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Certifier	M. Bell

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0302]

Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2." The guidance document is intended to assist facilities and their personnel to meet the Mammography Quality Standards Act of 1992 (the MQSA) final regulations. The final regulations implementing the MQSA became effective April 28, 1999, replacing the interim regulations.

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

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2" 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. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2" to the contact person listed below.

NAD-2

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. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the U.S. 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 FDA. In the **Federal Register** of October 28, 1997, 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) which, under the MQSA, previously regulated mammography facilities. The document addresses new questions that FDA has received since the publication of "Compliance Guidance: The Mammography Quality Standards Act Final Regulations" on August 27, 1998.

The guidance document was published as a draft proposal for public comment on March 19, 1999 (64 FR 13589). It was discussed with the National Mammography Quality Assurance Advisory Committee in November 1998 and a working group of the Conference of Radiation Control Program Directors in May 1999. The document has been modified from the original draft proposal to address public comments. While there are many clarifying changes in the 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.

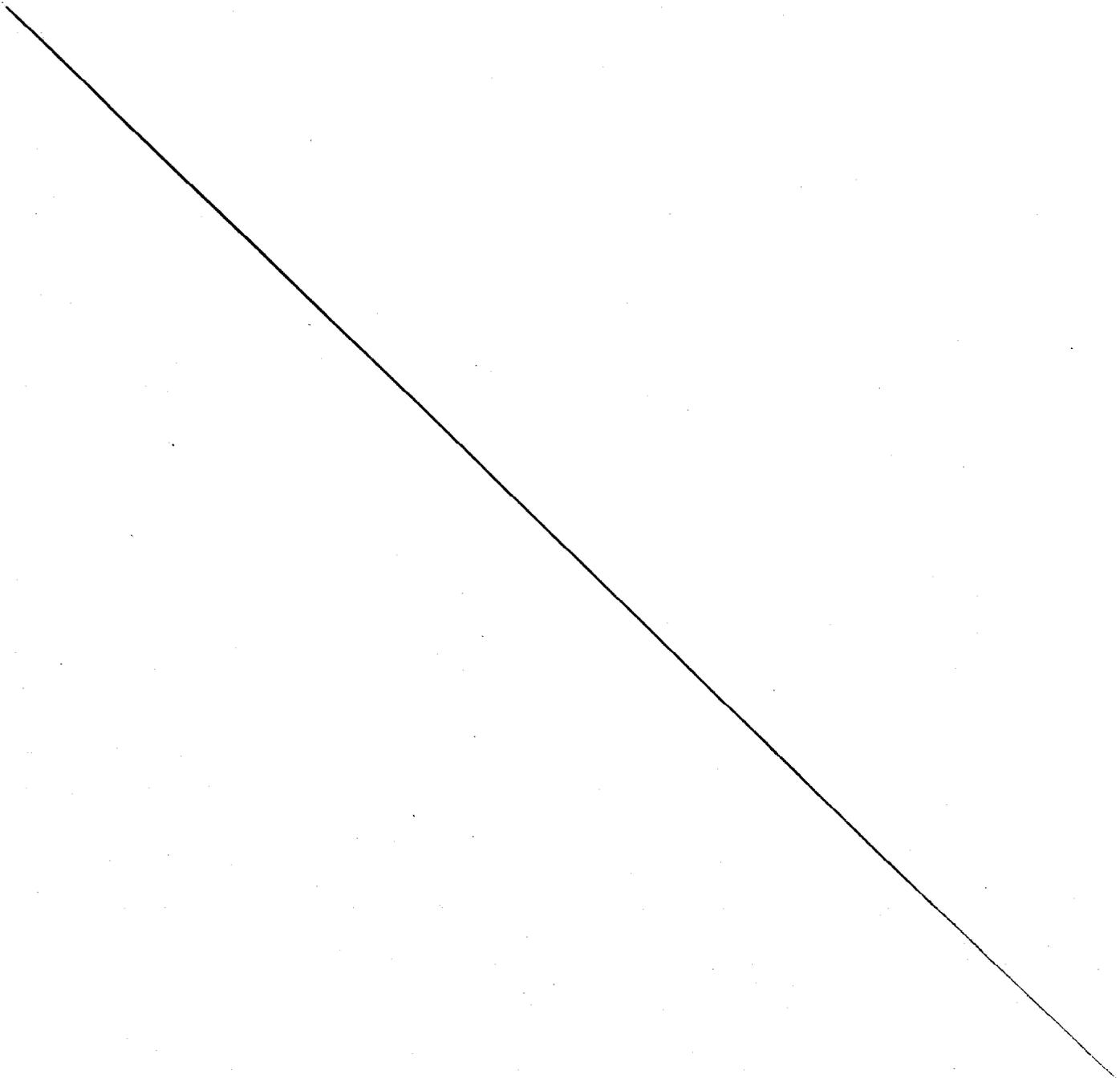
III. Electronic Access

In order to receive "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2" 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 access DSMA Facts, at second voice prompt press 2, and then enter the document number (1498) followed by the pound sign (#). Then 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 access to the Internet. Updated on a regular basis, the CDRH home page includes "Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2," 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 #2" will be available at <http://www.fda.gov/cdrh/mammography>.

IV. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this guidance. 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: 2/9/00
February 9, 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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