DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

January 28, 2002

Lawrence DiCapua, M.D.
Medical Director
Hemet Valley Medical Center
1117 East Devonshire Avenue
Hemet, California 92543-3084

W/L Number: 25 - 02
Inspection ID: 1530150007
CFN: 2029787
FEI: 1000519501

Dear Dr. DiCapua:

We are writing to you because on January 8, 2002, 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 specific problem, noted below, appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as REPEAT Level 2 because it identifies a failure to meet a significant MQSA requirement.

- 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 #2 (a Lorad Medical Systems Inc. machine, model MIV, serial number 19403991434) which is located in the mammography room. Specifically, on May 22nd and November 26th of 2001, the X-ray unit was out of compliance with no corrective action documented for May 22, 2001. Additionally,. on May 28, 2001 it was determined that a phantom check was missed, and on June 4, 2001 a phantom check was performed with no corrective action documented for that May 28, 2001 problem omission. This is a **REPEAT** violation.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents 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.

In addition, your response should address the Level 2 finding that was listed on the inspection report provided to you at the close of the inspection. This Level 2 finding is:

- Level 2: Medical audit and outcome analysis was not done for the facility as a whole.

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).

Further, on January 30, 2001, your facility was MQSA inspected (Inspection ID number 1530150006) and a similar like problem, as cited under REPEAT Level 2 herein, was observed. On February 8, 2001, Ms Helen J. King (Lead Mammography Technologist), of your medical facility, wrote us. The proposed corrective action, in her letter, reads in part "***It was found***I had not documented the corrective actions taken and had not documented the retesting of the phantom***. To avoid this in the future, I will highlight the +/- limits on my graphs and will document the retesting of the phantom and the corrective actions taken***. Because of her willingness to correct the problem in the 2001 inspection, we closed out the inspection with a letter to her dated February 20, 2001.

We are concerned that the problem has recurred and, additionally, your facility's corrective action plan has been, presumably, ineffective. Therefore, your response should specifically explain why the proposed corrective action, in January 2001, did not

solve the problem noted in the January 2002 inspection. Also, how has your quality assurance procedure(s) been revised and validated to permanently correct this recurring event?

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 yours,

Alonza E. Cruse
District Director