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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
300 River Place
Suite 5900
Detroit, MI 48207
Telephone: 313-393-8100
FAX: 313-393-8139

WARNING LETTER
2003-DT-16

May 19, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert E. Clutter, M.D.
Head Physician
Castleton Family Physicians
8060 Knue Road, Suite 120
Indianapolis, IN 46250

Dear Dr. Clutter:

On April 23, 2003, your facility was inspected by a representative of the State of Indiana acting on behalf of the Food & Drug Administration (FDA). The inspection revealed a serious problem involving the conduct of mammography at your facility. Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, 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 recent inspection at your facility revealed the following violations of the MQSA:

1. Your facility failed to produce any documentation to show that a temporary technologist (name unknown), employed during August 2002, met any initial requirements of either being licensed by the State of Indiana or holding a valid certificate from an FDA approved body. This is in violation of Title 21 Code of Federal Regulations (C.F.R.) § 900.12 (a)(4). See also 21 C.F.R. § 900.12(a)(2).

This violation appeared on your MQSA Facility Inspection Report (copy enclosed), which your facility received at the close of the inspection. This problem is identified as Level 1 because it represents a failure to meet a significant MQSA requirement. The following Level 2 findings were also listed on the inspection report:

1. Your facility failed to produce documentation to verify that your interpreting physician, [redacted] met the continuing education requirement of having taught or completed at least 15 category I continuing medical education

hours in mammography in the previous 36 month period. This is in violation of 21 C.F.R. § 900.12 (a)(4). See also 21 C.F.R. § 900.12 (a)(1)(ii)(B).

2. Your facility failed to produce documentation to verify that your technologist [redacted] met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in the previous 36 month period. This is in violation of 21 C.F.R. § 900.12(a)(4). See also 21 C.F.R. § 900.12 (a)(2)(iii)(A).

3. Your facility failed to produce documentation to verify that your temporary technologist (name unknown), employed during the month of August, 2002, met the continuing education requirement of having taught or completed at least 15 continuing education units in mammography in the previous 36 month period. This is in violation of 21 C.F.R. § 900.12 (a)(4). See also 21 C.F.R. § 900.12 (a)(2)(iii)(A).

Since these unresolved conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, FDA may take additional regulatory action. 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, seeking civil money penalties, seeking to suspend or revoke your facility's FDA certificate, or seeking a court injunction against performing further mammography. See 42 U.S.C.§ 263b (h)- (j) and 21 C.F.R. § 900.12(j).

It is necessary for you to act on this matter immediately. Please provide to this office in writing within fifteen (15) working days from the date you receive this letter:

- the specific steps you have taken to correct the Level 1 and 2 violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- the 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. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
300 River Place, Suite 5900
Detroit, MI 48207

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, you should consider the more stringent State requirements, if any. You should also send a copy of your response to the State of Indiana radiation control office that conducted the inspection referenced in this letter. You may choose to address both the FDA and any additional State requirements in your response.

There are many FDA requirements pertaining to mammography. This letter only concerns the findings of your recent 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 any questions regarding this letter or how to ensure that you are meeting MQSA standards, please call Mr. Dennis E. Swartz, Radiological Health Expert, at 313-393-8156.

Sincerely yours,

Joann M. Givens
District Director
Detroit District Office

Enclosure (MQSA Facility Inspection Report)