



WARNING LETTER

Certified Mail
Return Receipt Requested

June 12, 2001

June Chen, M.D.
Radiologist
Moran, Rowen and Dorsey, Inc. - Breast Imaging Center
705 West La Veta Avenue; Suite #107
Orange, CA 92668

W/L Number: 54 - 01
Inspection ID: 1498640008
CFN: 20-29,771
FEI: 1000519517

Dear Dr. Chen:

We are writing to you because on May 30, 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 REPEATED Level 2 finding at your facility:

- Level 2: Corrective action before further exams (for a failing image score), or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit #4 (a [REDACTED] - [REDACTED] machine, model [REDACTED], serial number [REDACTED]) which is located in a room described as "DMR Room #5". This is a REPEAT violation.

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 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

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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.

Further, your response should address the additional Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 finding is:

- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in twenty-four (24) months.

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 the repeat Level 2 violation, from your previous inspection which was conducted on April 4, 2000, was not corrected and/or corrective action actually implemented;
- 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).

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
U.S. Food & 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.

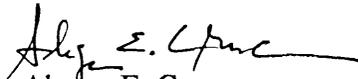
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Box #6057, Columbia, MD '21045-6057 (telephone: 1-800-838-7715) or through the Internet at <http://www.fda.gov>.

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:

Ms Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
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1891 Preston White Drive
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