the right.

Elaine C. Messa  
District Director

cc: Ms. Beverly Thomas, MQSA Inspector  
Orange County Health Care Agency  
Public Health  
2009 E. Edinger Avenue  
Santa Ana, CA 92705