DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

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

July 10, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

02-SWR-WL-49/7

Davey Hawthorne
Imaging Center Supervisor
The Imaging Center of Baxter Regional Medical Center
639 Broadmoore Circle
Mountain Home, AR, 72653

Dear Mr. Hawthorne:

Re: Inspection ID - 2222550003--Imaging Center & 2246580001--Mobile

We are writing to you because on May 29, 2002, a representative of the State of Arkansas, acting on behalf of the Food and Drug Administration (FDA), inspected your facilities. This inspection revealed serious regulatory problems involving the mammography at your facilities. Under the Mammography Quality Standards Act of 1992 (MQSA or the Act), 42 U.S.C. § 263b, and its implementing regulations set forth in Title 21, Code of Federal Regulations (CFR), Part 900, your facilities 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 at your facilities:

The Imaging Center of Baxter Regional Medical Center

Level 1: Processor QC records in the month of 1/2002 were missing for at least 30% of operating days, for processor 1, Kodak, RP X-OMAT, darkroom. (See 21 CFR 900.12(e)(1))

Level 1: Processor QC records in the month of 1/2002 were missing for at least 30% of operating days, for processor 2, Kodak, room ML 2000. (See 21 CFR 900.12(e)(1))

Level 1: Processor QC records were missing at least 5 consecutive days for processor 1, Kodak, RP X-OMAT, darkroom. (See 21 CFR 900.12(e)(1))

Level 1: Processor QC records were missing at least 5 consecutive days for processor 2, Kodak, room ML 2000. (See 21 CFR 900.12(e)(1))

Level 1: Phantom QC records were missing for at least 4 weeks for unit 1, Siemens Medical Systems, M3K, room Mammography. (See 21 CFR 900.12(e)(2))

Level 1: Phantom QC records were missing for at least 4 weeks for unit 2, Siemens Medical Systems, M3K, room 2. (See 21 CFR 900.12(e)(2))

Baxter Regional Medical Center -- Mobile

Level 1: Processor QC records in the month of 3/2002 were missing for at least 30% of operating days, for processor Mobile Daylight, Kodak. (See 21 CFR 900.12(e)(1))

Level 1: Processor QC records were missing at least 5 consecutive days for processor Mobile Daylight, Kodak. (See 21 CFR 900.12(e)(1))

Level 1: Phantom QC records were missing for at least 4 weeks for unit 1, Siemens Medical Systems, NOVA, room Mobile. (See 21 CFR 900.12(e)(2))

The specific problems 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.

Because these conditions 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 imposing statutory sanctions without further notice to you. These sanctions include, but are not limited to, placing your facility under a Directed Plan of Correction and/or charging your facility for the cost of on-site monitoring. Failure to correct these violations promptly could also cause FDA to seek civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the MQSA Standards, seek suspension or revocation of your facility's FDA certificate, or seek a court injunction against further mammography (see sections 263b(h) through (j) of the Act).

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. 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**).

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which corrections will be completed. 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 certain findings of your inspection and does not necessarily address other obligations you have under the law, including, but not limited to, correcting the other violations cited on your MQSA Facility Inspection Report. 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, ext. 138.

Sincerely yours,

Gary L. Pierce
Regional Food and Drug Director

Cc: Steve Erickson
Administrator
Baxter Regional Medical Center
624 Hospital Drive
Mountain Home, AR 72653