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**Department of Health & Human Services**  
**DEPARTMENT OF HEALTH & HUMAN SERVICES**  
Public Health Service  
**Food and Drug Administration**  
SOUTHWEST REGION

Office of the Regional  
Food and Drug Director  
7920 Elmbrook Drive, Suite 102  
Dallas, TX 75247-4982  
TELEPHONE: 214-655-8100  
FACSIMILE: 214-655-8130

March 14, 2000

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

00-SWR-WL-43/8

Steven R. Horn, M.D.  
Chief Radiologist  
Wyoming Medical Center  
1233 E. 2<sup>nd</sup> Street  
Casper, WY 82601

RE: Inspection ID – 1559520005

Dear Dr. Horn,

On January 31, 2000 a representative of the State of Wyoming, acting in behalf of the Food and Drug Administration (FDA) inspected your facility. This inspection revealed a serious regulatory problem involving the mammography at your facility.

The Mammography Quality Standards Act of 1992 requires your facility to meet specific standards. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 and level 2 findings at your facility:

Level 1: Phantom QC records were missing for 10 weeks for unit 2, General Electric Co. (GE Medical Systems).

Level 1: Processor QC records were missing 5 consecutive days for processor 1, Kodak, X-OMAT.

Level 2: There is no written procedure for handling consumer complaints at the site.

Level 2: There is no written procedure for infection control at the site.

Level 2: Corrective actions for processor QC failures were not documented at least once for process 1, Kodak, X-OMAT.

Level 2: Processor QC records were missing 5 out of 22 days of operation in month 06/1999. Processor QC records missing 23%, for processor 1, Kodak, X-OMAT.

Level 2: Corrective action for a failing image score (before further exams) was not documented for unit 2, General Electric Co. (GE Medical Systems).

Level 2: The phantom QC is not adequate for unit 2, General Electric Co. (GE Medical Systems) because: The image was not taken at clinical setting.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Level 1 findings may be symptomatic of serious underlying problem 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. 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, the Standards.
- Suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. You are required to respond to this office in writing within fifteen (15) working days from receipt of this letter. Please address the following:

- 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.
  
- 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:  
Deborah M. McGee, Radiation Specialist  
Food and Drug Administration  
7920 Elmbrook Drive, Suite 102  
Dallas, TX 75247-4982

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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 (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 Ms. McGee at (214) 655-8100, extension 138.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Edward R. Esparza', with a stylized flourish at the end.

Edward R. Esparza  
Regional Food and Drug Director