

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 2005D-0195

Guidance for Industry and FDA Staff; The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9; 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: Modifications and Additions to Policy Guidance Help System #9.” This guidance document is intended to assist facilities and their personnel in meeting the Mammography Quality Standards Act (MQSA) final regulations.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled “The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9” to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label 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 concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 15, 2005 (70 FR 41043), FDA issued a notice of availability for, and an opportunity for public comment on, “The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9” draft guidance. During the public comment period, 6 respondents submitted a total of 38 comments. In addition, the National Mammography Quality Assurance Advisory Committee reviewed the draft guidance during its September 26 to 27, 2005, meeting and provided additional comments. FDA reviewed and considered all the comments, and in response FDA has modified the draft guidance as follows by:

1. Further clarifying Small Field Digital Mammography (SFDM) requirements,

2. Adding the phrase “final interpretation quality” to the section on retention and transfer of Full Field Digital Mammography (FFDM) images,

3

3. Clarifying that FFDM images used for final interpretation contain certain identifying information,

4. Clarifying under what circumstances the 8 hours of new mammographic modality training can be included as part of other initial interpreting physician requirements,

5. Further clarifying the table describing acceptability of the American Registry of Radiologic Technologists (ARRT(M)) certificate,

6. Modifying the guidance regarding the testing of single use cushion pads,

7. Modifying the table listing medical physicist involvement in certain FFDM repairs,

8. Clarifying the conditions under which electronic Quality Control test data may be retained.

This document provides guidance on the following issues:

1. Definitions of final interpretation and lossless and lossy digital compression,

2. Use of Small Field Digital Mammography (SFDM) image receptors,

3. Clarification relating to reestablishing processor operating levels,

4. Impact of the Health Insurance Portability and Accountability Act (HIPAA) requirements on certain MQSA activities,

5. Retention of medical outcomes audit records,

6. Steps to take when patients do not wish to receive their lay summaries,

7. Combining medical reports,

8. The effect of film digitization and compression of Full Field Digital Mammography (FFDM) digital data on retention, transfer, and interpretation of mammographic images,

9. Clarification of continuing education requirements,

10. Use of foreign-trained physicians,

11. Use of the ARRT(M) certificate to meet certain radiologic technologist requirements,

12. Quality Control testing when using cushion pads on compression devices,

13. Medical physicist involvement in certain FFDM repairs,

14. Use of printers and monitors that were not specifically approved as part of an FFDM unit,

15. Digitization of paper records and personnel documents.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the issues described in the previous paragraphs. 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 and regulations.

III. Electronic Access

In order to receive "The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9" by 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 1538 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 by 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 device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control number 0910–0580.

V. Comments

Interested persons may submit to the Division of Dockets Management (See **ADDRESSES**), written or electronic comments regarding this document at any time. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 10, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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