DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 1000512488
Facility ID:144683
Inspection ID #1446830013

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

03-BLT-15

June 12, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Lucille C. Kahoe
University Imaging Center, LLC
419 W. Redwood Street
Suite 110
Baltimore, Maryland 21201

Dear Ms. Kahoe:

On April 23, 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 conduct of mammography at your facility. Under 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 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 violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report and the document *"Important Information about Your MQSA Inspection"* that the inspector left at your facility at the close of the inspection. The violations are identified below.

- **Level 1 Repeat** – Your facility failed to document that processor quality control was performed either on your primary or backup mammography processor on the following dates: 7/05/2002, 7/9/2002, 7/11/2002, 7/12/2002, 7/15/2002, 7/16/2002, 7/18/2002, 8/9/2002, 11/29/2002. **[21 CFR 900.12(e)(1)]**

- **Level 2 Repeat** – Your facility failed to document that corrective action was taken before further films were processed when your primary processor exceeded preset processing limits on 11/27/2002. **[21 CFR 900.12(e)(8)(ii), 21 CFR 900.12(e)(1)(i), (ii), and (iii)]**

- **Level 2 Repeat** – Your facility failed to document that phantom image testing was performed on the following dates:
  ----------: 6/30/2002, 2/16/2003
  ---------- 6/30/2002, 2/16/2003
  ----------: 6/30/2002, 8/25/2002, 2/16/2003

[21 CFR 900.12(e)(2)]

- **Level 2 Repeat** – Your facility failed to document that corrective action was taken before further exams were performed when phantom image test results exceeded the allowable regulatory limits on the following dates:
  ----------: 6/6/2002, 8/8/2002, 8/22/2002, 9/3/2002, 10/3/2002, 10/17/2002, 10/24/2002, 12/6/2002, 2/12/2003;
  ----------: 8/22/2002, 10/17/2002, 4/17/2003;
  ----------: 5/31/2002, 6/12/2002, 8/22/2002, 10/24/2002, 11/21/2002, 12/12/2002, 1/17/2003, 1/30/2003, 3/7/2003, 4/10/2003, 4/17/2003.
  [21 CFR 900.12(e)(8)(ii) and 21 CFR 900.12(e)(2)]

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

3. sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (**Note: Patient names or other information that would likely reveal the patient's identity should be deleted from any copies of records you submit).**

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 Officer.

We would also like to address two issues that were noted during a review of the processor quality control charts collected by the inspector during this inspection. During the month of July 2003, your facility was without a functioning sensitometer. During that time, your facility continued to perform and chart a weekly phantom image test for all three mammography machines located at your site. The approved alternative standard to sensitometric - densitometric testing of processor performance is based on **evaluating a phantom image each day clinical films are processed.** This phantom test must be processed, and evaluated before processing of clinical films. All results should be recorded and charted. If any limits are exceeded, the problem must be corrected before patient examinations are resumed.

The second issue noted was the use of five day averages. We were unable to determine the reason for the five days averages seen in the processor charts collected by the inspector. Re-establishing processor quality control levels using a 5 day average should only happen when your facility changes film brand, type of chemicals, replenishment rates, or development time, or when the film manufacturer makes a change to a film type currently in use. This is not an exhaustive list of conditions, but you may reference page 159 of the American College of Radiology Mammography Quality Control Manual, 1999 version. Five day averages should not be substituted for a crossover.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to violations related to the recent 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/index.html.

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