The Mammography Quality Standards Act Final Regulations: Modifications to the Policy Guidance Help System Due to the September 11, 2001 Terrorist Attacks; Final Guidance for Industry and FDA

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This document modifies and updates guidance appearing in the Policy Guidance Help System.

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Inspection Support Branch
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Charles Finder at (301) 594-3332 or email caf@cdrh.fda.gov.

Additional Copies

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Background

The Mammography Quality Standards Act was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the *Federal Register*. The final regulations, under which mammography facilities are currently regulated, became effective April 28, 1999. The FDA compiled all final guidance referable to MQSA into a computerized searchable Policy Guidance Help System in November 1998. The Policy Guidance Help System is available on the Internet at:
www.fda.gov/cdrh/mammography/guidance-rev.html
This compliance guidance document serves to update the Policy Guidance Help System to be consistent with more recently issued guidance.

Introduction

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations.

Under its own authority, a State may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with the State or local authorities regarding their requirements.

Since the terrorist attacks of September 11, our country has been dealing with their direct and indirect effects. All of us must adjust to the "new reality." The Mammography Quality Standards Act (MQSA) program is no exception. While only a relatively few mammography facilities were directly impacted by the attacks, the entire radiological community has been affected.

The Food and Drug Administration (FDA) is working with the American College of Radiology to help facilities in the immediate vicinity of New York's World Trade Center maintain their accreditation and certification. Additionally, FDA is aware that some mammography facility personnel have been unable, or will be unable for some period of time, to attend some continuing education (CME/CEU) programs due to program cancellations or inability to travel to the meetings.

If a facility is scheduled for an inspection and has personnel who fail to meet the CME/CEU requirement due to the terrorist attacks, it should:

1. Inform the MQSA inspector at the time of scheduling the inspection.
2. At the time of the inspection, provide verification that the personnel were scheduled to obtain the CME/CEU but were unable to attend as a consequence of the terrorist attacks. This verification may include copies of program registrations, travel/reservation arrangements, cancellation letters, or other similar documents.
3. At the time of the inspection, provide a written explanation of how the facility plans for the personnel to obtain the balance of the required CME/CEU as soon as reasonably possible.

If the above materials are provided, the facility should not be cited for failure of the CME/CEU requirement.