



DEPARTMENT OF HEALTH & HUMAN SERVICES M 998 N
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

June 13, 1997

97-PHI-30

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ronald Schad, President
Women's Mobile Diagnostic, Ltd.
1225 Vine St.
Philadelphia, PA 19107

GEN.	SPEC.
RELEASE	
F# _____	DATE <u>6/23/97</u>
Reviewed by: <u>William W. Kunkle</u>	

Inspection ID: 1540540002

Dear Mr. Schad:

Your facility was inspected on April 22, May 20 and 29, and June 2, 1997, by a representative from the Commonwealth of Pennsylvania, Bureau of Radiation Control, acting in behalf of the Food and Drug Administration. An inspector from the Food and Drug Administration accompanied the State representative on May 29, 1997. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12(d)(5), Part 900.12(a)(2), and Part 900.12(d)(1)(iii) as follows:

1. Records indicate that there was no completed medical physicist survey done for the [REDACTED] mammography x-ray unit (21CFR900.12(d)(5)). Please indicate when you expect the physicist survey to be completed and the procedures you will use to insure that an annual physics survey is conducted. Also, please furnish us a copy of the physicist survey as soon as possible.
2. The radiologic technologist, [REDACTED] was neither state licensed in radiography nor certified by one of the bodies approved by FDA to certify radiologic technologists (21CFR900.12(a)(2)). Please furnish us with documentation that [REDACTED] is state licensed in radiography or board certified by an approved body or indicate that Ms. Hanson will not perform mammography exams. Also, please furnish us with the procedures that you will use to insure mammography exams are performed by fully qualified technologists.
3. No processor QC records were present for the [REDACTED] processor (21CFR900.12(d)(1)(iii)). Please furnish us with the procedures that you will use to insure that processor QC records are adequately kept and the procedures that will be followed when the processor is out of limits or not operating.

The specific deficiencies noted above appeared under the Level 1 heading on your revised MQSA Facility Inspection Report, a copy of which is attached. These deficiencies may compromise the quality of mammograms at your facility.

In addition, your response should also address the following Level 2 noncompliances listed on the revised inspection report:

- Level 2**
4. Phantom image test results were not recorded for 4 months for the [REDACTED] mammography x-ray unit. Please furnish us with the procedures you will use to insure Phantom images are correctly recorded at the proper intervals and actions you will take when the phantom image is not acceptable.
 5. Data points for medium density (MD), density difference (DD), and base+fog (B+F) were missing for the months of January thru April, 1997 for the [REDACTED] processor. Please furnish us with the procedures you will use to insure that the medium density, density difference, and base + fog procedures will be conducted, measured, recorded, and evaluated at the proper intervals.
 6. No medical audit system was in place to track positive mammograms. Please furnish us with the procedures you will use to track positive mammograms.
 7. The radiologic technologist, [REDACTED] did not meet the requirement for specific training in mammography. If [REDACTED] is board certified or state licensed radiographic technologist, please provide documentation she has obtained 40 hours CEU/MEU in training specific to mammography or she may only conduct mammography exams under the direct supervision of a qualified individual. Direct supervision means that a qualified individual must be with her at all times during the mammography procedure with the exception of the actual exposure. If [REDACTED] does not have a state radiographic license or board certified by an approved body she may not perform mammography.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the above deficiencies and promptly initiate permanent corrective actions. FDA may reinspect your facility without advance notice to verify your corrective actions. *[NOTE: At your next MQSA inspection, the FDA will check to make sure that all problems in Levels 1, 2, and 3 are corrected]*

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- * Impose a directed plan of correction on a facility, including payment for the cost of onsite monitoring.
- * Impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards.

- **suspend or revoke a facility's FDA certificate for failure to comply with the Standards.**
- **seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.**

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. Therefore you should consider the more stringent State requirements, if any, when you plan your corrective action.

FDA may take other actions as deemed necessary based on your response. Within 15 working days of receipt of this letter, you should notify us in writing of:

- **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 recordkeeping procedures, if the noncompliances that were found relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).**

Your response should be sent to:

**Mr. Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220**

with a copy to:

**Ms. Rebecca Hunter
PA Dept. of Environmental Protection
Bureau of Radiation Protection
Suite 6010 Lee Park
555 North Lane
Conshohocken, PA 19428**

and

Ms. Joyce Zeisler
Radiation Protection Programs
Division of Environmental Safety,
Health and Analytical Division
Department of Environmental Protection
CN 415
Trenton, NJ 08625-0415

If you have any questions regarding this letter, please call Mr. Davis at 412-644-3394.

Sincerely,



Diana Kolaitis
District Director
Philadelphia District

Attachment: MQSA Facility Inspection Report
Inspection ID: 1540540002

cc: Jim Potter
Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

Rebecca Hunter
PA Dept. of Environmental Protection
Bureau of Radiation Protection
Suite 6010 Lee Park
555 North Lane
Conshohocken, PA 19428

Ms. Joyce Zeisler, Supervisor Mammography Implementation
Radiation Protection Programs
Division of Environmental Safety,
Health and Analytical Division
Department of Environmental Protection
CN 415
Trenton, NJ 08625-0415