The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #4; Guidance for Industry and FDA

Document issued on March 25, 2002

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
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 by email caf@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/mammography/pubs/1401.pdf, or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1401 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

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This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

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.

Guidance information is periodically updated. Individuals wishing to get automatic notification of such updates may subscribe to our E-mail ListServ by visiting http://list.nih.gov/cgi-bin/wa?SUBED1=mammography_cdrh-l&A=1 and following the directions there.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements

and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html.

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.

Addition to Equipment/General Equipment Requirement section of the PGHS

Question 4: Before 10/28/02, a facility learns (through a QC test, annual physics survey, mammography equipment evaluation or MQSA inspection) that one of its mammography units will not meet the new equipment requirements that go into effect on 10/28/02. Must the facility take the unit out of service as of 10/28/02?

Answer: No. The requirement to have the unit adjusted, modified, or replaced does not apply until a facility QC test, annual physics survey, mammography equipment evaluation or MQSA inspection that occurs after the 10/28/02 effective date, documents that the unit does not comply with the new requirements. For example, during the physicist's annual survey performed in July 2002 (prior to the 10/28/02 effective date of the new requirements), the focal spot does not pass the resolution test but does meet the focal spot dimension requirement. That unit will not have to be adjusted, modified, or replaced until it fails the resolution test the next time it is performed after 10/28/02 (usually during the next annual survey). While the unit may stay in service for the time period described above, FDA strongly recommends that the facility use this time to have the unit adjusted, modified or replaced. Once the unit is documented as non-compliant, the regulatory time limits for completion of repairs apply.