



WARNING LETTER

Cin WL - 11837-02
December 18, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph Ridgeway
Owner & Medical Director
Community Radiology Inc.
1430 S. High St.
Columbus, OH 43207

Facility I.D.#: 107227

Dear Mr. Ridgeway:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on December 14, 2001. 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:

Quality Assurance - Equipment - 21 CFR 900.12(e)(1)(i)-(iii)

Your records showed that your facility processed mammograms when the processor quality control records were missing 12 of 19 days or 63% of total days of operation in May 2001.

The inspection revealed that during the days of May 10 & 11, 14-18, and 21-25, 2001 your facility did not perform the required daily quality control tests on the processor used to process mammograms.

Because this condition may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, this represents 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 noncompliance items that were listed on the inspection report provided to your staff at the close of the inspection. These Level 2 noncompliance items are:

1. Quality Assurance – Equipment - 21 CFR 900.12(e)(2)

Your records revealed that your facility phantom quality control records for the mammography unit were missing for three (3) weeks. The MQSA regulation requires the mammography unit be evaluated by performing at least weekly the image quality evaluation test.

The inspection found that your facility failed to perform this weekly quality control test during the weeks of May 7-11, 14-18 and May 21-25, 2001.

2. Medical Records and Mammography Reports – Contents and Terminology

21 CFR 900.12 (c)(1)(iv)(A)-(E) &(v)

One of ten random interpreting physician mammography reports did not contain the required final assessment of findings.

NOTE: In the January 5, 2000 annual MQSA inspection, your facility was cited for four of five mammography reports that did not contain the required final assessment findings.

3. Quality Assurance – Mammography Medical Outcomes Audit 21 CFR 900.12(f)(1) -(3)

Your facility failed to show that a medical audit and outcomes analysis was performed annually. Your facility failed to show that the analyses of these outcome data were made individually and collectively for all interpreting physicians at your facility only.

You must act on these matters 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 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

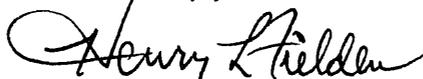
Also, please **send a copy** to the State radiation control office:

Ms. Stacey Melick
Ohio Department of Health
Radiologic Technology Section
P.O. Box 118
Columbus, OH 43266-0118

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,



Henry L. Fielden
District Director
Cincinnati District Office

c.
OH/SMelick

