



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

rn432pn  
 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 -5059-0  
 October 30, 2000

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

Clinton Cook, M.D.  
 Owner  
 Gray & Cook, P.S.C.  
 601 South Floyd, Suite 407  
 Louisville, KY 40202

Facility I.D.#: 110585

Dear Dr. Cook:

We are writing to you because on October 19, 2000, your facility was inspected by a representative of the Commonwealth of Kentucky, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act 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 October 19, 2000 inspection found that your facility failed to comply with the regulations under Title 21, Code of Federal Regulations (CFR), Part 900, as follows:

**Quality Assurance – Equipment (21 CFR 900.12(e)(1)(i)-(iii) – Level 1 Finding**

Your records revealed that your facility processed mammograms when the processor quality control records were missing for five (5) consecutive days in the month of April 2000.

In addition, the October 19, 2000 inspection found **Repeat** Level 2 and Level 3 findings. The findings are identified as **Repeat** Level 2 and Level 3 because they identify a failure to meet significant MQSA requirements and indicate failure by your facility to implement permanent correction of the problems found during your previous inspection on October 1, 1999.

**Quality Assurance – Equipment [21 CFR 900.12(e)(1)(i)-(iii), as required by 21 CFR 900.12(e)(8)(ii)] – Level 2 Finding**

Your facility records failed to show that corrective action was taken as a result of processor quality control failures that occurred on January 24, 2000.

**Quality Assurance – Equipment [21 CFR 900.12(e)(2)(i)-(iv), as required by 21 CFR 900.12(e)(8)(ii)]– Level 2 Finding**

Your records failed to document corrective actions taken as result of phantom image quality control failures that occurred on November 3, 10 & 24, 1999.

**Personnel Requirements – Retention of Personnel Records - 21 CFR 900.12(a)(4)  
– Level 3 Finding**

The required personnel qualification documents were not available during the inspection.

The other items listed in your October 19, 2000 inspection report identified, as Level 3 without the “(R)” notation 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.

Review of the our inspection records regarding your facility showed that your facility has been inspected annually since 1995. The 1995 through 2000 inspection records revealed that your facility has been cited for similar or equivalent noncompliance issues as indicated in this letter. The inspection records further revealed that your facility responded in writing indicating your facility performed corrective actions to these noncompliance issues.

FDA’s past and current inspection findings demonstrate that your facility has engaged in serious violations of the MQSA. FDA may, without further notice, initiate further regulatory action(s) such as:

- 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 further mammography.

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

- the specific steps you have taken or plan to take to correct all of the violations noted in this letter;
- each step your facility is taking **to prevent the recurrence of similar violations**;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- 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 and Drug Administration  
6751 Steger Dr.  
Cincinnati, OH 45237-3097

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

Mr. Steve Mays  
Commonwealth of Kentucky  
Kentucky Radiation Health & Toxic Agents Branch  
Mailstop HS 2E-D  
275 East Main St.  
Frankfort, KY 40621

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

Sincerely yours,

  
Henry L. Fielden  
District Director  
Cincinnati District Office

c.  
KY/SMays  
Carol Kinney, Lead Mammographer, Gray & Cook, P.S.C.

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