



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

August 11, 1999

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

99-SWR-WL-14/7  
CFN# 1647361  
Facility ID# 109314

Timothy Charles  
Chief Executive Officer  
Denton Hospital, Inc.  
d.b.a. Denton Community Hospital  
207 N. Bonnie Brae  
Denton, TX 76201

Dear Mr. Charles:

Your facility was inspected on July 19, 1999 by a representative of the State of Texas, acting on behalf of the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain parts of the Quality Standards for Mammography (Standards) as specified in Title 21, *Code of Federal Regulations (CFR)*, Part 900.12, as follows:

- 21 CFR900.12(c): The system to communicate results is not adequate for site because:
- There is no system in place to provide timely medical reports.
  - There is no system in place to provide timely lay summaries.
  - There is no system in place to communicate serious or highly suggestive cases ASAP.

The specific deficiency noted above appeared under the level 1 heading on your MQSA Facility Inspection Report, which was issued at the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality mammography at your facility.

**It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the causes of the deficiencies that the inspection identifies and promptly initiating permanent corrective actions.**

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If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- **impose civil money penalties** on a facility of up to \$10,000 **for each failure** to substantially comply with, **or each day** of failure to substantially comply with, the Standards.
- **suspend or revoke a facility's FDA certificate** for failure to comply with the Standards.
- **seek an injunction in federal court** to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- the specific steps you have taken to **correct** the violations noted in this letter;
- each step your facility is taking to **prevent the recurrence** of similar violations;

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 the corrections will be completed.

Please send the original copy of your response to Deborah M. McGee, Radiation Specialist, Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982. Also, send a copy to the State radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and State requirements in your response.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Ms. McGee at 214-655-8100, extension 138.

Sincerely yours,



Edward R. Esparza  
Regional Food and Drug Director

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cc: Thomas C. Cardwell  
X-Ray Branch Administrator  
Bureau of Radiation Control  
Texas Department of Health  
1100 West 49th Street  
Austin, TX 78756-3189

Director, Government Relations  
American College of Radiology  
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