



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

HFE-35

D1124B

PHILADELPHIA DISTRICT

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

Telephone: 215-597-4390

97-PHI-11

WARNING LETTER

January 23, 1997

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Eileen Hause, CEO  
Kensington Hospital  
136 West Diamond St.  
Philadelphia, PA 19122

GEN.	SPEC.
RELEASE	
F# _____	DATE <u>3/14/97</u>
Reviewed by: <u>Ann W. Krue</u>	

Inspection ID: 1827250002

Dear Ms. Hause:

Your facility was inspected on January 15, 1997, 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 900.12(a)(2), as follows:

The radiologic technologist, ~~XXXXXXXXXX~~ was neither state licensed nor certified by one of the bodies approved by FDA to certify radiologic technologists.

The specific deficiency noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, a copy of which is attached. This deficiency may be symptomatic of serious underlying problems that 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 causes of the above deficiencies and promptly initiating permanent corrective actions.

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

- \* **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. When you plan your corrective action, therefore, you should consider the more stringent State requirements, if any.

With respect to the above noncompliance, FDA understands that this deficiency was voluntarily corrected sometime in August, 1996. However because of its serious nature FDA is still requesting you provide us with the following documentation.

Within 15 working days of receipt of this letter, you should notify us in writing of:

1. a summary of the reasons why [REDACTED] was performing mammography exams without being board certified, the date the problem was discovered and corrected, the expiration date of her previous board certification, and how long [REDACTED] was performing mammography exams without board certification.
2. each step your facility is taking to **prevent the recurrence** of a similar violation.

If your facility is unable to complete the corrective action (or provide the documentation requested above) within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed or the documentation will be provided.

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 Pryber  
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,

*Gary E. Condit for*

Diana Kolaitis  
District Director  
Philadelphia District

Attachment: MQSA Facility Inspection Report  
Inspection ID: 1827250002

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

bcc:

[REDACTED]