941372

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 3003146839
Facility ID:223205
Inspection ID #2232050004

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

03-BLT-19

July 11, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Angie Lambert-Hall, Office Manager
Solomon's Island Medical Center
14090 Solomon's Island Road South
Solomon's Island, Maryland 20688

Dear Ms. Lambert-Hall:

We are writing to you because on June 12, 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 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 violations of Section 354(f) of the Act at your facility identified on your inspection report:

- **Level 1:** Your facility failed to document that a weekly phantom quality control test was performed on the weeks beginning 2/23/03, 3/2/03, 3/9/03, 3/16/03, 3/23/03, 3/30/03, 4/6/03, 4/13/03, 4/20/03, 4/27/03, and 5/4/03; **21 CFR 900.12(e)(2)**

- **Level 1:** Your facility failed to document that processor quality control was performed for the processor identified in your inspection report as #2 Mammo on: 3/17, 3/18, 3/19, 3/20, 3/21, 3/24, 3/25, 3/26, 3/27, 3/28, and 3/31/2003; **21 CFR 900.12(e)(1)**

- **Level 2:** Your facility's processor quality control testing exceeded preset limits on 9/4/2002, 3/17, 3/18, 3/19, 3/20, 3/21, 3/25, 3/26, 3/27, 3/28/ 4/1, 4/2, 4/3, and 4/4/2003 and no corrective action was documented. **21 CFR 900.12(e)(1)(i), (ii) and /or (iii) and (e)(8)**

- **Level 2:** Your facility failed to enter all positive mammograms into the medical audit tracking system. **21 CFR 900.12(f)(1)**

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 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 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**). {this item should only be included when the inspection had findings for QC or other records at the facility. The note about patient names or identification should only be included this item should only be included when the inspection had findings for patient records}.

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Elizabeth A. Laudig, 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,

Lee Bowers
Director, Baltimore District