DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

# WARNING LETTER

October 22, 2002

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

John Stef, M.D.
Chief Radiologist
Santa Paula Memorial Hospital
825 North 10th Street
Santa Paula, CA 93060-1309

W/L Number: 04 - 03
Inspection ID: 1352770008
CFN: 20-29,673
FEI: 1000518904
FACTS: 15239-0

Dear Dr. Stef:

On September 19, 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 19th. The inspection revealed three Level 1 and one Level 2 findings at your facility:

Level 1 - Processor quality control ("QC") records in the month of March 2002 were missing for twenty-one (21) operating days, which is 100% of the operating days when patients' mammograms were developed using processor #1 (a [redacted] machine, model [redacted]), which is located in the facility's main room. This is a violation of Title 21 Code of Federal Regulations sections 900.12(d)(2) and 900.12(e)(1).

Level 1 - Processor QC records were missing at least five (5) consecutive days for processor #1 (a [redacted] machine, model [redacted]) which is located in the facility's main room. This is a violation of Title 21 Code of Federal Regulations sections 900.12(d)(2) and 900.12(e)(1).

Level 1 - Phantom QC records were missing for twelve (12) weeks for unit #2 (a [redacted] machine, model [redacted], serial number [redacted]) which is located in the mammography room. This is a violation of Title 21 Code of Federal Regulations section 900.12(e)(2).

Level 2 - Corrective actions for processor QC failures were not documented at least once for processor #1 (a [redacted] machine, model [redacted]) which is located in the facility's main room. This is a violation of Title 21 Code of Federal Regulations section 900.12(e)(3)(ii).

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 ("DPC")
- 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; and,

3. 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.**

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, U. S. 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