DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1124269
Facility ID:1490050
Inspection ID #1490050009

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 779-5454

03-BLT-06

December 20, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Cathy L. Lahey, Mammography Supervisor
Edward W. McCready Memorial Hospital
Radiology Department
201 Hall Highway
Crisfield, Maryland 21817

Dear Ms. Lahey:

On November 13, 2002, a representative of the State of Maryland, acting on behalf of the Food and Drug Administration (FDA), inspected your facility. 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 [42 U.S.C. 263b], your facility must meet specific requirements to practice 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 violation of the MQSA at your facility, as identified on your inspection report:

- Your facility failed to document that processor quality control testing was performed on the following dates on which clinical films were processed: 1/3/02, 1/7/02, 1/8/02, 1/9/02, 1/10/02, 1/11/02, 1/14/02, 1/16/02, 1/28/02, 1/29/02, 3/1/02, 3/4/02, 3/5/02, 3/8/02, 3/11/02, 4/12/02, 5/6/02, 5/31/02, 6/6/02, 7/23/02. This is a violation of 21 C.F.R. § 900.12(e)(1).

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. A Level 1 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

The inspection also revealed the following Level 2 violations of the MQSA at your facility, as identified on your inspection report:

- Your facility failed to document that corrective action was taken on January 24, 2002 when processor quality control testing exceeded control limits. This is a violation of 21 C.F.R. § 900.12(e)(8)(ii).

- Your facility performed patient examinations on January 24, 2002 when processor quality control testing exceeded control limits. This is a violation of 21 C.F.R. § 900.12(e)(8)(ii)(A).

- Your facility failed to document that Radiologic Technologist [redacted] met the continuing experience requirement of having performed 200 mammography examinations in 24 months. This is a violation of 21 C.F.R. § 900.12(a)(2)(iv)(A).

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious 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, the MQSA Standards; suspension or revocation of your facility's FDA certificate; or seeking a court injunction against performing further mammography (see 42 U.S.C. §§ 263b(h) through (j) of the MQSA).

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 received this letter:

1. the specific steps you have taken to correct all of the violations noted in this letter;

2. each step your facility is taking to prevent the recurrence of similar violations;

In addition, please provides the following: 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).

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Steven Barber, Compliance Officer. Mr. Barber may be contacted at (410) 779-5134.

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

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 779-5441.

Sincerely,

for Lee Bowers
Director, Baltimore District