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

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WARNING LETTER
2003-DT-09

February 3, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jerry Dooley, CEO
Terre Haute Regional Hospital
3901 S. 7th Street
Terre Haute, IN 47802

Dear Mr. Dooley:

We are writing you because on January 7, 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 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, 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:

Your facility failed to produce documentation to show that your interpreting physician, [redacted] met the initial requirement of being certified in an appropriate specialty area by an FDA approved board or having 3 months of initial training in the interpretation of mammograms. This is in violation of Title 21 Code of Federal Regulations § 900.12 (a)(1)(i). (If [redacted] initially qualified as an interpreting physician before April 28, 1999, he would need to meet the interim regulation requirement of being certified by an FDA approved board or having 2 months of initial training in the interpretation of mammograms. See 21 C.F.R. § 900.12(a)(1)(iii) and FDA's interim regulation at 58 Federal Register 67565 (December 21, 1993)).

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

This condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility and 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, seeking to suspend or revoke 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. Your facility failed to produce documentation to verify that your interpreting physician, [redacted] met the initial experience requirement of having interpreted or multi-read at least [redacted] mammograms in a six (6) month period. This is in violation of Title 21 Code of Federal Regulations § 900.12 (a)(1)(i)(D).

2. Your facility failed to produce documentation to verify that your interpreting physician, [redacted] met the initial requirement of having at least 60 hours of medical education in mammography. This is in violation of Title 21 Code of Federal Regulations § 900.12 (a)(1)(i)(C). (If [redacted] initially qualified as an interpreting physician prior to April 28, 1999, he would need to meet the interim regulation requirement of having at least 40 hours of medical education in mammography. See 21 C.F.R. § 900.12(a)(1)(iii) and FDA's interim regulation at 58 Federal Register 67565 (December 21, 1993)).

It is necessary for you to act on these matters 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 Level 2 violations noted in this letter;

- each step your facility is taking to prevent the recurrence of similar violations;

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)