

HFI-35



DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN: 1124181
Facility ID: 135723
Inspection ID #1357230007



Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396

October 11, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Megan R. Perry, Administrator
Sentara Hampton General Hospital
3120 Victoria Boulevard
Hampton, Virginia 23661

Dear Ms. Perry:

A representative from the Commonwealth of Virginia under contract to the Food and Drug Administration (FDA) inspected your facility on September 27, 2000. This inspection revealed a serious regulatory problem involving mammography performed 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 public health by assuring that a facility can perform quality mammography. The inspection revealed the following Level 1 finding:

- **The system your facility has in place to communicate patient results is not adequate in that it does not communicate suspicious or highly suggestive cases as soon as possible.**

The specific problem noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection. This problem is identified as a Level 1 finding because it identifies a failure to comply with a significant MQSA requirement.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility, it represents a violation of the law that 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 further mammography.

In addition, the following Level 2 finding was listed on the inspection report provided to you at the close of the inspection:

- **There was no documentation available to verify that the interpreting physician, [REDACTED], meets the minimum requirement of 60 hours of continuing medical education in mammography.**

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 receive this letter:

- The specific steps you have taken to correct the violations noted in this letter.
- Each step your facility is taking to prevent the recurrence of similar violations.

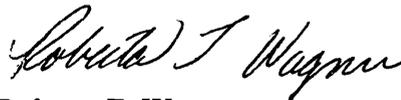
Your response should be submitted to:

Food and Drug Administration
900 Madison Avenue
Baltimore, Maryland 21201
Attn: Nancy Rose
Compliance Officer

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 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 technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 962-3591, extension 159.

Sincerely,



Roberta F. Wagner
Acting Director, Baltimore District

cc: Robert E. Gonsoulin, Radiation Safety Specialist
Bureau of Radiological Health
Division of Health Hazards Control
Department of Health
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