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Irvine, California 92612-2445
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FEB 22 2000

WARNING LETTER

Certified Mail
Return Receipt Requested

WL-28-00

Stuart Strausberg, M.D.
Panorama Diagnostic & Imaging
8121 Van Nuys Boulevard
Panorama City, CA 91402

Inspection ID: 1850820008

Dear Dr. Strausberg:

We are writing to you because on 12/17/1999, your facility was inspected by a representative of the state of California, acting in behalf of the 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 (MQSA) 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 findings at your facility:

1. **Processor QC records were missing 4 out of 4 days of operation in month 11/1999**
 - **Processor QC records missing 100%, for processor 0000000001, Fuji, FPM 4000, room Darkroom at site Panorama Diagnostic & Imaging**

According to the inspector's notes recorded at the time of the inspection, processor testing is not performed on the Saturdays when mammograms are processed. She also noted that the person assigned to be the facility's quality control technologist is not a qualified mammography technologist, as required by 21 CFR 900.12(d)(1)(iv). This technologist, who also performs processor quality control testing, does not work on the Saturdays when mammography is performed and the films are processed.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. This problem is identified as Level 1 because it identifies a failure to meet a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography 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 performing 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:

1. **The x-ray system for unit 1, General Electric Co. (GE Medical Systems), OTH, room Mammo does not include the following:**
 - **Image receptors for 2 sizes**
2. **The phantom image score (using an FDA-approved mammography phantom) is at least 2 but is less than 3 specks groups for unit 1, General Electric Co. (GE Medical Systems), OTH, room Mammo**
3. **There is no written procedure for handling consumer complaints at site Panorama Diagnostic & Imaging**
4. **There is no written procedure for infection control at site Panorama Diagnostic & Imaging**
5. **Processor QC records were missing 4 consecutive days for processor 0000000001, Fuji, FPM 4000, room Darkroom at site Panorama Diagnostic & Imaging**
6. **The phantom QC is not adequate for unit 1, General Electric Co. (GE Medical Systems), OTH, room Mammo because:**
 - **The operating level for background density was < 1.20**
7. **The interpreting physician did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24 month period: [REDACTED]**
8. **The radiologic technologist did not meet the continuing education requirement of having completed a min. of 15 CEUs in mammography in a 36 month period: [REDACTED] (12 CEU's in 36 months)**
9. **The radiologist technologist did not meet the requirement of having 40 supervised hours of training in mammography: [REDACTED]**
10. **5 of 5 random reports reviewed did not contain an assessment category for site Panorama Diagnostic & Imaging**
11. **Not all positive mammograms were entered in the tracking systems for site Panorama Diagnostic & Imaging**
12. **There were no examples of nor attempts to get biopsy results for site Panorama Diagnostic & Imaging**

At the time of your inspection, the inspector requested information regarding your system for providing mammography reports to patients and referring physicians within 30 days after the examination, to make reasonable attempts to ensure that the results are communicated to the

patient or referring physician as soon as possible, when the assessment is classified as "Suspicious" or "Highly suggestive of malignancy" and to send each patient a summary of the mammography report written in lay terms within thirty days of the mammographic examination. They had requested information or written procedures of the process your facility uses to meet these requirements, but could not get specific answers to what your procedures are to meet these requirements.

In your response to this Warning Letter, please explain your process for the issuance of mammography reports and lay summaries to meet the requirements outlined in the above paragraph. Please also include an explanation of your procedure for contacting patients with mammographic assessments is classified as "Suspicious" or "Highly suggestive of malignancy."

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.

Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445
Fax (949) 798-7771

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/cdrh/dmqrp.html> <<http://www.fda.gov/cdrh/dmqrp.html>>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas at (949) 798-7708 or Minh Phan at (949) 798-7711.

Sincerely,


Acting District Director