



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 -5760-0
December 22, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Anthony J. Rich, D.O.
Chief Executive Officer
East Palestine Family Medical Clinic, Inc.
50410 State Route 14
East Palestine, OH 44413

Facility I.D.#: 111310

Dear Dr. Rich:

A representative from the State of Ohio acting on behalf of the Food and Drug Administration (FDA) inspected your facility on December 13, 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:

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 at least twelve 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 in February 2000 to August 2000.

The specific problem noted above appeared on your MQSA Facility Inspection Report, which your facility received at the close of the inspection. The problem is identified as **repeat** Level 1 because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement permanent correction of the problem found during your previous inspection.

Because this condition may be symptomatic of serious underlying problems 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 and 3 findings that are listed in the inspection report that was provided to you at the close of the inspection. These findings are:

Level 2 Findings:

1. Quality Assurance – Equipment - 21 CFR 900.12 (e)(1) and as required by 21 CFR 900.12 (e)(8)(i)&(ii)(A).

During the December 13, 2000 inspection, your facility mammography processor speed using the S.T.E.P. procedure was found to be 74 units. The required range for the mammography processing speed is 80-120 units.

2. Quality Assurance – Equipment - 21 CFR 900.12(e)(2), as required by 21 CFR 900.12(e)(8)(ii)(A).

Your records showed that no corrective actions were documented on December 5, 2000 for phantom images that failed to meet the required phantom quality control limits. Your records showed that mammograms were performed on December 5, 2000 without performing an additional phantom image quality control test.

Level 3 Findings:

1. Quality Assurance – Equipment – *Quarterly Quality Control Tests* -21 CFR 900.12 (e)(3)

- a. Your fixer retention quality control records showed that this test was not performed at the required frequency.
- b. Your repeat analysis quality control records showed that this evaluation was not performed at the required frequency.

2. Quality Assurance – Equipment –*Semiannual Quality Control Tests* -21 CFR 900.12 (e)(4)

- a. Your compression device quality control records showed that this test was not performed at the required frequency.
- b. Your screen film contact quality control records showed that this test was not performed at the required frequency.
- c. Your darkroom fog quality control records showed that this test was not performed at the required frequency.

Quality Assurance – Equipment - 21 CFR 900.12(e)(5)(vi)

The inspection also found that the calculated average glandular dose for a typical and standard breast (approximately 4.2 cm thick compressed breast consisting of 50% glandular, 50% adipose tissue) was 333 mRad. This measured dose exceeds the 300 mRad limit however this is below 350 mRad. **Dose levels in this range warrant attention.** The national average for the calculated average glandular dose is 150-160 mRad.

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 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

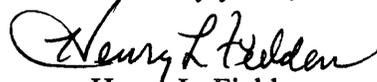
Also, please send a copy to the State radiation control office:

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,



Henry L. Fielden
District Director
Cincinnati District Office