



DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

m30847

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

WARNING LETTER

October 7, 1999
Certified Mail
Return Receipt Requested

99-SWR-WL-34/7

Frank Andrajack
Director of Outreach Imaging
United Diagnostic Center
1518 9th Street
Wichita Falls, TX 76301

RE: Inspection ID – 1851080003- United Regional Health Care System, Inc.
1600 8th Street, Wichita Falls, TX

1531550005-United Regional Health Care System, Inc.
1600 10th Street, Wichita Falls, TX

1638990006-United Regional Health Care System, Inc.
1600 11th Street, Wichita Falls, TX

1987210006-United Regional Health Care Systems, Inc.-MOBILE
1600 11th Street, Wichita Falls, TX

Dear Frank Andrajack,

We are writing to you because on 9/27-28/1999, your facilities were inspected by a representative of the State of TX, acting in behalf of the Food and Drug Administration (FDA). These inspections revealed a serious regulatory problem involving the mammography at your facilities.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, 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. These inspections revealed the following level 1 and level 2 findings at your facilities:

All four facilities

Level 1: The system to communicate results is not adequate because:

- There is no system in place to provide timely medical reports.
- There is no system in place to provide timely lay summaries.

Mobile facility only

Level 2: The processing speed (using the S.T.E.P. procedure) is greater than or equal to 65, but less than 80 for standard processing, processor (1), Kodak X-OMAT M35 or M35A-M.

Level 2: Performance verification test was not conducted after each move, Lorad Medical System, Inc., Mobile Van.

The specific problems noted above appeared on your MQSA Facility Inspection Reports, which were issued to your facilities at the close of their inspections.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facilities, 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 facilities under a Directed Plan of Correction, charging your facilities 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 FDA certificates, or obtaining a court injunction against further mammography.

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 facilities are taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- 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
Food and Drug Administration
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247

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>.

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 or fax (214) 655-8130.

Sincerely yours,


Edward R. Esparza
Regional Food and Drug Director