

Compliance Guidance

**The Mammography Quality
Standards Act Final Regulations
Motion of Tube-Image Receptor
Assembly**

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**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 Charles Finder, Division of Mammography Quality and Radiation Programs, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. 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.

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Compliance Guidance¹

The Mammography Quality Standards Act

Final Regulations- Motion of Tube-Image Receptor Assembly

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 will become effective **April 28, 1999**, and will replace the interim regulations (58 FR 67558 and 58 FR 67565) which, under MQSA, currently regulate mammography facilities.

The FDA is planning a variety of efforts to educate the public about the final regulations. These efforts include making presentations at key professional meetings and providing written materials to the public. The currently available written documents include the *Small Entity Compliance Guide* (October 1997), a quarterly newsletter *Mammography Matters*, and an Internet home page (<http://www.fda.gov/cdrh/dmgrp.html>). The latest edition of “*What a Mammography Facility Should Do to Prepare for the MQSA Inspection*” (June 1995 with a July 1996 addendum) is currently being revised to reflect the changes that will occur under the final regulations.

¹ 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 FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

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. This guidance uses a question-and-answer format to provide information about how FDA will implement its mammography program under the regulations and MQSA.

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.

A number of facilities have raised questions about whether their equipment needs to be replaced or modified in order to meet the requirements of the final regulations related to “motion of the tube-image receptor assembly.” In order to address these concerns we have compiled all our current guidance on this matter.

21 CFR 900.12(b)(3) *Motion of tube-image receptor assembly. (i) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion. (ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.*

Question: What is meant by the term “power interruption?”

Answer: Power interruption in this context means interruption of external electrical power to the mammography unit. It does not refer to internal system failure.

Question: What motion requirements must the tube-image receptor assembly meet?

Answer: There is no specific range of motion that the assembly must provide. However, once fixed in any operating position intended by the equipment design, it must remain fixed in that position, even during power interruption.

Question: Could you clarify what is meant by the statement that the mechanism "shall not fail in the event of power interruption"?

Answer: This means that if the power to the x-ray system is unexpectedly terminated during an examination, the image receptor assembly will not move without operator intervention. This requirement is intended to provide additional safety for the patient in the event of power interruption during an examination and to prevent patient injury that might occur if the assembly moves.

The system must prevent motion until the operator determines that such motion is acceptable. Depending on the circumstances in each facility, the time required for the operator to safely remove the patient from the unit may vary. Therefore, the length of time required for the system to remain locked in place will also vary. However, removing the patient from the unit can usually be accomplished in a minute or less. Note: systems that do not have built-in mechanisms to prevent unintended gantry motion may meet the requirement using external battery backup or mechanical mechanisms that prevent unintended motion for the amount of time it takes to remove the patient from the machine.

Question: How much tube-image receptor assembly motion is acceptable before a unit would be noncompliant with 900.12(b)(3)(ii)?

Answer: The amount of acceptable motion is dependent on the circumstances in each facility and should be evaluated on an individual basis. The intent of this regulation is to assure patient safety during power interruptions. Facilities should evaluate their machines to determine if the amount of gantry motion during power interruptions is sufficient to allow their typical patient to fall, be twisted,

or be pulled from the position that they were placed in by the technologist to such an extent that injury could occur. If such injury could reasonably occur, the regulation has not been met.