



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service *SEH*
g1274d
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

May 14, 2001

VIA FEDERAL EXPRESS

FACILITY ID# 223426

Robert Moss, Administrator
The Memphis Breast Center
1068 Cresthaven Road, Suite 230
Memphis, TN 38119

Warning Letter No. 01-NSV-26

Dear Mr. Moss:

Your facility was inspected on April 30, 2001 by a representative of the State of Tennessee on contract to the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 2 (Repeat Finding)

The measured fog density is equal to 0.14 for the darkroom at site The Memphis Breast Center.

This specific deficiency appeared on the Post Inspection Report, which was sent to your facility by the state inspector along with instructions on how to respond to this finding. This deficiency may be symptomatic of serious problems that could compromise the quality of mammography at your facility and potentially overexpose both patients and employees involved with mammography.

Additionally, it was noted during the inspection that Phantom Quality Control was out of limits on several occasions when mammograms were performed. This violates the regulations. Of great concern is the fact that on at least one of these occasions, June 15, 2000, corrective action comments stated that patient mammograms were not performed; however, review of the mammogram log book for that date showed that five mammograms were actually done.

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 cause of this deficiency as identified and to promptly initiate permanent corrective action.

If you fail to properly address this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

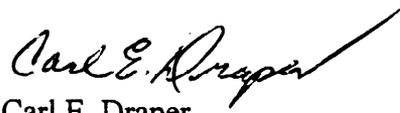
- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards
- seek an injunction in federal court to prohibit 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 each step your facility is taking to prevent the recurrence of any similar violations.

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

Your reply should be directed to Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125, with a copy to the State of Tennessee. Should you have questions regarding this letter or MQSA standards, you may call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,



Carl E. Draper
Director, New Orleans District

CED:KRS:man

Cc: Darlene Nalepa-Whitmill
TN Dept. of Environment & Conservation
2700 Middlebrook Pike, Suite 220
Knoxville, TN 37921

Jessica Soileau
2510 Mt. Moriah Road
Suite E-645 Perimeter Park
Memphis, TN 38115-1520

Priscilla F. Butler, MS
Dir. Breast Imaging Accreditation Programs
Standards and Accreditation Dept.
American College of Radiology
1891 Preston White Drive
Reston, VA 20191

Director, Government Relations
c/o American College of Radiology
1891 Preston White Drive
Reston, VA 20191