



DEPARTMENT OF HEALTH AND HUMAN SERVICES

555
8/24/97
EJH
Food and Drug Administration
Nashville District Office

297 Plus Park Blvd.
Nashville, TN 37217

August 26, 1997

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER-97-NSV-06

Quigley
JKA
8/24/97

FACILITY ID# 116657

James H. Edmondson
Administrator
Hillside Hospital
1265 E. College Street
Pulaski, TN 38478

Dear Mr. Edmondson:

Your facility was inspected on August 13, 1997 by a representative of the Food and Drug Administration. 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:

1. Processor QC; 90 percent of the data points for either medium density (MD), density difference (DD), or base plus fog (BF) were missing (month of November):
[REDACTED] Room ID= darkroom.

NOTE: THIS IS THE THIRD TIME THIS VIOLATION WAS NOTED IN ANNUAL INSPECTIONS RELATED TO THE QUALITY CONTROL TESTING OF THE FILM PROCESSOR

Normally, findings related to the processor are indicated in the List of Observations as the percentage of missing test data for the worst month during the year. While this is indicated in finding #1 on your report, we have also indicated in the Remarks section that significant amounts of data were missing for three different months. We have also found other findings during this inspection and the previous two annual inspections that indicate that your facility has not implemented adequate corrective action for your quality assurance program.

2. Phantom image test results were not recorded for 3 months:
[REDACTED] OTHER; Mammo.
3. The interpreting physician did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per month over 24 month: [REDACTED].

These specific deficiencies appear on the List of Observations which was faxed to your facility on August 22, 1997. These deficiencies are 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 cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

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

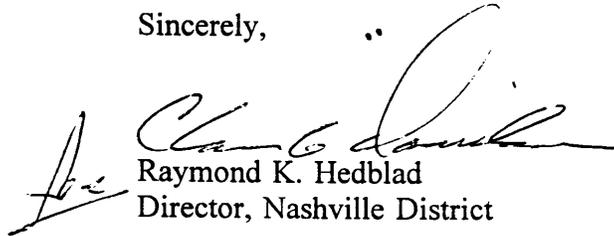
- impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to comply with the Standards.
- suspend or revoke a facility's FDA certificate for failure to comply with the Standards.
- seek an injunction in federal court to prohibit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

If your facility is unable to complete the corrective actions 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, U.S. Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217, telephone 615/781-5389, extension 125. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, C.S.O., at 615/781-5380, extension 144.

Sincerely,



Raymond K. Hedblad
Director, Nashville District

Enclosure: List of Observations, dated 8/22/97

RKH/ks

cc: State of Tennessee, Dept. of Envrnmnt. and Csvn., Div. of Rad. Hlth.