DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93691d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (714) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

November 6, 2002

William Duge, M.D.
Radiology Supervisor
Riverside Medical Clinic, Inc.
7160 Brockton Avenue
Riverside, CA 92506-2614

W/L Number: 06 - 03
Inspection ID: 1691100009
CFN: 20-29,890
FEI: 1000519093
FACTS: 15019-0

Dear Dr. Duge:

We are writing to you because on September 11, 2002, your facility was inspected by a representative of the State of California acting on behalf of the U. S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b , and the Quality Standards for Mammography set forth in Title 21, Code of Federal Regulations (21 C.F.R.), Part 900, 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 two repeat Level 2 violations and three initial Level 2 violations at your facility:

Level 2 - Failed to produce documents verifying that the radiologic technologist, [redacted] (10 continuing education units [CEU's] in 36 months), met the continuing education requirement of having taught or completed at least fifteen (15) continuing education units in mammography in thirty-six (36) months. This is a **REPEAT** violation of 21 C.F.R section 900.12(a)(2)(iii)(A).

Level 2 - Medical audit and outcome analysis was not done for the facility as a whole. This is a **REPEAT** violation of 21 C.F.R. section 900.12(f)(1).

Level 2 - The facility has not specified adequate procedures to be followed for infection control or did not follow them when required. This is a violation of 21 C.F.R. section 900.12(e)(13) and 21 C.F.R. 900.12(e)(13)(i) through (iii).

Level 2 - Failed to produce documents verifying that the interpreting physician, [redacted] (12 continuing medical education [CME's] in 36 months), met the continuing education requirement of having taught or completed at least fifteen (15) category 1 continuing medical education units in mammography in thirty-six (36) months. This is a violation of 21 C.F.R. section 900.12(a)(1)(ii)(B).

Level 2 - 1 of 10 random reports reviewed did not contain an acceptable assessment category. This is a violation of 21 C.F.R. section 900.12(c)(1).

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. 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 that may result in FDA imposing regulatory sanctions. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction (DPC) and/or charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly could also cause FDA to seek 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, suspension or revocation of your facility's FDA certificate, or a court injunction against performing further mammography (see 42 U.S.C. § 263b(h) through (j) of the MQSA)

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:

- 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;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

- please submit 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).

Your response should also specifically address the repeat violations which were not corrected from the previous inspection in August 2001. We are requesting why these repeat violations were not corrected prior to the inspection of September 11, 2002 and who, by name and title, had the responsibly and authority for implementing the correction. On August 17, 2001 Ms [redacted] (Director of Ancillary Services), of your facility, wrote us, in response to your 2001 year inspection, stating in

part "Also, from this time forward our Mammography Technicians will not perform mammography without documentation of 15 CME's.". We would like to know why your assurance to us was not fulfilled.

In accordance with 21 C.F.R. section 900.12(a)(2)(iii)(D), radiologic technologists who fail to meet the continuing education requirements may not resume performing unsupervised mammography examinations until the continuing education requirements are completed. Further, in accordance with 21 C.F.R. section 900.12(a)(1)(iv), interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall re-establish their qualifications before resuming the independent interpretation of mammograms.

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 (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 the content of this letter, please 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