



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

PHILADELPHIA DISTRICT
71403M

98-PHI-11

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

WARNING LETTER

February 9, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Henrietta Rosenberg, M.D., President
Center One Radiology Associates, Ltd.
9880 Bustleton Avenue @ Halderman
Philadelphia, PA 19107

GEN.	SPEC.
RELEASE	
F# _____	DATE <u>2/13/98</u>
Reviewed by: <u>Alan W. Kumpf</u>	

Inspection ID: 1920880003

Dear Dr. Rosenberg:

Your facility was inspected on January 21, 1998, by a representative from the Commonwealth of Pennsylvania, Bureau of Radiation Control, acting in behalf of the Food and Drug Administration. 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 as follows:

The radiologic technologist, Ms. [REDACTED], was neither state licensed nor certified by one of the bodies approved by FDA to certify radiologic technologists. [21CFR900.12(a)(2)]

The deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, a copy of which is attached. This deficiency could compromise the quality of mammograms at your facility.

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 cause of the above deficiency and promptly initiate permanent corrective actions. FDA may reinspect your facility without advance notice to verify your corrective actions.

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 on-site 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:

1. the specific steps you took to **correct** the violation noted in this letter.
2. each step your facility is taking to **prevent the recurrence** of similar violations.

Your response should be sent to:

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

with a copy to:

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

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

Sincerely,



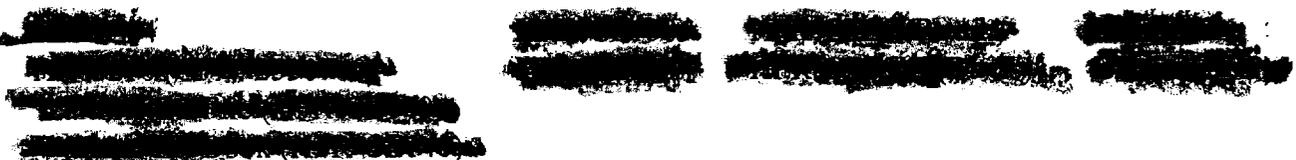
Diana Kolaitis
District Director
Philadelphia District

Attachment: MQSA Facility Inspection Report
Inspection ID: 1920880003

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

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

bcc:



HFI-35 (redacted copy for public display)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

MQSA Facility Inspection Report
Inspection ID: 1920880003
Inspection Date: 01/21/1998
Date: 01/30/1998
Time: 08:48:01 am

PAGE: 1

Center One Radiology
Associates, Ltd.
9880 Bustleton Ave @ Halderman
Philadelphia PA 19115

Facility Contact:
Kristine White, RTM
(215) 673-9729

Compliance Responsibility:
Henrietta Rosenberg, MD
President of Radiology
(215) 673-9729

EQUIPMENT TEST RESULTS

X-Ray Tests:

~~XXXXXXXXXXXXXXXXXXXX~~ OTHER Room = Room 1
Medical Physicist's Survey Date = 01/20/1998
Calculated Dose (phantom) = 149 mRad
Reproducibility Coefficient of Variation (4 exposures) = 0.001
Beam Quality: HVL (at 25 kVp) = 0.31 mm Al
Phantom Image Scores:
Number of Fibers = 4.0
Number of Speck Groups = 4
Number of Masses = 3.5

~~XXXXXXXXXXXXXXXXXXXX~~ Room = Room 2
Medical Physicist's Survey Date = 07/09/1997
Calculated Dose (phantom) = 177 mRad
Reproducibility Coefficient of Variation (4 exposures) = 0.000
Beam Quality: HVL (at 25 kVp) = 0.34 mm Al
Phantom Image Scores:
Number of Fibers = 5.5
Number of Speck Groups = 3
Number of Masses = 3.5

Processor S.T.E.P. Test:

~~XXXXXXXXXXXXXXXXXXXX~~, Room = Darkroom
Processing Speed = 99 Normal

Darkroom Fog Test:

Room: Darkroom

Fog OD = 0.02

MOSA Facility Inspection Report

Inspection ID: 1920880003

Inspection Date: 01/21/1998

Date: 01/30/1998

Time: 08:48:10 am

PAGE: 2

LIST OF OBSERVATIONS

level 1

1. The radiologic technologist did not meet the requirement of being licensed by a State or board certified by any of the approved boards: ~~XXXXXXXXXX~~

MQSA Facility Inspection Report
Inspection ID: 1920880003
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Date: 01/30/1998
Time: 08:48:10 am

PAGE:

(last page of report)

Inspector Remarks: None

Inspection conducted by: KOSHY, JOE (2166)
DEPARTMENT OF ENVIRONMENTAL PROTECTION

Name of State or DISTRICT: SOUTHEAST REGION
District Office: LEE PAV. SUITE 8010

Address: ~~643 NORTH LANE~~
~~COLENSHOCKET, PA 16808~~

Telephone: (610) 832-6025

Signature of Inspector: Joseph Koshy