



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

M330607

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 - 1250-0

January 5, 2000

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

James Burkhardt, D.O.  
 President  
 Upper Valley Family Care  
 41 Stanfield Rd.  
 Troy, OH 45373

Facility I.D.#: 171967

Dear Dr. Burkhardt:

A representative from the State of Ohio radiation control program under contract to the Food and Drug Administration inspected your facility on December 20, 1999. 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 standard operating procedures are inadequate for your facility in communicating to the patients the results of their mammograms. Your standard operating procedures fail to indicate that the serious or highly suggestive for malignancy mammography results will be communicated in a lay summary report to each patient. This shall be performed in addition to your practice of verbally informing the patient of the serious or highly suggestive for malignancy mammography results. **21 CFR 900.12(e)(1)**

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. Your facility has no written standard operating procedure for handling consumer complaints. **21 CFR 900.12(h)(1)-(4)**
2. Your facility has no written standard operating procedure for infection control that is specific to the mammography operations. **21 CFR 900.12(e)(13)(i)-(iii)**

3. Your records indicated that three of five mammography reports did not contain the proper assessment terminology. **21 CFR 900.12(c)(1)(i)-(iv)**

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:

- The specific steps you have taken to correct all of the violation noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violation;
- 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:

Ms. Allison Sincek  
Ohio Department of Health  
246 N. High St., 5<sup>th</sup> Floor  
Columbus, OH 43215

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/ASincek

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