



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35

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Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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Cin -3170-0
June 7, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Mark Neff, CEO
St. Claire Medical Center
222 Medical Circle
Morehead, KY 40351

Facility I.D.#: 138081

Dear Mr. Neff:

On September 24, 1998, 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 Level 2 finding whereby the mammography film processor speed was 73 optical density units. The required range for the mammography processing speed is 80-120 optical density units. Subsequent to the 1998 inspection your staff responded to this office in writing, the corrective actions taken.

On September 28, 1999, an annual inspection was performed also by a representative of the Commonwealth of Kentucky acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a Level 1 finding which is a serious regulatory problem involving the mammography at your facility.

During the September 28, 1999 inspection, your facility mammography processor speed using the S.T.E.P. procedure was found to be 51 optical density units. Again, the required range for the mammography processing speed is 80-120 optical density units. The specific problem observed appeared on your MQSA Facility Inspection Report, which was issued at the close of the inspection.

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.

Because the condition mentioned above, may be symptomatic of serious underlying problem that could compromise the quality of mammography at your facility, the problem 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.

On or about May 23, 2000, this office contacted Ms. Suanne Bushong, Radiology Manager of your facility and inquired on the corrective actions that may have been taken by the staff at your facility. Ms. Bushong promptly forwarded to this office via facsimile documentation demonstrating the corrective actions taken by the staff of your mammography department. Your facility conducted an extensive investigation and performed corrective actions in the time period between September 29, 1999 to the end of November, 1999.

On May 31, 2000, Mr. R. Terry Bolen, FDA, MQSA Compliance Officer visited your facility and conducted a limited inspection. This limited inspection covered the physical testing of the mammography unit and the mammography processing operation. The limited inspection found the processing speed to be 86 optical density units. This observed processing speed is within the required 80-120 optical density units range. During the close-out of the inspection, discussions were held and among the discussions, your staff indicated that your staff ordered a new mammography film processor with a proposed installation date of late June, 2000. The limited inspection also found two Level 3 deficiencies. These less serious deficiencies need to be corrected before the next annual inspection.

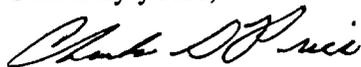
As result of the your facility written response of corrective actions of the Level 1 finding; the May 31, 2000, follow-up FDA inspection and the fact your staff ordered a new film processor, your facility adequately addressed Level 1 noncompliance issue found in the September 28, 1999 inspection. You need not to respond to this letter. If you have any further comment or if you desired to submit to this office any additional response, please submit your response to:

R. Terry Bolen
MQSA Compliance Officer
Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097
FAX: 513-679-2772

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to finding 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>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact R. Terry Bolen, MQSA Compliance Officer at 513-679-2700, extension 138.

Sincerely yours,



Charles S. Price
Acting Director, Compliance Branch
Cincinnati District Office