DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2002-DT-39

September 27, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Mark Crain, Vice President
Bloomington Hospital
601 W. Second Street
Bloomington, Indiana 47403

Dear Mr. Crain:

We are writing you because on September 4, 2002, 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 compromise in the quality of the mammography services offered by your facility.

Under the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b, and the Quality Standards for Mammography set forth in Title 21, Code of Federal Regulations (C.F.R.), Part 900, 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 Level 1 finding:

1. Your system for communication of results of mammography exams is inadequate in that there is no system in place to assure communication of serious or highly suggestive of malignancy cases to the health care provider as soon as possible. This is in violation of Title 21 Code of Federal Regulations § 900.12 (c)(3)(ii).

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

Since 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, seeking civil money penalties, suspension or revocation of your facility's FDA certificate, or seeking a court injunction against performing further mammography.

In addition, you should also address the following Level 2 findings that were listed on the inspection report provided to you at the close of the inspection:

1. There was no documentation of corrective action, before further exams, in instances where there was a phantom image failure for phantom background density or density difference because it was outside of the allowable regulatory limits. This is in violation of Title 21 code of Federal Regulations § 900.12 (e)(8)(ii)(A).
2. There was no documentation to show that [redacted] met the continuing experience requirement of having completed 960 exams within the previous 24 month period. This is in violation of Title 21 Code of Federal Regulations § 900.12 (a)(1)(ii)(A).
3. There was no acceptable documentation available to show that [redacted], met the continuing education requirement of having obtained at least 15 category I continuing medical education units in mammography during the previous 36 month period. This is in violation of Title 21 Code of Federal Regulations § 900.12 (a)(1)(ii)(B).
4. A random review of six (6) medical reports revealed that one report did not specify an acceptable assessment category. This is in violation of Title 21 Code of Federal Regulations § 900.12 (c)(1)(iv).

It is necessary for you to act on these matters 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 Level 1 and Level 2 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 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
1560 East Jefferson Ave.
Detroit, MI 48207-3179

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 313-226-6260 Ext. 155.

Sincerely yours,

Joann M. Givens
District Director
Detroit District Office

Enclosure (MQSA Facility Inspection Report)