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1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

Certified Mail
Return Receipt Requested

August 2, 2001

Russell B. Sadler, M.D.
Radiologist
Sadler Radiology Medical Corporation
72-855 Fred Waring Drive
Palm Desert, CA 92260

W/L Number: 61 - 01
Inspection ID: 2124720006
CFN: 2031587

Dear Dr. Sadler:

We are writing to you because on June 6, 2001, your facility was inspected by a representative of the State of California acting in behalf of the U. S. 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 of 1992 (MQSA), 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:

- Level 1: Phantom quality control (QC) records were missing for thirteen weeks (13) between the phantom test performed on November 14, 2000 through the test performed on February 14, 2001 for unit #1 (a [REDACTED] machine, model [REDACTED], serial number [REDACTED]) which is located in the mammography room.

- Level 1: Processor QC records for November 4, 8, 9, 10, 18 of the year 2000 were missing for at least 30% of operating days for processor #1 (a [REDACTED] machine, model [REDACTED]) which is located in the darkroom. On those missing dates, the X-ray film processor was developing mammography films for your patients.

- Level 1: Patient mammograms were processed in processor #1 (a [REDACTED] machine, model [REDACTED]), which is located in the darkroom, when it was

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out of limits on at least the following five (5) days: March 23rd, April 11th, April 16th, April 19th, and April 20th of the year 2001.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility 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, they represent a serious 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 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:

- Level 2: Corrective action before further exams, for a failing image score, or a phantom background optical density, or density difference outside the allowable regulatory limits, was not documented for unit #1 (a [REDACTED] machine, model [REDACTED], serial number [REDACTED]) which is located in the mammography room.
- Level 2: Processor QC records were missing at least two (2) but less than five (5) consecutive days for processor #1 (a [REDACTED] machine, model [REDACTED]) which is located in the darkroom.
- 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 darkroom.
- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the continuing experience requirement of having interpreted or multi-read 960 mammograms in twenty-four (24) months.

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- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED], met the initial requirement of having forty (40) hours of medical education in mammography prior to April 28, 1999.
- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED] met the initial experience requirement of having interpreted or multi-read 240 mammograms in six (6) months.
- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED] met the continuing experience requirement of having interpreted or multi-read 960 mammograms in twenty-four (24) months.
- Level 2: Failed to produce documents verifying that the interpreting physician, [REDACTED] (11.5 continuing medical education [CME's] in thirty-six [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.
- Level 2: 8 of 10 random reports reviewed did not contain an acceptable assessment category.

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; and
- please provide 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).

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

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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 Beverly Thomas (MQSA Auditor) at telephone number 949-798-7708.

Sincerely,



Alonza E. Cruse
District Director

cc:

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