



DEPARTMENT OF HEALTH AND HUMAN SERVICES

m34601
Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

Cin WL -1679-0

February 8, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Sutek Lie, M.D.
Chief of Mammography
University Hospitals Breast Center at Parkway
3609 Park East Drive
Beachwood, OH 44122

Facility I.D.#: 222463

Dear Dr. Lie:

A representative from the State of Ohio radiation control program under contract to the Food and Drug Administration inspected your facility on February 3, 2000. 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:

Your records revealed that your facility processed mammograms when the processor quality control parameters were out of limits for eight days in the months of June, August, November, 1999 and January 2000. **21 CFR 900.12 (e)(8)(A)**

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 noncompliance items that were listed on the inspection report provided to you at the close of the inspection. These Level 2 noncompliance items are:

1. The processing speed for your mammography processor was found to be 77 optical density units, which is outside the required range of 80-120 optical density units. **21 CFR 900.12 (e)(8)(a) and as further required in 21 CFR 900.12 (e)(1).**
2. Your records did not demonstrate that your facility performed corrective actions for processor quality control failures. **21 CFR 900.12 (e)(8)(A)**

3. Your records indicated that no processor quality control was charted on two consecutive days and five days out of 21 days in November 8, 9, 15, 26 and 29, 1999, yet mammograms were processed on these days. **21 CFR 900.12 (e)(1)**

4. Your records did not demonstrate that your facility performed corrective actions for failing phantom image score. **21 CFR 900.12 (e)(8)(A)**

The other items listed in your February 3, 2000 inspection report identified, as Level 3 should also be corrected. We will verify correction of these items during our next inspection. You are not required to address these Level 3 items in your written response.

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 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;
- Sample records that demonstrate proper record keeping procedures related to quality control.

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.

Please send the original copy of your response to:

R. Terry Bolen
MQSA Compliance Officer
Food and Drug Administration
6751 Steger Dr.
Cincinnati, OH 45237-3097

Also, please send a copy to the State radiation control office:

Mr. Dwight W. Leeseberg
Ohio Department of Health
Northeast District Office
Oliver R. Ocasek Government Office Building
161 S. High St., Suite 400
Akron, OH 44308-1616

If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, please call R. Terry Bolen at (513) 679-2700, extension 138.

Sincerely yours,



Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/DWLeeseberg

Director, Breast Imaging Accreditation Program
American College of Radiology
1891 Preston White Dr.
Reston, VA 20191