



CERTIFIED MAIL
RETRUN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2001-DT-22

June 26, 2001

Ms. Lauren B. West
Coordinator Womens Center
Howard Community Hospital
Women's Center- Outpatient Services
3500 South Lafountain
P.O. Box 9011
Kokomo, IN 46904-9011

Dear Ms. West:

We are writing you because on June 20, 2001, your facility was inspected by a representative of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), 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:

Mammograms were processed in processor 2 (new as of [REDACTED]), when it was out of control on at least five (5) days at Howard community Hospital, Women's Center Outpatient.

The specific problem noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which your facility received at the close of the inspection. This problem is identified as a Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems 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 were also listed on the inspection report that was provided to you at the close of the inspection. These Level 2 findings are:

1. Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limit, was not documented for - [REDACTED] model - [REDACTED] room #2.
2. Failed to produce documents verifying that radiologic technologist - [REDACTED] - [REDACTED] met the initial training requirement of having 40 hours training specific to mammography.
3. Medical audit and outcome analysis was not done separately for each Interpreting Physician at Howard Community Hospital, Women's Center Outpatient.
4. There were no examples of, nor attempts, to get biopsy results (when biopsies may be done elsewhere) for positive mammograms performed at Howard Community Hospital, Women's Center Outpatient.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct the Level 1 and 2 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 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. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207-3179

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under 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>.

If you have any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-226-6260 Ext. 155.

Sincerely yours,

for David M. Kaszubski
Raymond V. Mlecko
District Director
Detroit District

Enclosures: a/s