



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

D1183B *of*

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**

CFN# 1939454
ID# 181024

February 11, 1997

Geoffrey Crawley, M.D.
Department Chairman
Radiology Department
Offutt Air Force Base
55th Medical Group
2501 Capehart Road
Offutt AFB, Nebraska 68113

Dear Dr. Crawley,

Your facility was inspected on February 6, 1996, by a representative 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)(3): The medical physicist had neither a state license nor a state approval, nor board certification, and did not meet the alternative requirement (education, training, and experience). [REDACTED]

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

In addition, repeat Level 3 noncompliances were listed on the inspection report provided to you at the close of the inspection. These Level 3 noncompliances are:

21 CFR Part 900.(d)(1)(i): Processor QC: 20 percent of the data points for either medium density (MD), density difference (DD), or base plus fog (BF) were missing for the month of December, 1996: Kodak X-Omat M35 or M35A-M.

It is your responsibility to ensure adherence to each requirement of the Mammography

February 11, 1997

Page 2

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.

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.

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

- ▶ the specific steps you have taken to correct all of the violations noted in this letter;
- ▶ each step your facility is taking to prevent the recurrence of similar violations;
- ▶ equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- ▶ sample records that demonstrate proper record keeping procedures, if the noncompliances that were found relate to quality control or other records (**Note: Patient names or identification should be deleted from any copies submitted**).

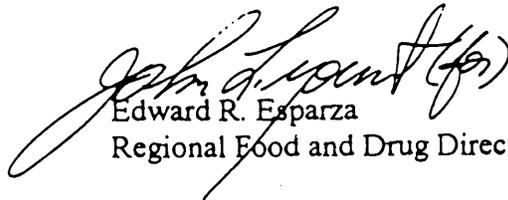
If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

February 11, 1997

Page 3

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


Edward R. Esparza
Regional Food and Drug Director

cc: HFA-224
HFC-230
HFC-240
HFI-35 (redacted copy for public display)
HFZ-240 ATTN: Denise Robinson
HFZ-322
RRHR (file)
R.D. Cope