



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

91163d

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

WARNING LETTER

Certified Mail
Return Receipt Requested

April 16, 2001

Brian King, M.D.
Radiologist
Medical Imaging Center of Southern California
2811 Wilshire Boulevard; Suite #950
Santa Monica, CA 90403

W/L Number: 36 - 01
Inspection ID: 1234480011
CFN: 20-29,603
FEI: 1000518974

Dear Dr. King,

We are writing to you because on February 13, 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 REPEAT finding at your facility:

- Level 2: The facility failed to produce documents verifying that the interpreting physician, [REDACTED], met the continuing education requirement (ten continuing medical education [CME] units in 36 months) of having taught or completed at least 15 category I CME units in mammography in 36 months. This is a REPEAT violation from the previous inspection.

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.

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re: Medical Imaging Center of Southern California
re: Warning Letter Number 36 - 01

Because this condition 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 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 REPEATED Level 3 findings that were listed on the inspection report provided to you at the close of the inspection. These repeated Level 3 findings are:

- Level 3: The fixer retention quality control (QC) is not adequate for processor #1 (a [REDACTED] machine, model [REDACTED]) in that the missing or incomplete fixer retention QC records were not done at the required frequency.
- Level 3: The required personnel qualification documents were unavailable during the inspection.

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;
- why these repeated findings, as noted during the previous inspection, had not been corrected prior to this current inspection;
- 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).

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re: Medical Imaging Center of Southern California
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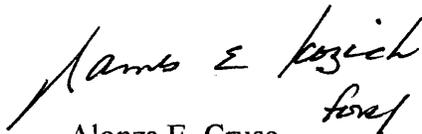
Please submit your response to:

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

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,



Alonza E. Cruse
District Director

cc:

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