



WARNING LETTER

Cin WL -6859-0
March 15, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Bapuji Narra, M.D.
Lead Interpreting Physician
Mingo Pike Radiology
411 Central Avenue, Suite 1
South Williamson, KY 41503

Facility I.D.#: 125807

Dear Dr. Narra:

A representative from the Commonwealth of Kentucky acting on behalf of the Food and Drug Administration (FDA) inspected your facility on February 27, 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 Assurance – Equipment - 21 CFR 900.12(e)(1)(i)-(iii)

Your records showed that your facility processed mammograms when the processor quality control records were missing six (6) of 20 days or 30% of total days of operation in September 2000.

Quality Assurance – Equipment - 21 CFR 900.12(e)(2)

Your records revealed that your facility phantom quality control records for the mammography unit were missing for four (4) weeks. The MQSA regulation requires the mammography unit be evaluated by performing at least weekly the image quality evaluation test. The inspection found that your facility failed to perform this quality control test during the weeks of July 31-August 4; August 7-11; August 14-18 and August 21-25, 2000.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, these represent violations 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.

In addition, your response should address the Level 2 noncompliance item that was listed on the inspection report provided to you at the close of the inspection. This Level 2 noncompliance item is:

Quality Assurance – Equipment - 21 CFR 900.12(e)(1)(i)-(iii)

Your records revealed that your facility processed mammograms when the processor quality control records were missing for six (6) consecutive days. The inspection found that your facility failed to perform this quality control test on these following days September 15, 18-22, 2000.

The other items listed in your February 27, 2001 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.

You must act on these matters immediately. 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 sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

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

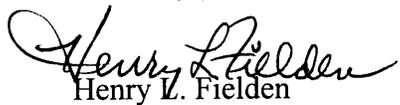
Also, please send a copy to the State radiation control office:

Mr. James Barnes
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,

A handwritten signature in cursive script that reads "Henry L. Fielden".

Henry L. Fielden
District Director
Cincinnati District Office

c.
KY/JBarnes

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Program
American College of Radiology
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