

Refer to: CFN 1123989
ID #107748

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4012

November 17, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Inspection ID #10774840004

Stephen Raskins, M.D.
Community Radiology of Virginia, Inc.
2000 Leatherwood Lane
Bluefield, Virginia 24605

Dear Dr. Raskins:

Your facility was inspected on November 5, 1998 by a representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA). This inspection revealed serious noncompliance involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act 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 at your facility:

Level 1 Violations:

1. The interpreting physician did not meet the requirement of being board certified by any of the approved boards or having received two months full-time training in the interpretation of mammograms: [REDACTED]
2. The interpreting physician did not meet the requirement of being licensed by a State to practice medicine: [REDACTED]

Also, the following deficiencies appeared under the Level 2 heading on your MQSA Facility Inspection Report:

Level 2 Violations:

1. The interpreting physician did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 months: [REDACTED]
2. The interpreting physicians did not meet the continuing education requirement of having completed a minimum of 15 credits in mammography over a 3-year period: [REDACTED]

3. **The interpreting physician did not meet the initial training requirement of having completed 40 hours of continuing medical education in mammography:** [REDACTED]

4. **The interpreting physician did not meet the requirement of having read and interpreted mammograms from the examinations of at least 240 patients in 6 months:** [REDACTED]

Because these violations may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, they represent violations 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, MQSA standards; suspension or revocation of your facility's FDA certificate; or obtaining a court injunction against further mammography.

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 all of the violations noted in this letter;
- ◆ Each step your facility is taking to prevent the recurrence of similar violations;
- ◆ Equipment settings (include technique factors), raw test data, and calculated final results, where appropriate;
- ◆ Sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records. (Note: Patient names or identification may be deleted from any copies submitted.)

Please submit your response to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: Wiley T. Williamson, III
Compliance Officer

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to deficiencies noted during the 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, Maryland 21045-6057 (1-800-838-7715), or through the Internet at <http://www.fda.gov>.

Dr. Stephen Raskins
Page 3
November 17, 1998

If you have any specific questions concerning mammography facility requirements or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, Ext. 159.

Sincerely yours,


Carl E. Draper
Acting District Director