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Guidance for Industry, MQSA Inspectors, and FDA

The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #12

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**This document modifies and updates guidance appearing in the Policy
Guidance Help System**

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**U.S. Department of Health and Human Services
Food and Drug
Administration
Center for Devices and Radiological Health
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs**

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Note: Questions and answers that are currently in the PGHS and are not being modified are not included in this document.

Additional Copies

Additional copies are available from the Internet at: <http://www.fda.gov/cdrh/mammography>. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (**1623**) to identify the guidance you are requesting.

Guidance for Industry, MQSA Inspectors, and FDA Staff

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Public Law 102-539). This guidance document updates previous guidance and deals with the issues of:

1. reducing the annual facility reporting requirements to accreditation bodies
2. quality control testing of infrequently used laser printers used for full field digital mammography
3. clarifying the information that needs to be supplied to the certificate extension program for computed radiography digital mammography systems.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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Under its own authority, a State may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with its State or local authorities regarding their requirements.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at <http://www.fda.gov/cdrh/ombudsman/>.

Background

MQSA was signed into law on October 27, 1992, to establish national quality standards for mammography. The MQSA required that, in order to lawfully provide mammography services after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary) or by an approved State certification body (section 354(b) of the MQSA; 42 USC 263b(b)). The authority to approve accreditation bodies, State certification bodies, and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published final regulations implementing the MQSA in the *Federal Register* (21 CFR Part 900).

In November 1998, FDA compiled all final FDA guidances related to MQSA and put them into a computerized searchable database called the Policy Guidance Help System (PGHS). The PGHS is available on the Internet at:
www.fda.gov/cdrh/mammography/robohelp/start.htm

FDA periodically updates the information in the PGHS and this document serves as a further update. Individuals wishing to receive automatic notification of future updates may subscribe to our E-mail ListServ by visiting http://service.govdelivery.com/service/subscribe.html?code=USFDACDRH_17 and following the directions there.

The following question and answer is being added to Accreditation and Certification/Accreditation Body Regulations

Background:

The MQSA interim regulations, published on December 21, 1993, required facilities to submit to their accreditation body on an annual basis the results of their annual physics

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survey. The MQSA final regulations, published on October 28, 1997, has a similar requirement (see below). The purpose of this regulation was for the accreditation body to evaluate these surveys as part of accreditation oversight and to serve as a check on the review done as part of the facility's annual MQSA inspection. However, accreditation bodies have been reviewing these surveys since 1994 and the need for an annual review has come into question. This matter was discussed with the National Mammography Quality Assurance Advisory Committee (NMQAAC) on September 28, 2006. It was the committee's consensus that annual reporting of the physics survey was no longer necessary. The Institute of Medicine also recommended that this requirement be deleted from the regulations. These groups concluded that having the accreditation body review the physics survey at the time of reaccreditation (once every three years) provides adequate oversight. Until such time as FDA can proceed with the notice and comment process for deleting this regulation, FDA intends to exercise enforcement discretion as to this requirement as of July 1, 2007. The purpose of this document is to inform the mammography community and make the necessary changes to the Policy Guidance Help System.

Citation:

900.4(e)(2) The accreditation body shall require that all facilities undergo an annual survey to ensure continued compliance with the standards referenced in paragraph (b) of this section and to provide continued oversight of facilities' quality control programs as they relate to such standards. The accreditation body shall require for all facilities that:

- (i) Such surveys be conducted annually;*
- (ii) Facilities take reasonable steps to ensure that they receive reports of such surveys within 30 days of survey completion; and*
- (iii) Facilities submit the results of such surveys and any other information that the body may require to the body at least annually.*

Question 1: Must a facility submit the results of its annual medical physicist survey to its accreditation body on an annual basis?

No. Due to recommendations from the National Mammography Quality Assurance Advisory Committee and the Institute of Medicine, FDA intends to propose deleting the requirement for annual submission of physicist surveys and in the interim, intends to exercise enforcement discretion as to this requirement as of July 1, 2007. Facilities are reminded that even after that date, they must continue to have the physicist survey performed annually and to submit the results of the physicist survey as part of the initial and reaccreditation process (21 CFR 900.4(e)(1)). Facilities must also follow their accreditation body's procedures for updating the body when significant changes take place in the facility (section 354(e)(3) of the MQSA).

The following question and answer is being added to Quality Assurance/Equipment/Other Modalities Quality Control Tests

Background:

When FFDM systems were first approved by the FDA, they were approved only for hard copy final interpretation (laser film). After FDA approved FFDM for soft copy (monitor)

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final interpretation, facilities started using both methods for interpretation. However, the majority of facilities now use only soft copy for final interpretation.

MQSA regulations require that all facilities transfer the original mammograms upon patient request (21 CFR 900.12(c)(4)). Whether or not the facility is using hard copy for final interpretation, it needs to be able to produce final interpretation quality hard copy images for those patients, their representatives, and health-care providers who request hard copy transfer of the mammogram. In order to conform to this requirement, all facilities need access to a printer. In addition, if the facility is retaining the mammogram in hard copy rather than electronic form, the hard copy image must be of final interpretation quality.

This matter was discussed with the National Mammography Quality Assurance Advisory Committee (NMQAAC) on September 29, 2006. It was the committee's consensus that facilities need to be performing quality control testing on laser printers in order for the facility to produce hard copy images of final interpretation quality.

Citation:

900.12(e)(6): Quality Control tests — other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

Question 4: Must a facility perform all the required QC testing on a laser printer even if the facility is using only soft copy for final interpretation and is using the printer only to provide final interpretation quality hard copy images to patients, their representatives, and health-care providers or for retention purposes? If not, is the facility subject to citation during an MQSA inspection?

Yes to both questions. Even if a facility is using the printer only for these purposes and never actually provides a final interpretation report based on the hard copy images, it still must perform all the required printer QC tests at their appropriate frequencies or, prior to printing clinical images for patients and health-care providers or for retention, whichever is less.

Because of a misunderstanding in the professional community regarding QC testing in these situations, we have not universally enforced this requirement. However, this guidance serves to clarify this matter and those facilities that fail to perform the required QC testing after July 1, 2007 will be subject to citation.

The following questions and answers are being added to Accreditation and Certification/ Full Field Digital Mammography (FFDM) Certification Extension Program

Background:

FDA has used the certificate extension program to allow facilities to legally use Full Field Digital Mammography (FFDM) systems that have been approved for commercial use by FDA's Office of Device Evaluation (ODE) but do not yet have an approved accreditation

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body to accredit the system. With ODE's approval of computed radiography systems for mammographic use, additional guidance to facilities is needed to address the physical differences between these systems and earlier approved FFDM units.

Question 14: FDA has approved a Computed Radiography (CR) system for mammography use. From an MQSA standpoint, are there any differences between a CR system and a full field digital mammography (FFDM) system?

While the systems have significant physical differences, FDA treats them the same from an MQSA regulatory standpoint. CR systems are considered part of the mammographic modality known as FFDM. This means that facilities wishing to use a CR system must meet all applicable MQSA requirements (21 CFR Part 900), including those specific to FFDM units. For example, all personnel using a CR system must have completed at least 8 hours of training specific to digital mammography prior to using the new CR system on patients (21 CFR 900.12(a)(1)(ii)(C), (a)(2)(iii)(E), (a)(3)(iii)(C)). However, because CR systems are part of the FFDM mammographic modality, personnel who have already obtained 8 hours of training in FFDM do not have to obtain another 8 hours in CR prior to use on patients.

Question 15: Under the Certification Extension Program, does a facility wishing to add a CR system to a screen film (S-F) unit need to keep accreditation for an existing unit?

Yes, the facility will need to maintain accreditation with an FDA-approved accreditation body (AB) for at least one unit *other than* the CR system. This means the facility must either keep accreditation for the S-F unit, with which the CR system shares the cassette holder, or another S-F unit or an FFDM unit. Once the FDA approves an AB to accredit CR systems, the facility will have to apply to that AB for accreditation of the CR system. Once it gets accreditation from the AB for the CR system, the facility will not need to maintain the additional accreditation unless it wishes to continue using the other units.

Note: Your facility is also required to undergo an annual onsite MQSA inspection of the CR unit(s) during the inspection of S-F and/or FFDM accredited unit(s) (section 354 of the MQSA).

Question 16: If we have multiple S-F units and plan to use CR with all of them, do we need approval to extend our accreditation and certification to add CR to all of them?

Yes. Since FDA grants accreditation and certification extension for the use of a CR system *only* with a specific mammography unit, the additional units are not covered even if they are the same make and model.

Question 17: What inspection costs are associated with CR certification?

FDA will treat an S-F unit that is equipped with a CR system as two separate units (one S-F; one FFDM). Therefore, inspectors will inspect a single physical unit that is used to perform S-F mammography and CR mammography as two separate units, and FDA will bill the facility for two units. Once FDA approves an accreditation body to accredit CR systems, a facility may begin the accreditation process for the CR unit and drop the S-F accreditation, thereby reducing their unit inspection and accreditation costs.

Question 18: How will an inspector inspect a CR unit?

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Using his/her laptop computer, the inspector will download for inspection the record for a mammography unit(s) that uses CR in the same manner as any other FFDM unit, and then open the applicable inspection procedure screens. If a unit(s) is being used for both S-F and CR on the same physical unit(s), the inspector will need to download a separate S-F record, as well.

If an inspector determines that CR is being used on an S-F unit(s) for which there is **no** certificate extension approval, the inspector will:

1. add a new record for the CR unit(s) into the database (e.g., with the same model, description, and serial number as the S-F unit(s) but with an image receptor type of CR);
2. mark it as unaccredited (resulting in a Level 1 or 2 inspection observation);
3. answer the mammography equipment evaluation (MEE) question and all of the applicable questions in the QC records and Survey Report sections accordingly; and,
4. instruct the facility that it should stop using the unit(s) until it applies to FDA for certificate extension on the unit(s) and has obtained certificate extension for the unit(s).

If a facility is performing both S-F and CR mammography using the same physical unit(s), the inspector will treat the inspection as 2 separate units and the facility will be billed accordingly.