



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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JUN 3 0 2000

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

WARNING LETTER

CERTIFIED MAIL- RETURN RECEIPT REQUESTED

Sim Hoffman, M. D., Owner
Advanced Professional Imaging Medical Group
585 South Knott Avenue
Anaheim, CA 92804

W/L -66-00
Inspection ID: 1004380008

Dear Mr. Hoffman:

We are writing you because on June 27th, 2000, your facility was inspected by a representative of the State of California, acting on behalf of the Food and Drug Administration (FDA) and 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 the facility can perform quality mammography. The inspection revealed the following level 1 findings at your facility:

1. **The interpreting physician did not meet the requirement of being licensed by a State to practice medicine:** [REDACTED]
2. **The medical physicist did not have a Master's degree or higher in a physical science, with 20 semester hours in physics:** [REDACTED]

The specific problems noted above appeared on your MQSA Facility Inspection Report which your facility received at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions 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 you at the close of the inspection. These Level 2 findings are:

1. **The interpreting physician did not meet the requirement having initial experience in mammography (read or interpreted 240 patient examinations in a 6-month period):** [REDACTED]
2. **The interpreting physician did not meet the continuing experience requirement of having to read or interpret 960 patient examination in a 24-month period:** [REDACTED]
3. **The medical physicist did not meet the requirement of conducting surveys for at least one facility and 10 units:** [REDACTED]
4. **The medical physicist did not meet the requirement of having a minimum of 20 contact hours of training in conducting surveys:** [REDACTED]

It is necessary for you to act on this matter immediately. Please explain the following elements to this office within fifteen (15) working days from the date you received 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 recurrence of similar violations,
- Equipment settings (including 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 should be deleted from any copies submitted**).*

Letter to Mr. Hoffman
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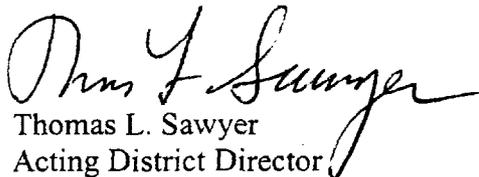
Please submit your response to:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd. Suite 300
Irvine, CA 92612-2445

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings on 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/dmgrp.html>.

If you have 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,


Thomas L. Sawyer
Acting District Director

cc: County of Los Angeles
Department of Health Services
Radiation Management
550 South Vermont Avenue, Room 600
Los Angeles, CA 90020

Jim Potter
Director, Government Relations
American College of Radiology
1891 Preston White Drive
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