



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

d2022b

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**

98-SWR-WL-15/7

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

August 29, 1998

Ernest Flores  
CEO  
Dimmit County Hospital  
704 Hospital Drive  
P.O. Box 1016  
Corrizo Springs, TX 78834

Dear Mr. Flores:

We have established that your facility conducts breast cancer screening or diagnosis through mammography activities and that your facility is not certified by the Food and Drug Administration (FDA) as required by the Mammography Quality Standards Act of 1992 (MQSA). This is a consequence of the fact that your facility is not accredited by an approved accreditation body nor has your facility submitted an acceptable application to an approved accreditation body, as is required by the MQSA as a prerequisite to certification.

As per an investigation conducted July 31, 1998 by the Texas Department of Health, your facility used the Bennett mammography x-ray unit, Model No. Contour, Serial No. [REDACTED] to produce human mammograms beginning 7/13/98 and ending 7/27/98 without being certified by the Food and Drug Administration.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the MQSA and regulations under the Act.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you will take to apply to an approved accreditation body within 30 days from the receipt of this letter. Failure to become certified may result in regulatory action being initiated by the Food and Drug Administration without further notice. You are advised that performing mammography without a certificate issued by the Food and Drug Administration is unlawful.

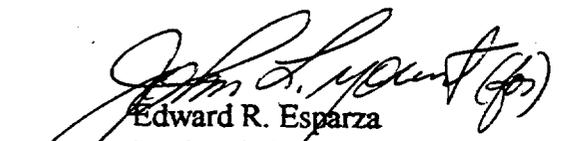
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under the MQSA. Among other things, a facility may be subject to civil money penalties up to \$10,000 for failure to obtain a certificate (42 U.S.C. 263b(h)(2)(A)). Continued operation of a facility without a certificate may also result in injunction.

Your response should be sent to Deborah M. McGee, Radiation Specialist, Food and Drug Administration, 7920 Elmbrook Drive #102, Dallas, TX 75247. If you have any question, Ms. McGee can be contacted at (214) 655-8100, ext. 138.

Sincerely yours,

  
Edward R. Esparza  
Regional Food and Drug Director  
Southwest Region

cc: Alphonso Rodriguez  
Director of Radiology  
Dimmit County Hospital  
704 Hospital Drive  
P.O. Box 1016  
Corrizo Springs, TX 78834

DM:dm