



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

April 4, 2001

Tim Jones
Regional Director
Centinela Medical Center of Fox Hills
6201 Bristol Parkway
Culver City, CA 90230

W/L Number: 32 - 01
Inspection ID: 1059320007
CFN: 20-29,490
FEI: 1000518820

Dear Mr. Jones:

We are writing to you because on February 8, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. 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 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 2 finding, at your facility, and this is a REPEAT violation from the prior inspection:

- Level 2: The facility has not specified adequate procedures to be followed for infection control or did not follow them when required.

The specific problem 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 2 because it identifies 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, it represents a serious 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

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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 and repeated Level 3 findings that were listed on the inspection report provided to you at the close of the inspection. The Level 2 and repeated Level 3 (from the prior inspection) findings are:

- Level 2: Failed to produce documents verifying that the interpreting physician [REDACTED] met the initial experience requirement of having interpreted or multi-read 240 mammograms in six (6) months.
- Level 3: The required personnel qualification documents were not available during the inspection. This is a REPEAT violation.

It is necessary for you to act on this matter immediately. 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; and
- please provide 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).

Your response should also specifically address the repeat violations which were not corrected from the previous inspection and why they were not corrected prior to the inspection of February 8, 2001.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U. S. Food and Drug Administration
19900 MacArthur Blvd.; Suite #300
Irvine, CA 92612-2445
phone: 949-798-7600

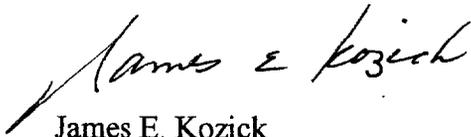
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Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general 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>.

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

Sincerely,



James E. Kozick
Acting District Director

cc:

State of California
Dept. of Health Services
Radiological Health Unit
550 South Vermont Avenue; Suite #601
Los Angeles, CA 90020