



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region *m283m*

Telephone (973) 526-6007

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

August 23, 1999

WARNING LETTER

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Ms. Joann Carrocino
Executive Director
Kimball Medical Center
600 River Avenue
Lakewood, New Jersey 08701

FILE NO.: 99-NWJ-32
Inspection ID NO.: 1194380009

Dear Ms. Carrocino:

We are writing to you because on August 10, 1999, a representative of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed serious regulatory problems involving the mammography at your facility. Your facility was operating without valid accreditation from an approved accreditation body in direct violation of the Federal Mammography Quality Standards Act of 1992 as amended. On August 20, 1999, you told Commander Heyward L. Rourk, Jr., Central Regional Radiological Health Representative, that Kimball Medical Center - Mobile had stopped using the system on August 9, 1999 and will not use the system until you have obtained a valid FDA MQSA Certificate.

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 and Level 2 findings at your facility:

LEVEL 1

- The Kimball Medical Center - Mobile Unit was performing mammography without a valid FDA MQSA Certificate. The

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facility accreditation expired 30 days before the FDA Certificate expired. An expired or failed accreditation invalidates the FDA MQSA Certificate.

LEVEL 2

- The Kimball Medical Center - Mobile unit was performing mammography without accreditation by an approved accreditation body.
- The measured fog density is equal to 0.37 for the darkroom specials at Kimball Medical Center - Mobile.
- The time period between the previous and current surveys for x-ray unit 1 [REDACTED] exceeded 14 months.

The specific problems noted above were discussed at the time of the inspection and appear on your MQSA Facility Inspection Report, which was mailed to your facility on August 20, 1999.

Because these conditions 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 further mammography.

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 that you receive 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 (include technique factors), raw test data, and calculated final results, where appropriate; and

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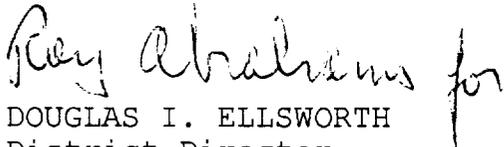
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to: Rosa L. Brown, Compliance Technician, Food and Drug Administration, New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054.

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 may 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 Commander Heywood L. Rourk, Jr., Central Regional Radiological Health Representative at (410) 962-4052.

Sincerely,


DOUGLAS I. ELLSWORTH
District Director
New Jersey District Office

/RLB

cc: Ms. Joyce Zeisler
Bureau of Radiological Health
Department of Environmental Protection
P.O. Box 415
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