

HFI-35



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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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 -5650-0  
December 12, 2000

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

James M. Goldfarb, M.D.  
Medical Director  
University OB-GYN Specialties, Inc.  
5850 Landerbrook Dr., Suite 300  
Mayfield Heights, OH 44124

Facility I.D.#: 144535

Dear Dr. Goldfarb:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on November 22, 2000. This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding at your facility:

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 "Incomplete" or "Additional imaging evaluation needed" mammography results will be communicated in a lay summary letter to each patient. This shall be performed in addition to your practice of verbally informing the patient of the "Incomplete" or "Additional imaging evaluation needed" mammography results. **21CFR 900.12 (c)(2)(i)&(ii)**

Because this condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against performing further mammography.

In addition, your response should address the Level 2 finding that is listed in the inspection report that was provided to you at the close of the inspection. The Level 2 finding is:

There was no example of or attempt to get biopsy results for the positive mammography cases. Your records indicated twelve positive mammography cases between January to September 2000. There was no documentation to support the attempt to obtain the pathology results for these positive cases. **21CFR 900.12 (f)(1)**

You must act on this matter immediately. Please explain the following elements to this office in writing within fifteen (15) working days from the date you received this letter:

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

Please submit sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Mr. R. Terry Bolen  
MQSA Compliance Officer  
Food & Drug Administration  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
FAX: 513-679-2772

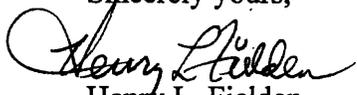
Also, please send a copy to the State radiation control office:

Ms. Terri Eckert  
Ohio Department of Health  
Radiologic Technology Section  
161 South High St., Suite 400  
Akron, OH 44308

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. R. Terry Bolen at 513-679-2700, extension 138

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Henry L. Fielden".

Henry L. Fielden  
District Director  
Cincinnati District Office

c.  
OH/TEckert

Priscilla F. Butler, M.S.  
Director, Breast Imaging Accreditation Program  
American College of Radiology  
1891 Preston White Dr.  
Reston, VA 20191