



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration  
158 - 15 Liberty Avenue  
Jamaica, New York 11433

WARNING LETTER

November 9, 2000

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

REF : NYK-2001-17

Barry Meisel, MD  
Chief Executive Officer (CEO)  
Westchester Gynecologists & Obstetricians, P. C.  
170 Maple Avenue, Suite #309  
White Plains, New York 10601

Facility ID : 166983

Dear Dr. Meisel:

Your facility was inspected on October 18th, 2000 by a representative of the New York State Department of Health, acting on behalf of the Food & Drug Administration. This inspection has revealed serious regulatory problems involving the mammography operation at your facility. Under a United States Federal Law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for conducting a mammography operation. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures. The inspection revealed the following repeat Level 2 finding at your facility:

- 1. The medical physicist's survey for x-ray unit 2, General Electric, Co. (GE Medical Systems) in the Mammography Room is incomplete because the decompression test was not done.*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of a problem found during your previous inspection.

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Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography operations at your facility, it represents a 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, MQSA standards, suspension or revocation of your facility's FDA Certificate, or obtaining a court injunction against further mammography operations.

There were also non-repeat Level 2 findings listed on the inspection report provided to you at the close of the inspection. The Level 2 findings were:

1. *One (1) of six (6) randomly reviewed reports did not contain an assessment category for the Westchester Gynecologists & Obstetricians, P. C. site.*
2. *The medical physicist's survey for x-ray unit 2, General Electric, Co. also lacked:*
  - *An artifact evaluation*
  - *A beam quality (HVL) measurement*
    - a) *Test not done at the kVp*
    - b) *Numerical results were not given*

It is necessary for you to act on these matters 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; and
- Sample of records that demonstrate proper record keeping procedures.

Please submit your response to the above issues to the attention of Arthur S. Williams, Jr., Compliance Officer, U. S. Food & Drug Administration, 158 - 15 Liberty Avenue, Jamaica, New York 11433, Tel. (718)/662-5568.

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Finally, you should understand that there are many FDA requirements pertaining to an mammography operations. This letter pertains only to the findings of our 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 & Drug Administration, P. O. Box 6057, Columbia, Maryland 21045-6057, 1(800)/838-7715, or through the Internet address of <http://www.fda.gov>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'E. W. Thomas', with a long horizontal flourish extending to the right.

Edward W. Thomas  
Acting District Director  
New York District

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cc: Ms. Priscilla F. Butler, M.S.  
Director, Breast Imaging Accreditation Programs  
Standards and Accreditation Department  
American College of Radiology  
1891 Preston White Drive  
Reston, Virginia 22091

cc: Mr. Gerald O'Connor  
New York State Department of Health  
Bureau of Environmental Radiation Protection  
Flanigan Square - Room #530  
547 River Street  
Troy, New York 12180

cc: Nelson Warren  
New York State Department of Health  
Bureau of Environmental Radiation Protection  
145 Huguenot Street – Suite #500  
New Rochelle, New York 10801