



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g1081d

19900 MacArthur Blvd., Ste 300  
Irvine, California 92612-2445  
Telephone (949) 798-7600

## WARNING LETTER

**Certified Mail**  
**Return Receipt Requested**

March 21, 2001

Thanh G. Phung, M.D.  
Perris Medical Imaging Center, Inc.  
126 Avocado Avenue; Suite #105  
Perris, CA 92571

W/L Number: 30 - 01  
Inspection ID: 2241900001

Dear Dr. Phung:

We are writing to you because on February 21, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. Food and Drug Administration (FDA). 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 Level 1 findings at your facility:

- Level 1: The system to communicate mammography results is not adequate because there is no system in place to provide timely medical reports nor any system in place to communicate serious or highly suggestive mammography result cases as soon as possible to the patient's physician.
- Level 1: Your mammography facility could not demonstrate, via documentation during the inspection and a repeated verbal request for such documentation after the inspection was completed, that the interpreting physician, [REDACTED], met the requirement of being licensed by a State to practice medicine.

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 because they identify a failure to meet a significant MQSA requirement.

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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, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

In addition, your response should address the Level 2 findings that were listed on the inspection report provided to you at the close of the inspection. These Level 2 findings are:

- Level 2: 3 of 10 random reports reviewed did not have identification of a qualified interpreting physician.
- Level 2: 7 of 10 random reports reviewed did not contain an assessment category.
- Level 2: The interpreting physician, [REDACTED] did not meet the requirement of having initial experience in mammography (read or interpreted 240 patient examinations in a 6 month period).
- Level 2: The interpreting physician, [REDACTED], did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period.
- Level 2: The interpreting physician, [REDACTED], did not meet the requirement of having a minimum of 40 CME credit hours of initial training in mammography.
- Level 2: A performance verification test was not conducted after each move for mobile unit #2 (a [REDACTED] machine, model [REDACTED]) located in room #T-350.
- Level 2: There were no examples of nor attempts to get biopsy results.

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:

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- 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; and
- please provide 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). Please further note that we are also specifically requesting documentation that Dr. [REDACTED], that your facility employs and/or did employ, is currently licensed to practice medicine in your State of operation.

Please submit your response to:

Thomas L. Sawyer  
Director, Compliance Branch  
U.S. Food & Drug Administration  
19900 MacArthur Blvd.; Suite #300  
Irvine, CA 92612-2445  
Phone: (949) 798-7600

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 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 more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas (MQSA Auditor) at telephone number (949) 798-7708.

Sincerely,



Alonza E. Cruse  
District Director

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cc:

State of California  
Dept. of Health Services  
Radiological Health Unit  
1800 East Lambert; Suite #125  
Brea, CA 92821