



WARNING LETTER

July 3, 1997

Cin 97-453

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Mr. Bob Miller
Assistant Director of Radiology
Columbia Lake Cumberland
Regional Hospital
305 Langdon St.
Somerset, KY 42501

Facility I.D.# 157990

Dear Mr. Miller::

Your facility was inspected on June 26, 1997 by a representative from the Commonwealth of Kentucky radiation control program under contract to 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, as follows:

Your records indicated that mammograms were frequently processed with the medium density, density difference or base+fog out of control ($>+/-0.15$ or $>+/- 0.03$ respectively)

The specific deficiency noted above appeared under the Level 2 Repeats heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency was also observed in the previous inspection dated July 20, 1995. This repeat Level 2 observation may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition to above the Level 2 Repeats finding, the current inspection also found Level 2 and Level 3 Repeats noncompliances. Your response should also address these identified noncompliances that were listed on the inspection report provided to you at the close of the inspection.

Level 2

- Your facility lacks record demonstrating that the radiological technologist [REDACTED] meets the specific training requirement in mammography.

Level 3 Repeats

- Corrective actions for processor quality control failures were not documented on at least one occasion. .

The other item listed in your June 26, 1997 inspection report identified as Level 3 should also be corrected. We will verify correction of this item during our next inspection and you are not required to address this 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 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.

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 violations noted in this letter;
 - each step your facility is taking to prevent the recurrence of similar violations;
- and
- sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

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:

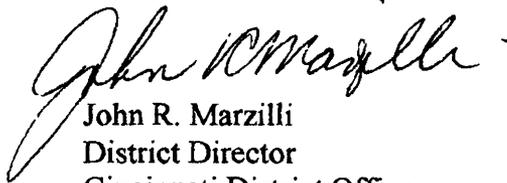
R. Terry Bolen
MQSA Radiological Health Officer
Food and Drug Administration
1141 Central Parkway
Cincinnati, OH 45202.

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

Mr. Steven L. Mays
Kentucky Radiation Control
275 E. 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)684-3501, extension 138.

Sincerely yours,



John R. Marzilli
District Director
Cincinnati District Office

c.
KY/SLMays