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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN:1124192
Facility ID:136192
Inspection ID #1361920008

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 100
Baltimore, MD 21215-3215
Telephone: (410) 773-5454

02-BLT-09

December 17, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Roslind I. McCoy-Sibley, M.D.
Sibley Medical Associates
2204 Executive Drive
Suite C
Hampton, Virginia 23666

Dear Dr. McCoy-Sibley:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on November 28, 2001. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 findings:

- **Your facility failed to document that processor quality control testing was performed for at least 30% of operating days in the month of August 2001.**
- **Your facility failed to document that phantom quality control testing was performed for at least 4 weeks.**

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 problems are identified as Level 1 findings because they identify a failure to comply with significant MQSA requirements.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent a 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

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for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

In addition, the following Level 2 finding was listed on the inspection report provided to you at the close of the inspection:

- **Your facility failed to document that corrective action was performed when your phantom image quality control test exceeded preset limits for image scoring or background density, or optical density differences.**

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 receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

Your response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Anita Richardson, Director, 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,



for

Lee Bowers
Director, Baltimore District