

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket No. 00D-1497]

The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA." The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) became effective April 28, 1999. The final guidance document is intended to assist facilities and their personnel to meet the MQSA final regulations.

DATES: Submit written comments at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, 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. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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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

The draft guidance document was issued for public comment in the **Federal Register** of September 13, 2000 (65 FR 55265). The comment period ended on December 13, 2000. The draft guidance was discussed with the National Mammography Quality Assurance Advisory Committee at the September 28, 2000, meeting. The final guidance document has been modified from the original draft guidance to address the seven public comments received. There were several clarifying changes made to the document, particularly dealing with the issues of what constitutes a "major repair" and when the physicist must perform onsite evaluations. Several decision tree flow diagrams were added to the document to help clarify these issues. Overall, there were no major substantive changes made to the document.

II. Significance of the Guidance

This guidance document represents the agency's current thinking on the MQSA final regulations guidance. 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 statutes and regulations.

The agency has adopted the good guidance practices (GGPs) regulation, which sets forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This guidance document is issued as a level 1 guidance consistent with GGPs.

III. Electronic Access

In order to receive "The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA" 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 (1159) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance 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 Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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>. "The Mammography Quality Standards Act Final Regulations Document #4; Final Guidance for Industry and FDA" will also be available on CDRH's mammography Web site at <http://www.fda.gov/cdrh/mammography>. Guidance documents are also available on the Dockets Management Branch Web site at <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance at any time. 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. The guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 5/16/01
May 16, 2001.

Linda S. Kahan

Linda S. Kahan,
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