



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

HFT-35M3470A

FEB 9 2000

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 17-00

Richard Gritz, M.D.
Encino-Tarzana Regional Medical Center Encino Hospital
16237 Ventura Boulevard
Encino, CA 91436

Inspection ID: 1118490005

Dear Dr. Gritz:

We are writing to you because on 1/31/2000, your facility was inspected by a representative of the State of California, acting in 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 Federal law, the Mammography Quality Standards Act (MQSA) 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 revealed the following level 1 findings at your facility:

1. Mammograms were processed in processor 0000000001, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Mammo at Encino-Tarzana Regional Medical Center Encino Hospital, when it was out of limits on 21 days.
2. Processor QC records were missing 21 consecutive days for processor 0000000001, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Mammo at site Encino-Tarzana Regional Medical Center Encino Hospital.
3. Processor QC records were missing 21 out of 21 days of operation in month 07/1999. Processor QC records missing 100%, for processor 0000000001, Kodak, RP X-OMAT M6B, 6AN, 6AW, room Mammo at site Encino-Tarzana Regional Medical Center Encino Hospital.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they 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 **money 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 performing further mammography.

In addition, your response should address the Level-2 finding **that was listed** on the inspection report provided to you at the close of the inspection. This **Level-2 finding** is:

1. Phantom QC records were missing for at least two weeks but less than four weeks for unit 1, Lorad Medical Systems Inc., OTH, room MAMMO.

It is necessary for you to act on this matter immediately. Please **explain** the following elements 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**).*

*this note is not applicable for letters which also address **patient notification**.

Please submit your response to:

Thomas L. Sawyer
 Director, Compliance Branch
 Food and Drug Administration
 19900 MacArthur Boulevard, Suite 300
 Irvine, CA 92612-2445
 Voice (949) 798-7755
 Fax (949) 798-7771

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/cdrh/dmgrp.html> <<http://www.fda.gov/cdrh/dmgrp.html>>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas at (949) 798-7708 or Minh Phan at (949) 798-7711.

Sincerely yours,


Acting District Director