



DEPARTMENT OF HEALTH & HUMAN SERVICES

1679d

New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

August 29, 2001

WARNING LETTER NYK 2001-117

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Laura A. Altieri  
Mammography Coordinator  
United Hospital Medical Center  
406 Boston Post Road  
Port Chester, New York 10573

RE: Facility ID Number 144261

Dear Ms. Altieri:

Your facility was inspected on August 27, 2001 by a representative of the New York State Department of Health, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed serious regulatory problems involving the mammography 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 health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 and Repeat Level 2 findings at your facility:

- *Failure to produce documents verifying the interpreting physician [REDACTED] met the initial requirement of being certified in the appropriate specialty by an FDA-approved board or having 2 months of initial training in the interpretation of mammograms prior to April 28, 1999. (Level 1)*
- *Failure to produce documents verifying the interpreting physician [REDACTED] met the initial requirement of holding a valid state license to practice medicine. (Level 1)*
- *One (1) of six (6) mammography reports reviewed at random did not contain an acceptable assessment category. (Repeat Level 2)*

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 and Repeat Level 2 because they identify a failure to meet significant MQSA requirements. In addition, the Repeat Level 2 observation indicates a failure by your facility to implement permanent correction of a problem found during your previous inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography 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, 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 that you receive this letter each step your facility is taking to correct these violations and to prevent the recurrence of similar violations.

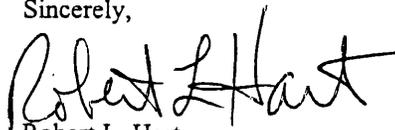
Your response should address the Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings are:

- *The medical physicist's survey for x-ray unit [REDACTED], is incomplete because an artifact evaluation was not conducted.*
- *Failure to produce documents verifying the interpreting physician [REDACTED] met the continuing education requirement of having taught or completed at least 15 category 1 continuing medical education units in mammography in 36 months.*
- *Failure to produce documents verifying the interpreting physician [REDACTED] met the initial requirement of having 40 hours of medical education in mammography prior to April 28, 1999.*
- *Failure to produce documents verifying the interpreting physician [REDACTED] met the initial experience requirement of having interpreted or multi-read 240 mammograms in six(6) months.*
- *Failure to produce documents verifying the interpreting physician [REDACTED] met the initial requirement of having 40 hours of medical education in mammography prior to April 28, 1999.*
- *Failure to produce documents verifying the interpreting physician [REDACTED] met the requirement of having eight (8) hours of training in the new mammographic modality.*
- *Failure to produce documents verifying the radiologic technologist [REDACTED] met the continuing experience requirement of having 200 mammography examinations in 24 months.*
- *Failure to produce documents verifying the medical physicist [REDACTED] met the continuing experience requirement of having surveyed at least two (2) mammography facilities and a total of at least six (6) mammography units in 24 months.*

Please submit your response to the above issues to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, NY 14202, telephone (716) 551-4461 ext. 3117.

Finally, you should understand 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 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>.

Sincerely,



Robert L. Hart  
Acting District Director

United Hospital Medical Center  
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cc: Priscilla F. Butler, M.S.  
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