



CERTIFIED MAIL
RETRUN RECEIPT REQUESTED

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

WARNING LETTER
2000-DT-42

September 28, 2000

Mr. David Hoff, CEO
Iron County General Hospital
1400 West Ice Lake Road
Iron River, MI 49935

Dear Mr. Hoff:

We are writing you because on September 19, 2000, your facility was inspected by a representative of the State of Michigan acting in behalf of the Food & Drug Administration (FDA). The inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), 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 inspection revealed the following Level 1 finding at your facility:

1. Your interpreting physician, [REDACTED], did not meet the initial qualification requirements for reading mammograms in that he is not certified by an FDA recognized board nor was there sufficient documentation to show that he met the alternative requirement of 3 months training in the interpretation of mammograms.

The specific problems noted above appeared on your MQSA Facility Inspection Report (copy enclosed), which was issued at the close of the inspection. These problems are identified as Level 1 because they identify a failure to meet a significant MQSA requirement.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a violation of 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 onsite monitoring, assessing civil money penalties up to \$10,000 for each 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, your response should address the Level 2 findings that were listed on the inspection report provided to your staff at the close of the inspection.

These Level 2 finds are:

1. There was no documentation available to show that processor QC failures were corrected prior to further processing of mammography films on at least on (1) occasion.
2. There was no documentation available to show that [REDACTED] met the initial training requirement of at least 60 CME credit hours of training in mammography.
3. There was no documentation available to show that [REDACTED] met the continuing experience requirement of having read or interpreted [REDACTED] patient exams within the prior 24 month period. Documentation available showed only [REDACTED] exams within the prior 24 month period.
4. There was no documentation available to show that technologist [REDACTED] met the continuing education requirement of having completed a minimum of 15 CEU's in mammography within the prior 36 month period . Documentation available showed only 9.5 hours of CEU's within the prior 36 month period.

Please be aware that personnel failing to maintain continuing experience or training are no longer qualified and must be immediately placed under direct supervision. Direct supervision must continue until sufficient hours of training are obtained or in the case of experience, until sufficient numbers of exams are conducted according to the requalification regulation under MQSA.

It was also noted during the inspection that your designated Lead Interpreting Physician, [REDACTED] resides in [REDACTED] with only an occasional visit to your facility since December, 1999. Please be aware that the Lead Interpreting Physician is responsible for the Quality Assurance Program, including personnel assignments, equipment QC tests, records and corrective actions. This designee is also responsible for the review of the medical outcome audit and discussion of the results with other interpreting physicians.

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 Level 1 violation noted in this letter; including the follow-up planned for exams interpreted by an unqualified physician.
- each step your facility is taking to prevent the recurrence of similar violations;

- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- 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.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter only pertains to findings of your inspection and does not necessarily address other obligations you have under 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 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,


for Raymond V. Mlecko
District Director
Detroit District

Enclosures: a/s