

HFI-35



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 – 5242-0
November 9, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Amy Mayhugh
Director of Imaging Services
Selby General Hospital
1106 Colegate Dr.
Marietta, OH 45750

Facility I.D.#: 167114

Dear Ms. Mayhugh:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on November 2, 2000. 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 - 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 five (5) consecutive days in the month of September 2000.

Because this condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, it represents a 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.

In addition, your response should address the Level 2 findings that are listed in the inspection report that was provided to you at the close of the inspection. The Level 2 findings are:

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 five of 20 days or 25% of total days of operation in September 2000.

Medical Records and Mammography Reports - 21 CFR 900.12 (c)(1)(iv)(A)-(E) &(v)

Five of five random interpreting physician mammography reports did not contain the required overall final assessment of findings.

You must act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date of receipt of this letter:

- the specific steps you have taken or plan to take to correct all of the violations noted in this letter;
- each step your facility is taking **to prevent the recurrence of similar violations**; and
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate.

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 D. Castle
Ohio Department of Health
Radiologic Technology Section
246 North High St., 7th Floor,
Columbus, OH 43216-0118

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 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.
OH/JCastle

Priscilla F. Butler, M.S.
Director, Breast Imaging Accreditation Program
American College of Radiology
1891 Preston White Dr.
Reston, VA 20191