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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CFN: 1124322
ID: 156653

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4099

March 5, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Denise M. Andrews
Administrative Director of Radiology
Sacred Heart Hospital
900 Seton Drive
Cumberland, Maryland 21502

Dear Ms. Andrews:

Your facility was inspected on February 19, 1998, by representatives of the Food and Drug Administration (FDA). This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards), as specified in Title 21, Code of Federal Regulations, Part 900.12, as follows:

Drs. [REDACTED] and [REDACTED] did not meet the initial training requirement of having 40 hours of continuing medical education (CME) in mammography. In response to a Warning Letter, [REDACTED] requested your assistance in providing documentation for 40 CMEs for these doctors. Your facility furnished [REDACTED] with *Attestations Regarding Requirements of the Mammography Quality Standards Act* (attestations) documenting 40 CMEs in mammography for each doctor. [REDACTED] submitted the attestations for our review. Our review of the attestations and inspection of your facility revealed that a Sacred Heart Hospital employee forged each of the doctor's signatures.

Your facility must submit attestations for Drs. [REDACTED] and [REDACTED] documenting this initial training requirement. Please also explain in detail what your facility plans to do to ensure that this will not recur.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA regulations. You are responsible for investigating and

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determining the cause of the deficiency that the inspection identified and promptly initiating permanent corrective action.

If you fail to do so, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- Impose civil money penalties on a facility of up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards;
- Suspend or revoke a facility's FDA certificate for failure to comply with the Standards;
- Seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own mammography laws and regulations. These requirements may be more stringent than FDA's. When you plan your corrective action, therefore, you should consider the more stringent State requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

- The specific steps you have taken to correct all of the violations noted in this letter;
- Each step your facility is taking to prevent the recurrence of similar violations;
- Sample records that demonstrate proper record keeping procedures, if the noncompliance found relate to quality control or other records. (Note: You should delete patient names or identification from any copies submitted.)

If your facility is unable to complete the corrective action within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to the Food and Drug Administration, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Thomas C. Knott, Compliance Officer.

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If you have any questions regarding this letter or how to ensure you are meeting MQSA standards, you may contact Lori A. Holmquist at (410) 962-3591, Ext.175.

Sincerely yours,



Elaine Knowles Cole
District Director

cc: Maryland Department of the Environment
2500 Broening Highway
Baltimore, Maryland 21224

Mr. Jim Potter, Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091

Mr. William Bradel
Sacred Heart Hospital
900 Seton Drive
Cumberland, Maryland 21502