



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

HFI-35

D1120 B

PHILADELPHIA DISTRICT

97-PHI-10

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

Telephone: 215-597-4390

WARNING LETTER

January 22, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Barry Levin, M.D.
Associate Director of Radiology
The Graduate Hospital Imaging Center
University City - 5th Floor
3550 Market Street
Philadelphia, PA 19104

GEN.	SPEC.
RELEASE	
F# _____	DATE 3/14/97
Reviewed by: <i>Wm. W. Kuse</i>	

Inspection ID: 1146290004

Dear Dr. Levin:

Your facility was inspected on January 10, 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)(1), as follows:

A phantom image taken on the [redacted] mammography unit in room Mammo 502 found that the number of masses scored in the phantom image was [redacted] which does not meet the required number. The minimum number required for masses is 3.0.

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.

In addition, your response should address the level 2 and repeat level 3 noncompliances listed on the attached inspection report. These noncompliances are:

1. The calculated mean glandular dose was 368 Mrads, which exceeds the maximum allowable dose of 300 mRads.
21CFR900.12(c)

2. [REDACTED] 27% of the data points for either Medium Density (MD), density difference (DD), or base+fog (BF) were missing for the month of August, 1996. 21CFR900.12(d)(1)(i)

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.

Evaluation of the level 1 phantom image failure suggests processing and other artifacts may be the major contributor to the failure and FDA strongly recommends that your facility stop processing mammograms until you correct the phantom image quality. Further, FDA recommends that you consult with your medical physicist and correct all problems indicated in this letter immediately.

To minimize the risk to your patients, FDA strongly urges you to voluntarily enlist the services of a qualified interpreting physician to conduct an independent clinical image review for all the patient mammograms taken during the periods that such artifacts were experienced. If you decide to do this, please provide FDA with the details of this review 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 all of the violations noted in this letter.
2. each step your facility is taking to prevent the recurrence of similar violations.
3. sample records such as service records, physicist reports etc., showing correction of the violations, including a phantom image and techniques used to take the image, calculation results of the mean glandular dose and a summary of the changes made to achieve an acceptable mean glandular dose, and a copy of the standard operating procedure (SOP) for performing processor QC which describes processor QC responsibilities when the primary QC technologist is absent.

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,



Diana Kolaitis
District Director
Philadelphia District

Attachment: MQSA Facility Inspection Report
Inspection ID: 1146290004

cc: David Mayer, M.D.
Medical Director
The Graduate Hospital Imaging Center
1840 South St. 3rd Fl.
Philadelphia, PA 19146

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

bcc: HFA-224 HFR-MA150 HFR-MA25 (Rourk)
HFC-210 (CFN: 2530359) HFR-MA100 HFR-MA1515 (Davis)
EF (PGH-RP) HFZ-240
Warning Ltr File (HFR-MA140)
Warning Ltr Book (HFR-MA140)
HFI-35 (redacted copy for public display)