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**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (714) 798-7600

**WARNING LETTER**

December 2, 1997

WL-08-8

Dr. Anthony Disher, MD  
Radiologist  
KingDrew Medical Center  
12021 S. Wilmington Avenue  
Los Angeles, California 90059

Inspection ID: 1194950004

Dear Dr. Disher:

Your facility was inspected on October 27, 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: SIEMENS MEDICAL SYSTEMS MAMMOMAT 2; Mammo.

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 was noted during the inspection that medical health surveys have been conducted on this unit, however they are approximately nineteen 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.

In addition, at the close of the inspection there were two instances of "Documentation Pending". These were printed out and given to you as part of the inspection report.

2. Interpreting physician's board certificate: [REDACTED]
3. Interpreting physician's license to practice medicine: [REDACTED]

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.

Dr. Disher/Page 2

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;
- example records that demonstrate proper record keeping 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).

Please send the original of your response to:

Robert W. Nicol  
Compliance Officer  
Food and Drug Administration  
19900 MacArthur Boulevard, Suite 300  
Irvine, California 92715-2445

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,

  
Elaine C. Messa  
District Director

cc: Mr. Roger Gailey, MQSA Inspector  
County of Los Angeles  
Department of Health Services  
Radiation Management  
550 South Vermont  
Los Angeles, CA 90020



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (714) 798-7600

December 24, 1997

Ref: WL-08-8

Dr. Anthony Disher, MD  
Radiologist  
KingDrew Medical Center  
12021 S. Wilmington Avenue  
Los Angeles, California 90059

Inspection ID: 119495

Dear Dr. Disher:

This letter is being sent to you to correct information in your Warning Letter of 12/2/97. The Warning Letter stated that your health physics surveys had been conducted nineteen months apart. I have received updated information from Los Angeles County that this was incorrect. The correct time period was just over fourteen months. This new information does not change the Level One citation, but does change the time period statement between surveys. We appreciate Mr. Hank Williams of your staff for pointing this error out to us.

Please be aware that it is our policy to always confirm the facts with the County MQSA Inspector (official FDA contractor) just prior to the issuance of each Warning Letter. In your case this was done, but an incorrect survey time period was mistakenly transmitted to FDA. For the record, this corrected information will be copied to FDA Headquarters HFZ-240 and the official FDA legal files. If you have any questions regarding this matter I can be reached at (714) 798-7667.

Robert W. Nicol  
Compliance Officer  
Los Angeles District

cc: Mrs. Kathlene Kaufman, Director  
County of Los Angeles  
Department of Health Services  
Radiation Management  
550 South Vermont, room 600  
Los Angeles, CA 90020

cc: Mr. Hank Williams  
Radiology Department  
KingDrew Medical Center  
12021 S. Wilmington Avenue  
Los Angeles, California 90059

Los-Do correction letter Ref: W/L 08-8/Page 2

bcc:

HFA-224

HFC-230

HFC-240/R.Pack

HFI-35/FVM

HFZ-240

HFR-PA200

Minh Phan/MQSA Inspector

Los Files (CFN 2029569)

Chron/RWN

legal file