



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

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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

April 14, 1999

WARNING LETTER

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

99-SWR-WL-08/7
CFN# 1647374
Facility ID# 110437

Re: Doris Kupferle Breast Center
1300 West Terrell
Fort Worth, TX 76104

Barclay E. Berdan, CEO
Harris Methodist Fort Worth
1301 Pennsylvania Avenue
Fort Worth, TX 76104

Dear Mr. Berdan:

On March 10, 1999, a representative of the Food and Drug Administration conducted an investigation at the Doris Kupferle Breast Center located at 1300 West Terrell, Fort Worth, Texas. This investigation revealed that your facility failed to comply with the Mammography Quality Standards Act of 1992 (MQSA). This is a consequence of the fact that your facility knowingly conducted screening and diagnostic mammography from September 26, 1997 through March 1, 1999 utilizing the unaccredited Instrumentarium Alpha RT (S/N) 6397 mammography unit, located in Room 3-C.

In order to meet the requirements of MQSA certification to lawfully operate under the statute, a facility must meet the accreditation requirements as stated in 21 CFR Part 900.11(a). The approved accrediting body for your facility is the American College of Radiology (ACR). ACR requires that all of a facility's mammography units must meet accreditation. Failure to meet the accreditation requirements can jeopardize your certification. The operation of an unaccredited mammography unit has the potential to seriously compromise the ability to provide quality patient evaluations and may lead to other problems in providing overall service to your patients.

April 14, 1999

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 deficiencies at your facility and promptly initiating permanent corrective actions.

When deficiencies are not corrected, FDA may initiate regulatory action without further notice. 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.

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

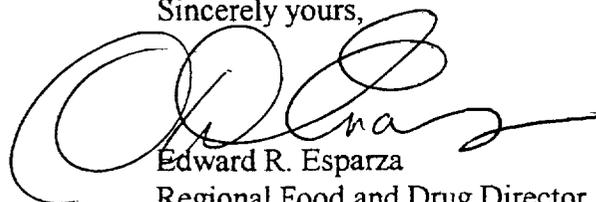
- ▶ the specific steps you have taken to **correct** the violation noted in this letter, including a copy of the corrective action plan (CAP) submitted to ACR for the completion of your accreditation of the unit.
- ▶ each step your facility is taking to **prevent the recurrence** of similar violations;

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 correction will be completed.

Please send 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 your State radiation control office.

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

for

Page 3

April 14, 1999

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
1891 Preston White Drive
Reston, Virginia 22091