



M 2053N

Certified Mail Return Receipt Requested

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

WARNING LETTER

September 2, 1998

WL-42-8

Ms. Audrey O'Donnell
Chief Executive Officer
L.A. Metropolitan Medical Center
2231 S. Western Avenue
Los Angeles, California 90018

Inspection ID: 1878560004

Dear Ms. O'Donnell:

We are writing you because on May 26, 1998, and July 28, 1998, your facility was inspected by a representative of the Los Angeles County Health Department, acting on 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 Law, the Mammography Quality Standards Act of 1992(MQSA), 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. The radiologic technologist did not meet the requirement of being licensed by a State or board certified by any of the approved boards: [REDACTED]

The specific deficiency noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as Level 1, because it identifies 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 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 further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

2. The interpreting physician did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months: [REDACTED]

3. The interpreting physician did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year): [REDACTED]
4. The interpreting physician did not meet the continuing education requirements of having completed a minimum of 15 credits in mammography over a 3-year period (an average of 5 credits/year): [REDACTED]
5. The interpreting physician did not meet the initial training requirement of having 40 hours of continuing medical education in mammography: [REDACTED]
6. The interpreting physician did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months: [REDACTED]

It is necessary for you to act on this matter immediately. We are in receipt of your correspondence sent to FDA on 7/28/98, and you can refer to it if you wish as to not repeat your response verbatim. Please explain 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)

Please submit your response to:

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

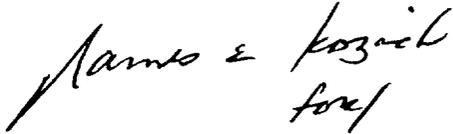
Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the

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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>.

If you have more specific questions about mammography facility requirements, or about the
content of this letter, please feel free to contact Robert W. Nicol at (949) 798-7667.

Sincerely yours,

Handwritten signature in cursive script that reads "Messa & Kozick" on the top line and "for" on the bottom line.

Elaine C. Messa
District Director

cc: Ms. Bonnie Long, MQSA Inspector
County of Los Angeles
Department of Health Services
Radiation Management
550 South Vermont Avenue, Room 600
Los Angeles, CA 90020