



9/14/01

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

June 28, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 68

Ben Sanderson
President
DMS Imaging, Inc.
3801 Bemidji Avenue North, Suite 6
Bemidji, Minnesota 56601

Dear Mr. Sanderson:

On May 14-15, 2001, representatives of the States of Minnesota and North Dakota, acting on behalf of the Food and Drug Administration (FDA), inspected your mobile mammography facilities (FDA certificates 128017 and 128025) and the remote sites where they perform mammography. 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. Based on the documentation your site presented at the time of the inspection, the following Level 1 and Level 2 findings were documented at your facility:

Certificate #128025

Level 1 Non-Compliances:

1. Failure to produce documents verifying that interpreting physicians (*[redacted]*) met the initial requirement of holding a valid state license to practice medicine.
2. Failure to produce documents verifying that interpreting physicians (*[redacted]*) met the initial requirement of being certified in

Page Two

Ben Sanderson

June 28, 2001

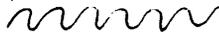
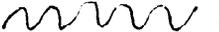
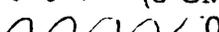
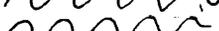
the appropriate specialty by an FDA-approved board or having two months of initial training in the interpretation of mammograms prior to April 28, 1999.

Repeat Level 2 Non-Compliances:

3. Two of 10 random reports reviewed did not contain an acceptable assessment category for DMS Imaging, Inc. mobile site.
4. Not all positive mammograms were entered in the tracking system for DMS Imaging, Inc. mobile site.
5. There were no examples of, nor attempts to obtain, biopsy results for DMS Imaging, Inc. mobile site.
6. There is no designated audit (reviewing) interpreting physician for DMS Imaging, Inc. mobile site.

Level 2 Non-Compliances:

7. A performance verification test was not conducted after each move for Mobile Unit 2, Other, OTH, Mobile.
8. 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 2, Other, OTH, Mobile.
9. Failure to produce documents verifying that interpreting physicians met the continuing education requirement of having taught or completed at least 15 Category I continuing medical education units in mammography within 36 months:

 (0 CMEs in 36 months)
 (0 CMEs in 36 months)
 (0 CMEs in 36 months)
 (0 CMEs in 36 months)
 (0 CMEs in 36 months)
 (0 CMEs in 36 months)
 (0 CMEs in 36 months)
 (0 CMEs in 36 months)
 (0 CMEs in 36 months)
 (0 CMEs in 36 months)
 (0 CMEs in 36 months)

Ben Sanderson

June 28, 2001

- (0 CMEs in 36 months)
- (6 CMEs in 36 months)
- (0 CMEs in 36 months)
- (0 CMEs in 36 months)
- (6 CMEs in 36 months)

10. Failure to produce documents verifying that interpreting physicians (.....) met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.
11. Failure to produce documents verifying that interpreting physicians (.....) met the initial experience requirement of having interpreted or multi-read 240 mammograms in six months.
12. Failure to produce documents verifying that interpreting physicians (.....) met the initial requirement of having 40 hours of medical education units in mammography prior to April 28, 1999.
13. Medical audit and outcome analysis was not done for the facility as a whole at DMS Imaging, Inc., mobile site.
14. Medical audit and outcome analysis was not performed annually at DMS Imaging, Inc., mobile site.

Repeat Level 3 Non-Compliance:

15. The QA program is inadequate for DMS Imaging, Inc., mobile site. The missing or incomplete item is listed below:

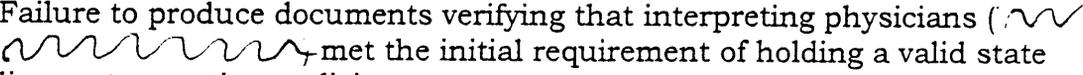
Personnel responsibilities

Page Four

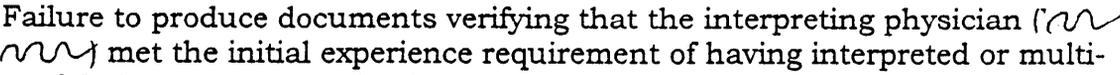
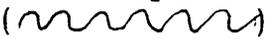
Ben Sanderson
June 28, 2001

Certificate #128017

Level 1 Non-Compliances:

16. Failure to produce documents verifying that interpreting physicians () met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having two months of initial training in the interpretation of mammograms prior to April 28, 1999.
17. Failure to produce documents verifying that interpreting physicians () met the initial requirement of holding a valid state license to practice medicine.
18. The system to communicate results is inadequate for DMS Imaging, Inc., mobile site, because there is no system in place to provide timely lay summaries.

Level 2 Non-Compliances:

19. The mammography equipment evaluation by a medical physicist for Unit 2, Other, OTH, mammography room, or related processor was not done.
20. A performance verification test was not conducted after each move for mobile unit 2, Other, OTH, mammography room.
21. 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 2, Other, OTH, mammography room.
22. The phantom QC is inadequate for Unit 2, Other, OTH, mammography room, because the image was not taken at clinical setting.
23. Failure to produce documents verifying that the interpreting physician () met the initial experience requirement of having interpreted or multi-read 240 mammograms in six months.
24. Failure to produce documents verifying that the interpreting physician () met the continuing experience requirement of having interpreted or multi-read 960 mammograms in 24 months.
25. Failure to produce documents verifying that the interpreting physicians met the continuing education requirement of having taught or completed at least

Page Five

Ben Sanderson
June 28, 2001

15 Category I continuing medical education units in mammography in 36 months:

 (11 CMEs in 36 months)
 (6 CMEs in 36 months)

26. Failure to produce documents verifying that the interpreting physician () met the initial requirement of having 40 hours of medical education in mammography prior to April 28, 1999.
27. Nine of 9 random reports reviewed did not contain an acceptable assessment category for DMS Imaging, Inc., mobile site.
28. Medical audit and outcome analysis was not done for the facility as a whole at DMS Imaging, Inc., mobile site.
29. Medical audit and outcome analysis was not performed annually at DMS Imaging, Inc., mobile site.
30. There were no examples or, nor attempts to get, biopsy results for DMS Imaging, Inc., mobile site.
31. Not all positive mammograms were entered in the tracking system for DMS Imaging, Inc., mobile site.

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

Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography independently. Conditions for "Direct Supervision" of unqualified personnel are specified in regulation and formal FDA policy. Policy references may be found at the Internet address below.

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.

Page Six

Ben Sanderson
June 28, 2001

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 technique factors), raw test data, and calculated final results, where appropriate, and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas P. Nelson, Compliance Officer, at the address on the letterhead.

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/cdrh/mammography/index.html>.

Sincerely,


James A. Rahto
Director
Minneapolis District

TPN/ccl

RF

xc: Sue McClanahan
Supervisor, Radiation Unit
Minnesota Department of Health
1645 Energy Park Drive, Suite 300
St. Paul, MN 55108-2970

Jeffrey Burgess
Director, Division of Environmental Engineering
North Dakota Department of Health
P.O. Box 5520
Bismarck, North Dakota 58506-5520

Priscilla F. Butler
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, VA 20191