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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN:1124064
Facility ID:115410
Inspection ID #1154100024

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

03-BLT-03

October 18, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Sherry Roberts, Director of Imaging Services
Harford Memorial Hospital
501 South Union Avenue
Havre de Grace, Maryland 21078

Dear Ms. Roberts:

A representative of the State of Maryland, acting on behalf of the Food and Drug Administration (FDA), inspected your facility on September 23, 2002. 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. 263], 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 Section 354(f) of the Act at your facility identified on your inspection report:

- **Your facility failed to produce documentation verifying that the medical physicist [redacted] Lucas met the initial requirement of having a masters degree or higher in a physical science with at least 20 semester hours of physics. 21 CFR 900.12(a)(3)(i)(B)**

- **Your facility failed to conduct the phantom quality control test at your clinical setting. 21 CFR 900.12(e)(2)(i)**

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection

These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, and they represent a serious violation of the law that 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 Standards, suspension or

revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography (see Sections 354(h) through (j) of the Act).

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;

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 Vinetta Howard-King, Compliance Officer.

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,

Anita Richardson

for Lee Bowers
Director, Baltimore District