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ejs**DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION**4298 Elysian Fields Avenue
New Orleans, LA 70122
Telephone (504) 589-7166
Fax (504) 589-4657

May 23, 1997

WARNING LETTER NO. 97-NOL-49**CERTIFIED MAIL**
RETURN RECEIPT REQUESTEDMs. Kathy Levy
Director of Radiology
Chalmette Medical Centers
9001 Patricia Street
Chalmette, LA 70043

Dear Ms. Levy:

Your facility was inspected on March 21, 1997, by a representative of the Food and Drug Administration (FDA). 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:

- The interpreting physician is unqualified to interpret mammograms due to the lack of both board certification from any of the approved boards and 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.

In addition, your response should address the Level 2 noncompliances that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliances are:

- The interpreting physician did not meet the continuing experience requirement, i.e. interpreting an average of [REDACTED] patient examinations per month over [REDACTED] months: [REDACTED]
- The interpreting physician does not have the initial training of 40 hours of continuing medical education in mammography: [REDACTED]

- The interpreting physician's initial experience was inadequate (reading and interpreting mammograms from the examinations of at least [REDACTED] patients in [REDACTED] months): [REDACTED]

This letter is not intended to be an all-inclusive list of deficiencies 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 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:

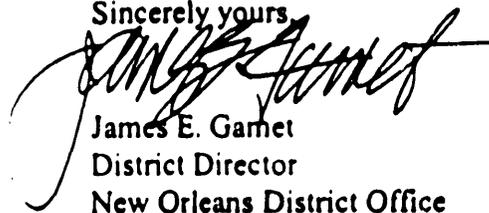
- each step your facility is taking to prevent the recurrence of similar violations.
- each step you will take to re-evaluate all mammograms read by [REDACTED]

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

Please send your response to Nicole F. Hardin, Compliance Officer, Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, LA 70122.

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call Ms. Hardin at (504) 589-7166.

Sincerely yours,


James E. Gamet
District Director
New Orleans District Office

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**cc: Mr. Jim Potter
Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091**

**Department of Environmental Quality
Office of Air Quality and Radiation Protection
Radiation Protection Division
P.O. Box 82135
Baton Rouge, LA 70884-2135**

bcc:

HFA-224 Records Section Attn: Carrie Russell (PKLN)
HFC-210 (CFN: 2319629) DCMO Attn: Sandra Whetstone (TW)
HFI-35 (purged NFH) FOI Staff (PKLN)
HFZ-240 CDRH, DMQRP Attn: Florence Houn, MD (PI50)
HFZ-322 CDRH, Diagnostic Devices Branch Attn: Thomas M. Jakub (OAK4)
HFR-SE1 (RFDD) ATL-RO
Legal file
EI file (CFN: 2319629)
Warning Letter file
NOL-DO R/F
CB R/F
TLK/Rad. Health Spec.
DFOB/LLL/SGM

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