



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration
CINCINNATI DISTRICT OFFICE

6751 Steger Drive
Cincinnati, OH 45237-3097

WARNING LETTER

November 4, 1998

Cin WL-99-31

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John Grah
Administrator
Williamson Appalachian Regional Hospital
.260 Hospital Drive
South Williamson, KY 41503

Inspection I.D.#:1641780004

Dear Mr. Grah:

Your facility was inspected on October 13, 1998 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 lack the required information that the following interpreting physician is qualified to interpret mammograms: [REDACTED]. Your records did not demonstrate that [REDACTED] has either board certification from any of the approved boards or two months full-time training in the interpretation of mammograms.

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 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:

1. There were no records or attestations regarding the initial training of 40 hours of continuing medical education in mammography for the following interpreting physician:
[REDACTED]

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2. There were inadequate records or attestations regarding the interpreting physician's initial experience reading and interpreting mammograms of at least 240 patients in six months for the following interpreting physician: [REDACTED]

The other items listed in your October 13, 1998 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 these 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 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;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; 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

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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:

Mr. R. Terry Bolen
MQSA Radiological Health Officer
Food and Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097.

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

Ms. Julie Keightley
Commonwealth of Kentucky
Cabinet For Human Resources
Department for Health Services
275 East Main St.
Frankfort, KY 40621-001

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,



R. Duane Satzger, Ph.D.
Acting District Director
Cincinnati District Office

c.
KY/JKeightley