



WARNING LETTER

Cin WL -9932-01
September 10, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kerry Wehmeyer
Chief Executive Officer
Bourbon County Hospital
9 Linville Dr.
Paris, KY 40361

Facility I.D.#: 116053

Dear Mr. Wehmeyer:

A representative from the Commonwealth of Kentucky acting on behalf of the Food and Drug Administration (FDA) inspected your facility on September 6, 2001. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings at your facility:

Quality Standards—Personnel—Interpreting physicians—21 CFR 900.12(a)(1)(i)-(iii)

1. Your records lack the required information that the interpreting physician, [REDACTED] is qualified to interpret mammograms. Your facility failed to demonstrate that [REDACTED] has either board certification from any of the approved boards or two months of initial training in the interpretation of mammograms prior to April 28, 1999.
2. Your facility failed to demonstrate that [REDACTED] holds a valid state license to practice medicine.

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:

Quality Standards—Personnel—Interpreting physicians-21 CFR 900.12(a)(1)(i)-(iii)

1. Your facility failed to provide documents verifying that the interpreting physician: [REDACTED] met the initial requirement of having 40 hours of medical education in mammography prior to April 28, 1999.
2. Your facility failed to provide documents verifying that the interpreting physician: [REDACTED] met the initial experience of having interpreted or multi-read 240 mammograms in six months.

Because this condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, this represents violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

The other item listed in your September 6, 2001 inspection report identified, as Level 3 should also be corrected. We will verify correction of this item during our next inspection. You are not required to address the Level 3 item in your written response.

The inspector reported that the noncompliance issues regarding [REDACTED] was corrected before inspection. Your staff indicated to the inspector that your facility corrected the deficiencies by dismissing [REDACTED] in May 2001. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

- The specific steps you have taken to correct the violations noted in this letter; and
- Each step your facility is taking **to prevent the recurrence of similar violations.**

Please submit your response to:

Mr. R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

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

Ms. Julie Keightley
Commonwealth of Kentucky
Radiation Control
275 East Main St.
Frankfort, KY 40621

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,


for Henry L. Fielden
District Director
Cincinnati District Office

c.
KY/JKeightley

Priscilla F. Butler, M.S.
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