



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

d1592b

1/2

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

December 9, 1996

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

CFN #1939577  
Facility ID #201715

H.R. Bradley, M.D.  
Medical Director  
Medical Arts Clinic  
A Cotton O'Neil Clinic, P.A., Facility  
1601 State Street, Suite 200  
Emporia, Kansas 66801

Dear Dr. Bradley,

Your facility was inspected on November 19, 1996 by a representative of the State of Kansas, acting on behalf of the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, *Code of Federal Regulations (CFR)*, Part 900.12, as follows:

21 CFR 900.12(a)(1)(ii)(A) & (B): The interpreting physician is unqualified to interpret mammograms due to the lack of board certification from any of the approved boards or two months full-time training in the interpretation of mammograms: [REDACTED]

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 of 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 initiate permanent corrective actions.**

If you fail to promptly correct this deficiency, 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**

December 9, 1996

Page 2

**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 action(s), 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 :

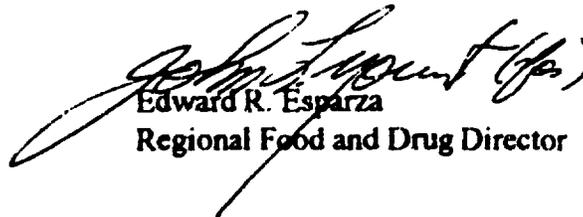
- ▶ the specific steps you have taken to correct the violations noted in this letter;
- ▶ each step your facility is taking to prevent the recurrence of similar violations;

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 B. Belinda Collins, Regional Radiological Health Representative, 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. Collins at 214-655-8100, extension 148.

Sincerely yours,

  
Edward R. Esparza  
Regional Food and Drug Director

December 9, 1996

Page 3

cc: Vick L. Cooper, Acting Chief  
X-Ray and RAM Control Section  
Department of Health and Environment  
Bureau of Air and Radiation  
Forbes Field, Building 283  
Topeka, Kansas 66620

HFA-224

HFC-230

HFC-240

HFI-35 (redacted copy for public display)

HFZ-240

HFZ-322