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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

Certified Mail
Return Receipt Requested

April 29, 2002

Dennis Brown, C.R.T.
Director of Diagnostic Imaging
San Gabriel Medical Center
438 West Las Tunas Drive
San Gabriel, CA 91776-1216

W/L Number: 39- 02
Inspection ID. 1350380017
CFN: 20-29,663
FEI: 1000518914

Dear Mr. Brown:

A representative of the State of California acting under contract to the U. S. Food and Drug Administration (FDA) inspected your facility on February 27, 2002. 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), 42 U S.C. § 263b, 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: Processor quality control (QC) records for processor #1 (a [redacted] machine), which document the performance of processor QC testing, were missing for at least thirty percent (30%) of the operating days from July 17th through 24th of the year 2001. (see Title 21 Code of Federal Regulations section 900.12(e)(1)).

- Level 1: Processor QC records for processor #1 (a [redacted] machine), which document the performance of processor QC testing, were missing at least five (5) consecutive days in the month of July 2001. (see Title 21 Code of Federal Regulations section 900.12(e)(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. 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 (DPC), 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. (see 42 U.S.C. § 263 (h)-(j)).

In addition, Level 2 and repeated Level 3 findings were listed on the inspection report provided to you at the close of the inspection. A Level 2 finding indicates that the inspector did find deviations from MQSA standards that, although less severe than those comprising Level 1, still may compromise the quality of mammography services offered at your facility. These Level 2 and repeated Level 3 findings are:

- Level 2: Phantom QC records for unit #3 (a [redacted] machine, serial number [redacted]) which document the weekly performance of Processor QC testing were missing for at least two weeks but less than four weeks. (see Title 21 Code of Federal Regulations section 900.12(e)(2)).

- Level 2: The mammography processor equipment evaluation (by a medical physicist) for processor #1 (a [redacted] machine) was not performed. (see Title 21 Code of Federal Regulations section 900.12(e)(9)).

- 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 #3 (a [redacted] machine, serial number [redacted]). (see Title 21 Code of Federal Regulations section 900.12(e)(3)(ii)).

- Level 3: The required personnel qualification documents were not available during the inspection. This is a **REPEAT** violation. (see Title 21 Code of Federal Regulations section 900.12(a)(4)).

In reference to this repeat violation, your inspection on February 5, 2001 (Inspection ID number: 1350380016) found the identical type of problem. Your response letter of April 16, 2001 explained that all required personnel records were now available and stored at your facility.

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 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).

Your response should also specifically address the repeat violation that was not corrected from the previous inspection in February 2001. We are requesting an explanation why this repeat violation was not corrected prior to the inspection of February 27, 2002. Additionally, who, by name and title, had the responsibility and authority for implementing the correction.

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

re: San Gabriel Medical Center
re: Warning Letter Number 39 – 02

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

cc:

Kathleen A. Kaufman, Director
State of California
Department of Health Services
Radiological Management Health Unit
3530 Wilshire Blvd.; 9th Floor
Los Angeles, CA 90010-2310