



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

D172B  
PHILADELPHIA DISTRICT

97-PHI-14

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

WARNING LETTER

February 7, 1997

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Joseph Kalowsky, D.O.  
Medical Director of Radiology Services  
Hazleton General Hospital  
700 East Broad St.  
Hazleton, PA 18201

GEN. SPEC.  
RELEASE  
F# \_\_\_\_\_ DATE 3/14/97  
Reviewed by: *Wm. N. Knie*

Inspection ID: 1156750003

Dear Dr. Kalowsky:

Your facility was inspected on December 12, 1996, 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)(1), as follows:

Your facility was not able to document that the interpreting physician, [REDACTED], meets the training requirements established under the Mammography Quality Standards Act.

[REDACTED] is not certified by any of the bodies designated by FDA to certify interpreting physicians and has not had at least 2 months of documented full-time training in the interpretation of mammograms, including instruction in radiation physics, radiation effects, and radiation protection.

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 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 deficiency and promptly initiate permanent corrective actions.

If you fail to promptly correct this deficiency, 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 strongly recommends that you initiate a plan to reinterpret all mammography exams interpreted by ██████████ at Hazleton General Hospital since October 1, 1994. These should be reinterpreted by an interpreting physician(s) who meet the MQSA requirements for interpreting physicians.

We also strongly suggest that these reviews be documented in the patients' files by having the reviewing interpreting physician sign/initial the original medical reports. Your plan should also ensure that patients will be informed of any problems with the original interpretation by Dr. Ellison, if necessary. If you decide to do this, please provide FDA with a timeline and details of your plan to complete this task in your response.

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

1. the specific steps you have taken to correct the violation noted in this letter. It is our understanding that Dr. Ellison has not interpreted mammograms at your facility since December 24, 1996. Please acknowledge this in your response.

2. each step your facility is taking to **prevent the recurrence** of a similar violation.
3. a list of dates during which [REDACTED] interpreted mammograms at your facility from October 1, 1994 to the present and the total number of mammograms read during this time period.

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:

David Gaisior  
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,

*Terry S. Conder for*  
Diana Kolaitis  
District Director  
Philadelphia District

Attachment: MQSA Facility Inspection Report  
Inspection ID: 1156750003

cc: Richard Moore, CEO  
Hazleton General Hospital  
700 East Broad St.  
Hazleton, PA 18201

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