DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service 932824

Food and Drug Administration
Southwest Region
7920 Elmbrook Drive
Suite 102
Dallas, TX 75247-4982

Telephone: 214-655-8100
FAX: 214-655-8130

May 13, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

02-SWR-WL-42/8

Filbert Garduno
Radiology Director
Mt. San Rafael Hospital
410 Benedicta Ave.
Trinidad, CO 81082

Re: Inspection ID - 1747140012

Dear Mr. Garduno:

We are writing to you because on April 16, 2002, your facility was inspected by a representative of the State of Colorado, acting on behalf of the U.S. Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under 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 violations of the MQSA at your facility:

Level 1: Mammograms were processed in processor 1, Konica (Sakura), SRX 301, when it was out of limits on at least 5 days. (see 21 CFR 900.12(e)(1)).

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. A Level 1 or repeated Level 2 finding indicates that the inspector found one or more deviations from MQSA standards that may seriously compromise the quality of mammography services offered by the facility.

In addition, the inspection report provided to you at the close of the inspection listed the following Level 2 violation, which may compromise the quality of mammography services offered by the facility:

Level 2: The x-ray unit 3, General Electric Co. (GE Medical Systems), DMR, is not accredited. (see 21 CFR 900.4©(4)(I), 900.4(d)(4), and (900.12(b)(2)).

The inspection also revealed a Level 3 violation, a minor deviation from MQSA Standards:

Level 3: The compression device quality control (QC) tests were not done at the required frequency (see 21 CFR 900.12(e)(4)).

Because some of these violations may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent serious violations 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 (see 42 U.S.C. §§ 263b(h)-(j)).

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:

1. the specific steps you have taken to **correct** all of the violations noted in this letter;

2. each step your facility is taking to **prevent the recurrence** of similar violations;

3. equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and

4. 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:

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

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 (1-800-838-7715) or through the Internet at http://www.fda.gov/cdrh/mammography/index.html.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Deborah M. McGee at (214) 655-8100 extension 138.

Sincerely yours,

Gary L. Pierce
Regional Food and Drug Director