



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service *m4283n*
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

October 6, 2000

VIA FEDERAL EXPRESS

FACILITY ID# 100925

Roland Bradford, Administrator
ACIPCO Health Services
1500 32nd Avenue North
Birmingham, AL 35207

Bradford
10/4/00
jd

WARNING LETTER-01-NSV-02

Dear Mr. Bradford:

Your facility was inspected on September 29, 2000 by a representative of the State of Alabama 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 noncompliance from previous inspection)

1 of 9 random reports did not contain an assessment category for site American Cast Iron Pipe Co., Health Services

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 these findings. 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.

According to your facility's response dated October 19, 1999 to the initial Level 2 finding from your inspection of September 17, 1999, assessment categories were implemented as required starting September 20, 1999. As a result of this response, your facility was returned to compliance with a letter from this office dated October 29, 1999. We are enclosing a copy of your October 19, 1999 letter.

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 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:

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- **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 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. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please call Karen Smallwood, Radiation Specialist, at 615/781-5380, extension 144.

Sincerely,


Carl E. Draper
Director, New Orleans District

CED:KRS:man

Enclosure: Derrington/Smallwood Letter dated 10/19/1999

cc: State of Alabama
Dept. of Public Health
Office of Radiation Control
201 Monroe Street, Suite 700
P.O. Box 303017
Montgomery, AL 36104
ATTN: Richard Glass

Priscilla F. Butler, MS
Director, Breast Imaging Accreditation Programs
Standards and Accreditation Department
American College of Radiology
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