



DEPARTMENT OF HEALTH & HUMAN SERVICES
 PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION

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PHILADELPHIA DISTRICT

98-PHI-05

WARNING LETTER

900 U.S. Customhouse
 2nd and Chestnut Streets
 Philadelphia, PA 19106

Telephone: 215-597-4390

November 24, 1997

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Donna Mulholland
 President and Chief Executive Officer
 Easton Hospital
 250 South 21st Street
 Easton, PA 18042-3892

GEN.	SPEC.
RELEASE	
F# _____	DATE _____
Reviewed by: <i>Wm. W. Kruse</i>	

Facility ID: 159574

Dear Ms. Mulholland:

On November 3 and 4, 1997, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving your mammography operations. Under a Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility is required to have a valid FDA MQSA certificate to perform mammography. Only facilities that have applied to an approved accreditation body and either 1) are being evaluated for accreditation by that body, or 2) have been accredited by that body are entitled to a certificate.

The accreditation process is a necessary requirement of the law for every facility that performs mammography. This process helps to protect the health of women by ensuring that a facility is qualified to perform quality mammography. The evidence collected by the FDA shows that you have performed mammography without a valid FDA MQSA certificate.

Your original FDA MQSA Certificate expired on October 7, 1997. Our investigator found that your facility performed mammography examinations after this date and without a valid certificate or Interim Notice on the following days, 10/8,9,10,13,14,15,16,17,20,21,22,23/97. Approximately [redacted] patients were given mammography exams during this time period. Your facility ceased performing mammography on October 23, 1997 after performing one mammography exam.

Performing mammography without a valid certificate is 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, assessing civil Money penalties up to \$10,000 or obtaining a court injunction against further mammography.

It is our understanding that your facility is voluntarily having the ~~patient~~ patient mammographic examinations, that were performed without a valid certificate, reevaluated by hospital physicians. Your facility also plans to contact all of the referring physicians for the patients to inform them that their patients were examined after your FDA MQSA certificate expired and that you will offer their patients free repeat exams, if they wish. We believe that you are taking appropriate corrective actions for this situation. **Please send us a summary of the results of your proposed plan upon completion.** This summary should include a log documenting the review of all identified exams, the number of exams with a discrepancy with the original interpretation, and resultant followup of all discrepant exams.

We acknowledge receipt of your letter dated November 13, 1997, sent to my attention which summarized a chronology of events regarding your performance of mammography without a valid MQSA Certificate. We understand that there was confusion on the part of your facility in understanding the various letters generated regarding your re-accreditation application. However, FDA's letter dated September 5, 1997 sent to your facility does clearly state: "Under the Mammography Quality Standards Act (MQSA) of 1992, **once your certificate expires, you are no longer certified and cannot continue to offer mammography services.**"

We also acknowledge that the ACR has accepted your application for Provisional Reinstatement of Accreditation and that FDA has sent a new provisional FDA MQSA certificate which expires on May 3, 1998. Thus you now have a valid FDA MQSA Certificate and can legally perform mammography exams as of November 3, 1997.

Please inform this office in writing within fifteen (15) working days from the date you received this letter, of the specific steps you will take to assure that in the future your facility will only perform mammography examinations when you are in possession of a valid FDA MQSA Certificate. Please submit your response to:

Robert E. Davis
Mammography Specialist
U.S. Food & Drug Administration
7 Parkway Center, Rm 390
Pittsburgh, PA 15220

Finally, you should understand that there are other FDA requirements pertaining to mammography. This letter pertains only to the issue of the performance of mammography under a valid FDA MQSA certificate 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/dmqrp.html>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Robert E. Davis at 412-644-3394.

Sincerely,



Diana Kolaitis
District Director
Philadelphia District

cc: Jim Potter
Director, Government Relations
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