

HFI-35 M3249 N



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL 930-0

December 9, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert A. Stanbury, M.D.
Lead Radiologist
Kentuckiana X-Ray Associates.
1169 Eastern Parkway, Suite 2221
Louisville, KY 40217

Facility I.D.#: 155366

Dear Dr. Stanbury:

A representative from the Commonwealth of Kentucky radiation control program under contract to the Food and Drug Administration inspected your facility on October 20, 1999. 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, as follows:

1. Your records revealed that your facility processed mammograms when the processor quality control parameters were out of limits for eight days. **21 CFR 900.12(e)(1)**
2. Your facility phantom quality control records were missing for twelve weeks for your facility mammography unit. Mammograms were performed on patients during these twelve weeks without the required weekly phantom film checks on the mammography units. **21 CFR 900.12(e)(2)**

The specific deficiencies noted above appeared under the Level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. These deficiencies may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance items that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

1. Your records did not demonstrate that your facility performed corrective actions for processor quality control failures. **21 CFR 900.12(e)(8)(ii)(A)**
2. Your records showed that no corrective actions were conducted for the failed phantom image data. **21 CFR 900.12(e)(8)(ii)(A)**

3. Your records showed that the phantom quality control background density were not greater than 1.20 optical density units. 21 CFR 900.12 (e)(2)(i)

4. Five of five random interpreting physician mammography reports did not contain the required overall final assessment of findings. 21 CFR 900.12 (c)(1)(iv)(A)-(E) &(v)

The other items listed in your October 20, 1999 inspection report identified, as Level 3 should also be corrected. We will verify correction of these items during our next inspection. You are not required to address the Level 3 items in your written response.

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 deficiencies that the inspection identifies 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 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.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violation noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violation;
- Sample records that demonstrate proper record keeping procedures related to quality control.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to:

R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Mr. Steve Mays
Commonwealth of Kentucky
Cabinet for Human Resources
Department for Health Services
Radiation Producing Machines & Operator Certification
275 East Main St.
Frankfort, KY 40621

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,



Henry L. Fielden
District Director
Cincinnati District Office

c.
KY/SMays