



MD829M

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

July 30, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 37

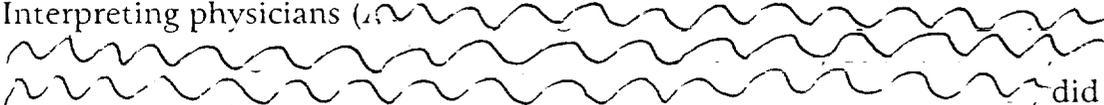
Dennis Clemenson
President
DMS Imaging, Inc.
3801 Bemidji Avenue North, Suite 6
Bemidji, Minnesota 56601

Dear Mr. Clemenson:

On June 9, 1999, a representative of the State of Minnesota acting on behalf of the Food and Drug Administration (FDA) inspected your facility (inspection ID - 1280170007). This inspection revealed a serious regulatory problem involving the mammography provided by your mobile service.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your mobile mammography service must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your sites presented at the time of the inspection the following Level 1 and Level 2 findings were documented at your facility:

Level 1 Non-compliance:

- A. Interpreting physicians (if
- 
- did

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not meet the requirement of being certified by an FDA- recognized board or having the alternative of 2 months training in the interpretation of mammograms.

Level 2 Non-compliance:

- B. The film processing speed (using the S.T.E.P. procedure) is less than 80 for standard processing using the [redacted] processor located at your Baudette, MN remote site.
- C. The film processing speed (using the S.T.E.P. procedure) is less than 80 for standard processing: using the [redacted] processor located at your NMC Walker, MN remote site.
- D. Interpreting physicians [redacted] did not meet the continuing education requirement of having completed a minimum of 15 CME credits in mammography in a 36-month period. Note: See additional doctors listed below (based on your post-inspectional mailings).
- E. Interpreting physicians [redacted] did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography:
- F. Interpreting physicians [redacted] did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6-month period).
- G. Interpreting physician [redacted] did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.

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H. Claimed Items: Documents showing state licensing for interpreting physicians ([redacted])

I. Claimed Items: Documents showing 15 CME credits in mammography in the preceding 36 months for physician [redacted]

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility following the close of the inspection.

FDA acknowledges that your company has supplied additional documentation to our contractor, the State of Minnesota, via July 5 and July 14, 1999, mailings. Based on either the originally reviewed records or the documentation your site has supplied since the inspection, the following items remained unresolved:

- 1) [redacted] Supply copy of ABR (or equivalent) certificate (or proof of 2 months full time training (e.g. residency letter).
- 2) [redacted] Supply letter from residency program regarding initial training and experience (40 CME/240 exams in 6 months). Note: An attestation for events after October 1, 1994, is unacceptable.
- 3) [redacted] Supply readable copy of current license. Supply letter from residency program regarding initial training and experience (40 CME/240 exams in 6 months). Note: An attestation for events after October 1, 1994, is unacceptable.
- 4) [redacted] Supply proof of initial training and experience. This includes either a copy of his ABR (or equivalent) certificate, or proof of 2 months full time mammography training (e.g. residency letter). Proof of interpretation of 240 mammographic exams (must be under direct supervision if completed after October 1, 1994). If initial training is documented via Certificate route, supply documentation that he has obtained 40 CME in mammography. Note: An attestation for events after October 1, 1994, is unacceptable. Supply proof of 15 mammography CME since May 1, 1996.
- 5) Supply proof that Doctors [redacted] earned at least 15 CME in mammography since May 1, 1996. Photocopies of actual certificates are required.
- 6) Item B above has not been resolved.
- 7) Item G above has not been resolved.

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Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography independently. For "Continuing" requirements, this includes either lack of appropriate CME/24 months or Number of Interpretations/36 months. Requirements for re-qualification are listed in the Final Regulation that became effective on April 28, 1999. Contact Radiological Health Specialist Thomas Garvin (see below) if you have questions or concerns regarding this requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent 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, the 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 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 control factors) for the cited film processor.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, FDA, 2675 N. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

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

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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 specific questions about mammography facility requirements or about the content of this letter feel free to contact Mr. Garvin at (414) 771-7167 x 12.

Sincerely,


James A. Rahto
Director
Minneapolis District

TWG/ccl

xc: Judith A. Ball
Manager
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P.O. Box 64975
St. Paul, MN 55164-0975



Lead Interpreting Physician / Accreditation Body Contact
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Walker, MN 56484

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