



Food and Drug Administration
Cincinnati District Office
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2772

WARNING LETTER

November 23, 1999

Cin-WL-387-0

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Cliff Lehman
President and CEO
Blanchard Valley Regional Health Center
145 West Wallace Street
Findlay, Ohio 45840

Facility: Blanchard Valley Regional Health
Center (BVRHC)-Bluffton Campus
MQSA ID#: 103572
CFN#: 1529342

Dear Mr. Lehman:

Mr. R. Terry Bolen, of our office, inspected your facility (Bluffton Campus) on September 17, 22-24, 1999 and found that your facility performed mammography after the June 30, 1999 expiration of its Food and Drug Administration (FDA) certificate. According to documents we obtained from the American College of Radiology (ACR), it sent a letter addressed to Sina Hazneci, M.D on June 28, 1999, stating that it denied your facility re-accreditation due to clinical image review (CIR) failure. During FDA's inspection of your facility, Dr. Sina Hazneci stated that, prior to September 21, 1999, he was not aware of nor did he receive the ACR letter denying your facility re-accreditation. Information obtained during the inspection indicated that [REDACTED] lead mammography technologist, received the June 28, 1999 ACR letter. On July 1, 2, 6-9, 12-17, 19-24, 26-30, August 2-7, 9-14, 16-21, 23-28, 30, 31, and September 1-4, 7-11, 13-16, 20, 21, 1999, your facility conducted mammography on 227 patients without a valid FDA certificate.

The Mammography Quality Standards Act of 1992 (MQSA), under 42 U.S.C. 263b(b)(1)(A)), provides that no facility may conduct examinations or procedures involving mammography after October 1, 1994, unless the facility has a valid certificate.

Mr. Bolen discussed these problems with your staff at the close of the inspection and provided your facility with an MQSA Facility Inspection Report. Conducting mammography without a valid FDA certificate is a very serious violation of the law.

In addition, FDA found that your facility failed to comply with the regulations under Title 21, Code of Federal Regulations (CFR), Part 900, as follows:

Personnel Requirements - Radiologic Technologist (21 CFR 900.12(a)(2)) – Level 1 Finding

██████████, a radiologic technologist who performed mammography at your facility, did not meet the requirement of being licensed by a State or certified by an FDA recognized board (i.e., the American Registry of Radiologic Technologists (ARRT)), as required by 21 CFR 900.12(a)(2)(i). ██████████ was also the facility's quality control technologist.

Personnel Requirements – Medical Physicist (21 CFR 900.12(a)(3)) – Level 1 Finding

██████████, a medical physicist who performed mammography survey at your facility, did not meet the requirement of having a Masters degree or higher in a physical science, with 20 semester hours in physics or having a bachelor's degree or higher in physical science with no less 10 semester hours of physics, if ██████████ was qualified as a medical physicist under the FDA/MQSA interim regulations prior to April 28, 1999. This is required as indicated in 21 CFR 900.12(a)(3)(i) & (ii).

In addition, we found other areas where your facility failed to comply that were listed as Level 2 findings on your inspection report:

Equipment (21 CFR 900.12(b)) – Level 2 Finding

Your facility does not have separate compression paddles for the two different image receptor sizes used on the General Electric 600T mammography system, as required by 21 CFR 900.12(b)(8)(ii).

Medical Records and Mammography Reports (21 CFR 900.12(c)) - Level 2 Finding

Seven mammography reports, selected at random, did not contain the required overall final assessment of findings, are required by 21 CFR 900.12 (c)(1)(iv) and (v).

Quality Assurance – Equipment (21 CFR 900.12(e)) – Level 2 Finding

The measured darkroom fog density is equal to 0.29 for the darkroom at the Bluffton Campus site, which exceeds the requirement under 21 CFR 900.12(e)(4)(i).

Your records showed that no corrective actions were documented on May 11, August 21 and August 31, 1999 for phantom images that failed to meet the required score (21 CFR 900.12(e)(2)(iii)), as required by 21 CFR 900.12(e)(8)(ii).

Your facility did not have records for the weekly phantom tests for the weeks of August 29-September 4; September 5-11; September 12-16, 1999, as required by 21 CFR 900.12 (e)(2).

Consumer Complaint Mechanism 21 CFR 900.12(h) – Level 2 Finding

Your facility has no procedure for handling consumer complaints for the Bluffton Campus site.

As a result of our investigational findings, FDA has serious concerns about the quality of mammography performed by Blanchard Valley Regional Health Center (BVRHC)-Bluffton Campus. Therefore, your facility must undergo Additional Mammography Review (AMR) to assess the quality of all mammography performed by Blanchard Valley Regional Health Center (BVRHC)-Bluffton Campus required under 21 CFR 900.12(j)(1). You must send us your plan for this AMR with the response to this letter. Your plan must include the following:

1. Identification of the interpreting physician(s) who will conduct the image review. You must use a physician(s) that meets all of the requirements found in 21 CFR 900.12(a)(1). In addition, the physician(s) may not have a relationship with the facility, conduct the review when it would otherwise be a conflict of interest for them to do so, or when they have a bias in favor of or against the facility. Along with the physician's name, please send us a list of the facilities where this physician(s) currently reads and interprets mammograms, along with any other information you may have on this physician's training and experience in mammography.
2. An indication of whether the review will consist of an evaluation of all of the mammograms conducted between July 1 to September 21, 1999 by [REDACTED] or a representative sample of the examinations. If you decide that the review will consist of a sample of the films, the sample should consist of no fewer than 30 patient examinations.
3. A target date when you believe that the review can be completed.

If you do not wish to select an interpreting physician(s) to conduct the AMR or cannot locate a suitable physician(s) that meets the criteria outlined under item 1 above, you may contact your accreditation body, the American College of Radiology (ACR), and request that they conduct the AMR. You should be aware that the ACR may require that your facility reimburse it for the costs of conducting an AMR. The ACR may require a portion or all of this payment prior to the start of the AMR. You may contact the following individual at the ACR for more information on the AMR at your facility:

Priscilla F. Butler, M.S., FAAPM,
Director, Breast Imaging Accreditation Programs
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091

Once the AMR has been completed, you must send us a detailed report of the review by the physician(s). This report would usually include the total number of examinations evaluated by the physician(s), a list of examinations with films showing image quality problems that may need to be repeated, and an overall assessment by the reviewing physician(s) of the quality of mammography from July 1, 1999 to September 21, 1999. If we determine that the quality of mammography performed by your facility was so inconsistent with the MQSA quality standards established in this section as to present a significant risk to individual or public health, we may require you to notify patients who received mammograms at your facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as we may require.

You must act on this matter immediately. Please provide the information requested above regarding your plans for an AMR and explain to this office in writing within fifteen (15) working days from the date of receipt of this letter:

- the specific steps you have taken or plan to take to correct all of the violations noted in this letter;
- 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.

Please submit your response to:

Mr. R. Terry Bolen
MQSA Radiological Health Officer
Food and Drug Administration
6751 Steger Drive.
Cincinnati, Ohio 45237-3097
Telephone: 513-679-2700 x138; FAX: 513-679-2772

FDA's investigational findings demonstrate that your facility has engaged in serious violations of the MQSA, including performing mammography examinations or procedures without a valid FDA certificate and otherwise failing to comply with the MQSA. FDA may, without further notice, initiate further regulatory action(s) such as:

- 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.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to the findings of your 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>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Bolen.

Sincerely yours,


Henry L. Fielden
District Director
Cincinnati District Office

c.

Margie C. Wanchick
Ohio Department of Health
Radiologic Technology Section
246 North High St.
Columbus, OH 43215

Priscilla F. Butler, M.S., FAAPM
Director, Breast Imaging Accreditation Programs,
American College of Radiology
1891 Preston White Drive
Reston, Virginia 22091