

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 99D-4910]

**Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3." The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) became effective April 28, 1999, replacing the interim regulations. The guidance document is intended to assist facilities and their personnel to meet the MQSA final regulations.

**DATES:** Submit written comments concerning this guidance document at any time.

**ADDRESSES:** Submit written requests for single copies on a 3" diskette of the guidance document entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document. Submit written comments on the guidance document to the contact person listed below.

**FOR FURTHER INFORMATION CONTACT:** Charles A. Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This guidance document was published as a draft proposal for public comment in the **Federal Register** of December 8, 1999 (64 FR 68696). It has been discussed with the National Mammography Quality Assurance Advisory Committee at two separate meetings (July 1999 and January 2000). The guidance document has been modified from the original draft proposal to address public comments. While there are several clarifying changes in the guidance document, there were no major substantive changes.

**II. Significance of Guidance**

This guidance document represents the agency's current thinking on the final regulations implementing the MQSA. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

**III. Electronic Access**

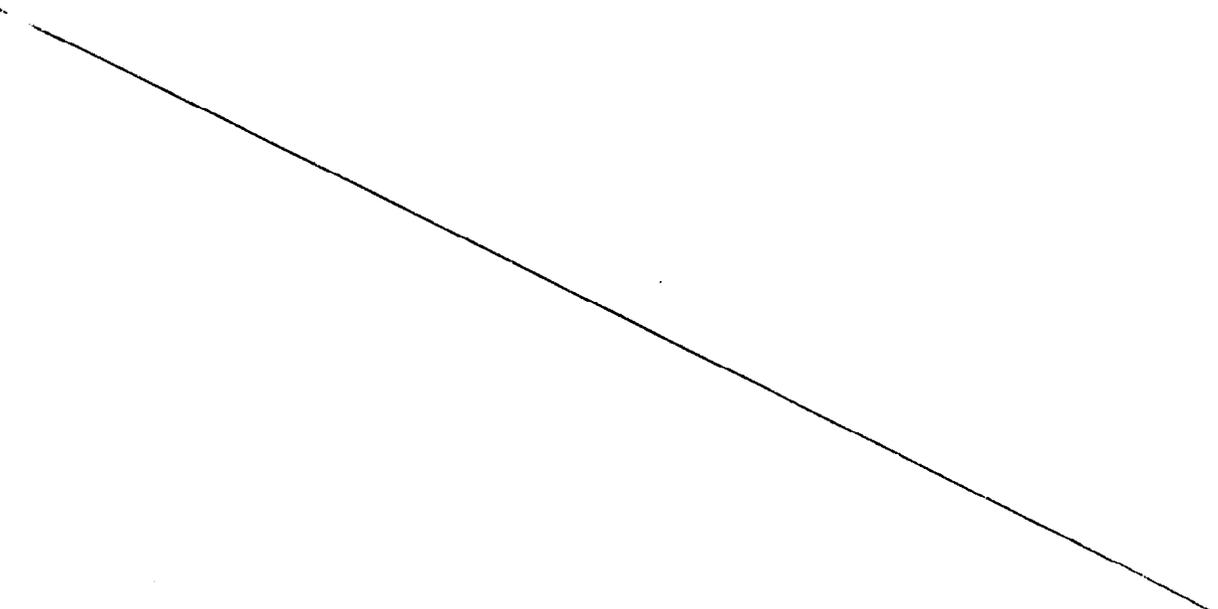
In order to receive "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touchtone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number

(1496) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes previously issued “Compliance Guidance for the Mammography Quality Standards Act Final Regulations Document #3,” device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturers’ assistance, information on video conferencing and electronic submissions, mammography matters, and other device oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. “Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3 will be available at <http://www.fda.gov/cdrh/mammography/guidance-rev.html>.

#### **IV. Comments**

Interested persons may submit to the contact person (address above) written comments regarding this guidance at any time. Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, except that



individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Dated: 6/29/00  
June 29, 2000

Linda S. Kahan

Linda S. Kahan,  
Deputy Director for Regulations Policy,  
Center for Devices and Radiological Health.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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COPY OF THE ORIGINAL**

Stephanie N. Bass