



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 -3889-0
July 28, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Allison P. Pryce, M.D.
Lead Mammography Radiologist
Regional Diagnostics
9500 Mentor Ave., Suite 340
Mentor, OH 44060

Facility I.D.#: 222315

Dear Dr. Pryce:

We are writing to you because on July 5, 2000, your facility was inspected by a representative of the State of Ohio, 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 inspection revealed the following Level 1 finding at your facility:

Your records revealed that your facility phantom quality control records for the mammography unit were missing for four 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 quality control test during the weeks of October 18, November 8, November 29 and December 13, 1999. **21 CFR 900.12(e)(2)**

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, this condition represents a serious 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 the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

The other items listed in your July 5, 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 the Level 3 items in your written response.

It is necessary for you to act on this matter immediately. Please explain 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 violation noted in this letter; and
- each step your facility is taking to prevent the recurrence of similar violation.

Please include sample records with an explanation that demonstrate proper record keeping procedures that are now being followed. (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

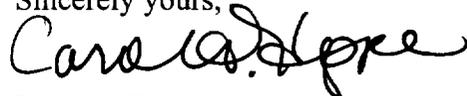
Also, please send a copy to the State radiation control office:

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 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>.

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,



Carol A. Heppe
Acting District Director
Cincinnati District Office