



DEPARTMENT OF HEALTH AND HUMAN SERVICES

9/706d
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 -9908-01
September 6, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Patrick Romano
Administrator
Mary Chiles Hospital
50 Sterling Ave.
Mt. Sterling, KY 40353

Facility I.D.#: 122291

Dear Mr. Romano:

A representative from the Commonwealth of Kentucky acting on behalf of the Food and Drug Administration (FDA) inspected your facility on August 21, 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 finding at your facility:

Quality Assurance – Equipment – *Weekly Quality Control Tests* -21 CFR 900.12(e)(2)

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 demonstrate that the weekly quality control tests were performed during the weeks beginning August 2000 to the beginning of March 2001.

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 items listed in your August 21, 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.

The inspector reported that the noncompliance issue regarding the weekly quality control tests was corrected before inspection. Your staff indicated to the inspector that your facility corrected this deficiency by hiring a new mammography technologist and your facility has included as part of the facility's protocol a procedure that will prevent recurrence. 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 violation 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 finding 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 black ink, appearing to read "Henry L. Fielden". The signature is fluid and cursive, with a large initial "H".

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
1891 Preston White Dr.
Reston, VA 20191