DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1123981
Facility ID:106401
Inspection ID #1064010009

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

03-BLT-10

March 20, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Re: MQSA Inspection ID #1064010009

Amile A. Korangy, M.D., Radiologist
Baltimore Imaging Centers
4000 Old Court Road
Suite 103
Pikesville, Maryland 21208

Dear Dr. Korangy:

We are writing to you because on January 10, 2003, 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 problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), which is codified in Section 263b of Title 42 of the United States Code (USC), 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 violations of the MQSA at your facility identified on your inspection report:

- **Level 1: On the following dates, your facility processed patient mammographic films when your film processor was out of limits: 1/4/2002, 1/7/2002, 1/8/2002, 1/15/2002, 1/16/2002, 1/18/2002, 1/21/2002, 1/22/2002, 1/25/2002, 1/31/2002, 2/1/2002, 2/6/2002, 2/11/2002, 2/12/2002, 2/14/2002, 2/18/2002, 2/19/2002, 2/21/2002, 2/22/2002, 2/26/2002, and 2/28/2002. [21 CFR 900.12(e)(1)]**

- **Level 1: On the following dates, your facility processed patient mammographic films in your film processor, but did not document that processor quality control testing was performed: 4/23/2002, 5/7/2002, 5/9/2002, 5/14/2002, 5/16/2002, 5/21/2002, 5/23/2002, 5/28/2002, 5/30/2002, 6/25/2002, 6/27/2002, 7/11/2002, 8/2/2002, 8/20/2002, 10/1/2002, 10/3/2002, 10/10/2002, 10/23/2002, and 10/31/2002. [21 CFR 900.12(e)(1)]**

- **Level 2: Your facility failed to document that weekly phantom image testing was performed during the weeks of 4/28/2002, 6/30/2002, and 8/4/2002. [21 CFR 900.12(e)(2)]**

- **Level 2: Your facility failed to document that corrective actions for processor quality control failures were performed. [21 CFR 900.12(e)(1)]**

- **Level 2: Your facility failed to follow your procedures for machine infection control in that documentation of infection control was not maintained as required by your written procedure. [21 CFR 900.12(e)(13)]**

- **Level 2: Your facility failed to provide documentation verifying that Dr. [redacted] met the continuing education requirement of having taught or read at least 15 category 1 continuing education units in mammography in the 36 months preceding the date of your inspections. [21 CFR 900.12(a)(1)(ii)(B)]**

- **Level 2: Your facility failed to produce documentation verifying that Radiologic Technologist [redacted] met the continuing experience requirement of having performed 200 mammography examinations in the 24 months preceding the date of your inspection. [21 CFR 900.12(a)(2)(iv)(A)]**

- **Level 2: Your facility failed to produce documentation verifying that Radiologic Technologist [redacted] met the continuing education requirement of having completed 15 continuing education units in mammography in the 36 months preceding the date of your inspection. [21 CFR 900.12(a)(2)(iii)(A)]**

- **Level 2: Your facility failed to perform an annual medical audit and outcome analysis for the facility as a whole. [21 CFR 900.12(f)]**

- **Level 2: Your facility failed to designate an audit reviewing interpreting physician. [21 CFR 900.12(f)(3)]**

The specific problems 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.

Because the continued failure to resolve these violations may be indicative of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- placing your facility under a Directed Plan of Correction
- charging your facility for the cost of on-site monitoring

- seeking 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
- seeking to suspend or revoke your facility's FDA certificate
- seeking a court injunction against your facility

See 42 USC 263b(h)-(j) and 21 CFR 900.12(j).

FDA may need to perform a Compliance Follow-up Inspection to determine that each problem at your facility has been corrected.

If you choose to respond to the above violations, your response should include:

1. the specific steps you have taken, or will take, to **correct** all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. each step you have taken, or will take, to **prevent the recurrence** of similar violations, including projected timeframes for implementing those steps;

3. 3. 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 B. Barber, Compliance Branch.

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 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,

/s/

Lee Bowers
Director, Baltimore District