DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
93542d

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

WARNING LETTER

October 8, 2002

Certified Mail
Return Receipt Requested

John P. Anderson, M.D.
Medical Director
West Anaheim Medical Center
3033 West Orange Avenue
Anaheim, CA 90602-3156

W/L Number: 01 - 03
Inspection ID: 1461340008
CFN: 20-29,741
FEI: 1000519547
FACTS: 14972-0

Dear Dr. Anderson:

On September 10, 2002, a representative of the State of California, acting on behalf of the Food and Drug Administration ("FDA") inspected your facility. This inspection revealed serious problems involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 ("MQSA"), which is codified in Section 263b of Title 42 of the United States Code, your facility must meet specific requirements to practice mammography. These requirements help to protect the health of women by assuring that a facility can perform quality mammography.

The inspection revealed violations of the MQSA at your facility. These violations were noted on the MQSA Facility Inspection Report (*"Important Information about your Mammography Quality Standards Act (MQSA) Inspection"*) that the inspector left at your facility at the close of the inspection on September 10th. The report revealed two REPEAT Level 2 findings and one new Level 2 finding at your facility:

Level 2 - Failed to produce documents verifying that the radiologic technologist [redacted] met the continuing experience requirement of having performed 200 mammography examinations in 24 months. This is a REPEAT violation under Title 21, Code of Federal Regulations, Section 900.12(a)(2)(iv)(A).

Level 2 - Failed to produce documents verifying that the radiologic technologist [redacted] met the continuing experience requirement of having performed 200 mammography examinations in 24 months. This is a REPEAT violation under Title 21, Code of Federal Regulations, Section 900.12(a)(2)(iv)(A).

Level 2 - The facility has not specified adequate written procedures for collecting and resolving consumer complaints. Specifically, the letter to inform the patients/complainants where to address unresolved consumer complaints indicates, incorrectly, the American College of Radiology as your accrediting body. Your mammography facility's accrediting body is the State of California. This is a violation of Title 21, Code of Federal Regulations, Sections 900.12(h)(1) through (4).

This inspection was a follow up to an earlier inspection on July 19, 2001. The follow up inspection indicated that problems that the inspector identified during the initial inspection were not adequately addressed and that additional problems were identified.

Because these violations may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional actions, including, but not limited to, the following:

- requiring your facility to undergo an Additional Mammography Review
- placing your facility under a Directed Plan of Correction
- charging your facility for the cost of on-site monitoring
- seeking civil money penalties of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards
- seeking to suspend or revoke your facility's FDA certificate
- seeking a court injunction against your facility.

See Title 42, United States Code, Sections 263b(h)-(j) and Title 21, Code of Federal Regulations, Section 900.12(j).

You should respond in writing to FDA within fifteen (15) working days from the date you received this letter. Your response should include:

1. the specific steps you have taken, or will take, to correct all of the violations noted in this letter, including projected timeframes for implementing those steps;

2. the specific steps you have taken, or will take, to prevent the recurrence of similar violations, including projected timeframes for implementation of those steps;

3. please provide sample records that demonstrate proper record keeping procedures.

Note: patient names and other information that would likely reveal the patient's identity should be deleted from any copies of records you submit.

We are concerned about the repeat violations. Your response should specifically address the repeat violations and explain why they were not corrected before the September 10, 2002, inspection. Please also identify who, by name and title, had the responsibility and authority for implementing the corrections. [redacted] from your facility, wrote us a letter on July 24, 2001 (pertaining to the year 2001 inspection) stating in part, "Immediately following the inspection, we documented each mammographer's experience.***A log has been created and a section has been added to our QC Journal to keep future totals current." Please specifically explain why this "log" was not current and what revisions, if any, have been or will be implemented to prevent recurrence of these repeat violations. Please provide copies of the revised quality assurance and/or quality control procedures detailing how this log should be maintained and by whom. Finally, if the two mammography radiologic technologists have not been requalified under Title 21, Code of Federal Regulations, Section 900.12(a)(2)(iv)(B), please advise whether these two individuals are still performing mammography examinations at your facility.

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

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 (telephone number: 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 this letter, feel free to contact Scott Goff (the Compliance Officer assigned to this case) at telephone number 949-798-7644.

Sincerely,

Alonza E. Cruse
District Director

cc:

Ms Sarah Svob
State of California
Dept. of Health Services
Radiological Health Unit; Region #5
1800 East Lambert; Suite #125
Brea, CA 92821-4370

Edward W. Gloor
Director and Health Physicist
Inspection Compliance and Enforcement
State of California
Department of Health Services
Radiologic Health Branch; Mammography Program
P.O. Box 942732, MS-178
Sacramento, CA 94234-7320