



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m4057n

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

AUG 01 2000

WARNING LETTER

Certified Mail
Return Receipt Requested

WL-67-00
Inspection ID: 1909000008

Keith Arnold
Director of Professional Services
Lincoln Hospital Medical Center
443 S. Soto Street
Los Angeles, CA 90033

Dear Mr. Arnold:

We are writing to you because on 6/7/2000, your facility was inspected by a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA) and 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:

- **Processor QC records were missing 21 consecutive days for processor 0000000001, Kodak, X-OMAT M35 or M35A-M, room Mammo at site Lincoln Hospital Medical Center.**
- **Processor QC records were missing 21 out of 21 days of operation in month 10/1999. Processor QC records missing 100%, for processor 0000000001, Kodak, X-OMAT M35 or M35A-M, room Mammo at site Lincoln Hospital Medical Center.**

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 this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents 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 your facility performing further mammography.

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.

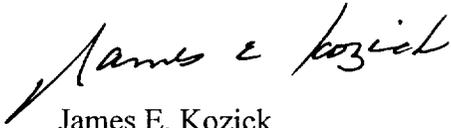
Please submit your response to:

Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

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>.

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,



James E. Kozick
Acting District Director

CC:
Los Angeles County Department of Health Services
550 S. Vermont Avenue, Room 601
Los Angeles, CA 90020

Penny Butler, Director
Breast Imaging Accreditation
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091