



DEPARTMENT OF HEALTH & HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
SOUTHWEST REGION

M 989N

*BJK*

Office of the Regional  
Food and Drug Director  
7920 Elmbrook Drive, Suite 102  
Dallas, TX 75247-4982  
TELEPHONE: 214-655-8100

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

June 11, 1997

Edmund Dennis Harris, MD, President  
East San Antonio Images  
1954 East Houston, Suite 105  
San Antonio, Texas 78202

Central File #1647716

Dear Dr. Harris:

Under the Mammography Quality Standards Act of 1992 (MQSA), no facility may conduct examinations or procedures involving mammography after October 1, 1994, without a valid mammography certificate from the Food and Drug Administration (FDA) (42 U.S.C. 263b(b)(1)(A)). The Provisional Certificate you received on May 30, 1995, became ineffective on November 10, 1995, following your failure to become accredited by the American College of Radiology (ACR). We have established that your facility continued to conduct breast cancer screening or diagnosis for almost a year after your certificate expired in violation of MQSA.

Following your facility's attempt to become accredited, the ACR performed an on-site survey of your facility on November 5, 1996. During this on-site survey of your facility, the ACR sampled clinical images taken during the months you operated without a certificate and concluded that many of the 24 of the images sampled were of inadequate quality. ACR further determined that the technologist employed at your facility during the on-site survey needed additional training and experience in positioning, compression, and recognizing good and deficient image quality. Following notification by the ACR, the FDA conducted a joint investigation of your facility with the Texas Department of Health, Bureau of Radiation Control on December 3, 1996. During the on-site survey, our investigator found that from November 10, 1995 through October 23, 1996, your facility had been performing mammography without a certificate from FDA. Records maintained by your facility documented that East San Antonio Images continued to perform mammography after it failed accreditation and its provisional certificate had expired.

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As you have been previously advised, performing mammography without a valid FDA certificate is unlawful. Under MQSA, you may be subject to civil money penalties of up to \$10,000 for each violation or for each day your facility operates in violation of the MQSA or the mammography regulations (42 U.S.C. 263b(h)(2)).

Because ACR's evaluation of clinical images during the on-site survey revealed inadequate image quality, all patients who received mammography from your facility during the period of operation without a certificate and their physicians should be contacted. FDA requests that you implement a Patient/Physician Notification Program. This Notification Program is intended to alert physicians and patients about a potential health risk. The notification letters should provide information about the possible risks involved and the importance of appropriate medical follow-up. Patients should be advised and encouraged to contact their physician to discuss their individual situations.

FDA advises sending notification letters printed on the facility's stationary:

1. To all referring physicians whose patients received mammography services at East San Antonio Images between November 10, 1995, and October 23, 1996; and
2. One week after the physician notification mailing is completed, to all patients who received mammography services at East San Antonio Images between November 10, 1995, and October 23, 1996.

FDA's experience with other facilities doing notification has shown that such programs are more effective when the notification letters are sent by certified mail, restricted delivery (addressee only) and return receipt. If a patient's letter is returned to you because she has moved and left no forwarding address, you should take reasonable steps to locate the patient through her referring physician.

The information that should be communicated in the Patient and Physician Notification Letters is provided in enclosures 1 and 2, respectively. The patient notification letters should be written at a sixth to seventh grade reading level and for the patient who has little or no medical knowledge. The patient and physician letters should be written in English accompanied by a Spanish translation.

FDA would oversee the notification program, including the review and approval of the letters before you mail them. The physician notification letters should be mailed no later than five (5) business days after the FDA has approved the finalized letters. The patient notification letters should be mailed ten (10) business days after the last physician letter is mailed. FDA will provide specific dates for the mailings at the time the sample letters receive final approval.

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If you implement this notification program, you must submit the English and Spanish language drafts of the physician and patient notification letters to the FDA for review and approval no later than July 14, 1997. We will review the letters and provide you with our comments by mail or facsimile. **Under no circumstance should letters be sent to physicians or patients until FDA has reviewed and sent you written approval of the finalized documents.** FDA will provide copies of the letters to Texas Department of Health officials. FDA will monitor and audit the implementation of the notification program. Details about this portion of the program will be sent to you under a separate cover.

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. Therefore, you should consider the more stringent State requirements, if any, when you plan your corrective action.

Please notify this office in writing, within 15 working days of receipt of this letter, whether you intend to implement the Patient/Physician Notification Program and, if so, describe the specific steps you will take. Your response should also state whether you intend to submit a corrective action plan to the ACR for approval as part of accreditation efforts, or have decided to permanently discontinue mammography.

The sample notification letters you prepare, along with other responses to this letter, should be sent to:

B. Belinda Collins, Regional Radiological Health Representative  
Food and Drug Administration  
7920 Elmbrook Drive  
Suite 102  
Dallas, Texas 75247-4982.

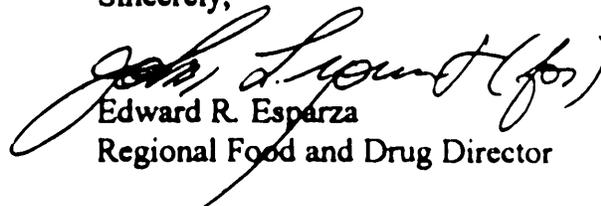
Telephone number (214) 655-8100, extension 148.  
Facsimile number (214) 655-8130

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If you have any questions, please contact Ms. Collins or Scotty Hargrave, by telephone at (214) 655-8100 ext. 148 or (214) 655-8100 ext. 139, respectively.

Sincerely,

  
Edward R. Esparza  
Regional Food and Drug Director

cc:

HFA-224

HFC-230

HFC-240

HFI-35(redacted copy for public display)

HFZ-240

HFZ-322

Thomas Cardwell, X-Ray Branch Administrator  
Bureau of Radiological Control  
Texas Department of Health  
1100 West 49th Street  
Austin, TX 78756-3189

Enclosures:

1. Physician Notification Letter Information
2. Patient Notification Letter Information
3. Federal Register, dated Tuesday, December 21, 1993: 21 CFR Part 900.