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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1497]

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| Certifier | SNReese |

Draft Compliance Guidance: The Mammography Quality Standards Act
Final Regulations Document #4; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4." This draft guidance is neither final nor is it in effect at this time. The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) became effective April 28, 1999. The draft guidance document is intended to help facilities and their personnel meet the MQSA final regulations.

DATES: Submit written comments concerning this draft guidance by [insert date 90 days after date of publication in the FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft guidance entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug

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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 Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft guidance.

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 MQSA was passed on October 27, 1992, to establish national quality standards for mammography. After October 1, 1994, the MQSA required all mammography facilities, except facilities of the U.S. Department of Veterans Affairs, to 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 FDA. In the FEDERAL REGISTER of October 28, 1997 (62 FR 55976), FDA published the

MQSA final regulations. The final regulations became effective April 28, 1999, and replaced the interim regulations (58 FR 67558 and 58 FR 67565, December 21, 1993). Development of this guidance document began in December 1999.

II. Significance of Guidance

This draft 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 draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

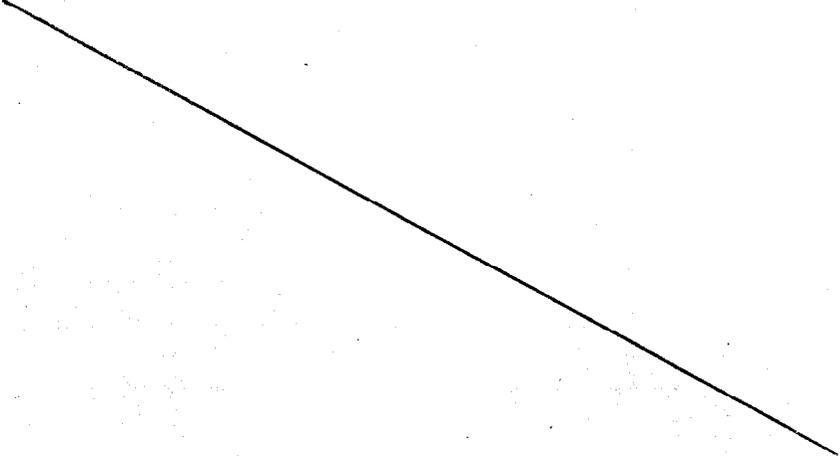
In order to receive the draft guidance entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4" via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to enter 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 draft 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 access to the Internet. Updated on a regular basis, the CDRH home page includes "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #4," 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 #4" will be available at <http://www.fda.gov/cdrh/mammography>.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by [insert date 90 days after date of publication in the FEDERAL REGISTER]. Two copies of any comments are to be submitted, except that individual may submit one copy. Comments are to be identified with the docket



number found in brackets in the heading of this document. The draft 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: 8/29/00
August 29, 2000.

Linda S. Kahan

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

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

Suzette N. Reese