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12/23/97

Public Health Service
Food and Drug Administration

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

December 11, 1997

WL-11-8

Dr. Terry S. Becker, M.D.
Radiologist
Madison Radiology
65 North Madison Avenue-LL
Pasadena, California 91101

Inspection ID: 130120

Dear Dr. Becker:

Your facility was inspected on October 30, 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. Records indicate that there was no medical physicist survey done for the x-ray system: LORAD MEDICAL SYSTEMS, INC. OTHER; room 1.
2. Records indicate that there was no medical physicist survey done for the x-ray system: LORAD MEDICAL SYSTEMS, INC. OTHER; room 2.

It was noted during the inspection that medical health surveys have been conducted on these units, however they have exceeded fourteen months apart. The section of the MQSA regulations that addresses equipment surveys, 21 CFR 900.12 (d)(5) states in part, "****Such surveys shall be performed at least annually ****". FDA is requesting your written assurance that these surveys will be performed annually.

The specific deficiencies 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. These deficiencies 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 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).

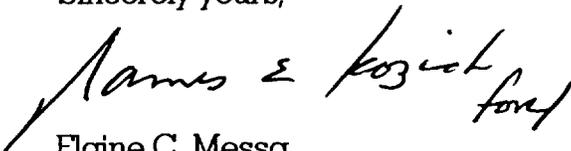
Dr. Becker/Page 3

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.

Sincerely yours,

A handwritten signature in cursive script that reads "Elaine C. Messa" with a flourish at the end.

Elaine C. Messa
District Director

cc: Mrs. Michelle Whitney, MQSA Inspector
County of Los Angeles
Department of Health Services
Radiation Management
550 South Vermont Avenue, Room 600
Los Angeles, CA 90020