

Guidance for Industry, MQSA Inspectors and FDA Staff

The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13

Document issued on: November 16, 2010

The draft of this document was issued on October 9, 2009.

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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. Alternatively, electronic comments may be submitted to <http://www.regulations.gov>. When submitting comments, please refer to Docket No. FDA-2009-D-0448. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at:

<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm>.

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 1695 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) (42 U.S.C. 263b). This guidance updates the Policy Guidance Help System and addresses or contains the following:

1. Updated contact information for accreditation bodies and certification agencies;
2. General guidance regarding Additional Mammography Reviews (AMRs);
3. Previously approved alternative standards;
4. Centers for Medicare and Medicaid Services (CMS) reimbursement;
5. Mechanisms to inform physicians and patients of mammography results;
6. Mammographic modality and its impact on personnel requirements;
7. Clarification of the personnel 6-month exemption period;
8. Information on calibrating the air kerma measuring instrument;
9. Medical physicist involvement as it applies to cassette replacement;
10. Full Field Digital Mammography (FFDM) and use of single-use cushion pads;
11. Quality control testing of computer controlled compression devices;
12. Mammography equipment evaluations of laser printers;
13. Quality control testing of monitors and laser printers;

14. Mammography equipment evaluations of new FFDM units; and
15. Mammography equipment evaluations of off-site laser printers and monitors.

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.

For purposes of this document, additions to the Policy Guidance Help System (PGHS) are shown in red and underlined (**Example**) while deletions are shown in blue with strikethroughs (~~Example~~). Note: Questions and answers that are currently in the PGHS and are not being modified are not included in this document.

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.

Background

The Mammography Quality Standards Act (MQSA) was signed into law on October 27, 1992 (Public Law 102-539), to establish national quality standards for mammography. It is codified at 42 U.S.C. 263b. The MQSA requires 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 agency (section 354(b) of the MQSA; 42 USC 263b(b)). In June 1993, the authority to approve accreditation bodies and State certification agencies, and to certify facilities, was delegated by the Secretary to the FDA (58 FR 32543). On October 28, 1997, the FDA first published final regulations implementing the MQSA in the *Federal Register* (21 CFR Part 900). The MQSA has twice been amended since its enactment, through the Mammography Quality Standards Reauthorization Acts (MQSRAs) of 1998 and 2004 (Public Laws 105-248 and 108-365).

The draft of this guidance was made available for comment in the Federal Register on October 9, 2009. Four respondents submitted a total of 14 comments on the draft guidance. In addition, the National Mammography Quality Assurance Advisory Committee reviewed the draft guidance during its January 25, 2010 meeting and provided additional comments. FDA reviewed and considered all the comments and in response FDA has modified the draft guidance by:

1. providing the most current accreditation body and certification agency contact information
2. clarifying that original or lossless compressed digital image files may be acceptable for record transfer

3. clarifying the conditions under which an Additional Mammography Review conducted by an outside entity (AMROE) would be acceptable to FDA
4. deleting the question and answer dealing with image labeling
5. modifying the section on the use of attestation to include attesting to the specific mammographic modality included in personnel's initial training
6. clarifying the guidance on the use of non-invasive kVp meters
7. recommending the inclusion of cushion pad(s) when performing AEC testing

In November 1998, FDA compiled all to-date 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:

<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/default.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=USFDA_45 and following the directions there.

The Accreditation and Certification/Accreditation and Certification Overview is being modified as follows

Citation:

900.11(a) General. After October 1, 1994, a certificate issued by FDA is required for lawful operation of all mammography facilities subject to the provisions of this subpart. To obtain a certificate from FDA, facilities are required to meet the quality standards in section 900.12 and to be accredited by an approved accreditation body or other entity as designated by FDA.

Discussion:

The Mammography Quality Standards Act (MQSA) requires that before a mammography facility can legally perform mammography, it must be certified. Before a facility can be certified, it must meet applicable MQSA requirements including those established by its accreditation body to obtain accreditation. To begin the process, the facility must first contact its accreditation body and apply for accreditation.

~~Currently the~~ The FDA-approved accreditation bodies (ABs) are:

American College of Radiology (ACR)
Mammography Accreditation Program
1891 Preston White Drive
Reston, Virginia 20191-4397

1-800-227-6440

State of Arkansas

Arkansas Department of Health

Division of Health

Radiation Control Section

Mammography Program

4815 W. Markham, Slot 30

Little Rock, Arkansas 72205-3867

1-501-661-2301

State of Iowa

Mammography Accreditation Program

Bureau of Radiological Health

Iowa Department of Public Health

Lucas State Office Bldg., 5th Floor

321 East 12th Street

Des Moines, Iowa 50319

1-515-281-3478

State of Texas

Texas Department of State Health Services

Mammography Accreditation Program

Machine Source Group

P.O BOX 149347

Mail Code 2835

Austin, TX 78714-9347

1-512-834-6688 extension 2246

Note: Under MQSA regulations, a facility located in a State approved by FDA as an accreditation body (AB) may be accredited by the State AB or by the American College of Radiology (ACR). See 21 C.F.R.-CFR 900.4(a)(7). State law may require facilities to meet additional requirements. State requirements are independent of MQSA. See 42 U.S.C. 263b(m). You may want to contact your State about its requirements.

The regulations require the AB to review a mammography facility's equipment, personnel (interpreting physicians, radiologic technologists, and medical physicists), and practices. The AB will accredit the facility if its review establishes that the mammography facility meets the quality standards established under MQSA. 21 C.F.R.-CFR 900.4.

Certification is a process separate from accreditation. It is administered by a Certifying Agency (FDA or an FDA-approved Certifying State Certifying Agency(SCA)). 21 CFR 900.21. FDA generally does will not certify facilities located in states that have an FDA- approved SCA-Certifying States. Certifying States SCAs only certify facilities within their State borders. Currently tThe FDA-approved Certifying States SCAs are:

State of Illinois
Office of Radiation Safety
[Division of Registration and Certification](#)
[Department of Nuclear Safety](#)
1035 Outer Park Drive
Springfield, IL 62704
217-785-9974

[State of Iowa](#)
Mammography ~~Accreditation~~ [Certification](#) Program
[Bureau of Radiological Health](#)
Iowa Department of Public Health
Lucas State Office Bldg., 5th Floor
321 East 12th Street
Des Moines, Iowa 50319
515-281-3478

State of South Carolina
Mammography Certification Program
Department of Health and Environmental Control
[Bureau of Radiological Health](#)
[Division of Electronic Products](#)
2600 Bull Street
Columbia, SC 29201
803-545-4400

[State of Texas](#)
[Texas Department of State Health Services](#)
[Mammography Certification Program](#)
[Machine Source Group](#)
[P.O BOX 149347](#)
[Mail Code 2835](#)
[Austin, TX 78714-9347](#)
[512-834-6688, Extension 2245](#)

Question 15: Which FFDM units can be accredited by which accreditation bodies?

The American College of Radiology has been approved to accredit the General Electric Senographe 2000D, General Electric Senographe DS, Fischer SenoScan, Lorad/Hologic Selenia, [Selenia S and Selenia Dimensions 2D](#), Siemens Mammomat Novation DR and [Novation S](#), General Electric Senographe Essential, and Fuji Computed Radiography FFDM units.

The State of Arkansas has been approved to accredit the Lorad/Hologic Selenia, [Selenia S and Selenia Dimensions 2D](#), General Electric Senographe 2000D, General Electric Senographe DS, General Electric Essential, [Siemens Mammomat Novation DR and Novation S](#), and Fuji Computed Radiography FFDM units.

The State of Iowa has been approved to accredit the General Electric Senographe 2000D, General Electric Senographe DS, General Electric Senographe Essential, Lorad/Hologic Selenia, [Selenia S and Selenia Dimensions 2D](#), [Siemens Mammomat Novation DR and Novation S](#), and Fuji Computed Radiography FFDM units.

The State of Texas has been approved to accredit the General Electric Senographe 2000D, General Electric Senographe DS, General Electric Senographe Essential, Fischer SenoScan, Lorad/Hologic Selenia, [Selenia S and Selenia Dimensions 2D](#), Siemens Mammomat Novation DR [and Novation S](#), and Fuji Computed Radiography FFDM units.

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

Citation:

900.11(b)(1)(i)(ii): Application.

(1) Certificates.

(i) In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body, or to another entity designated by FDA. The facility shall submit to such body or entity the information required in 42 U.S.C. 263b(d)(1).

(ii) Following the agency's receipt of the accreditation body's decision to accredit a facility, or an equivalent decision by another entity designated by FDA, the agency may issue a certificate to the facility, or renew an existing certificate, if the agency determines that the facility has satisfied the requirements for certification or recertification.

Question 12: We are planning on moving our mammography unit. Whom do we need to notify about the move?

The answer to the question is available in a table on the following webpage:

<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/ucm219621.htm>

Question #4 in Accreditation and Certification/Accreditation and Certification Overview, Question #5 in Accreditation and Certification/Definition of Certificate and Question #5 in Definitions/Certificate are being modified as follows

Question: What should a facility do if it closes or decides that it will no longer provide mammography services?

Before a facility permanently stops performing mammography, it should do the following:

1. Inform its accreditation body that it will no longer be performing mammography;
2. Notify its State radiation control program; and
3. Arrange transfer of each patient's medical record (original mammography films and/or original or lossless compressed digital files and reports) to the mammography facility where the patient will be receiving future care, the patient's referring physician or health care provider, or the patient. This transfer will address the statutory and regulatory requirement that the facility maintain the patient's permanent medical record for a period of not less than 5 years, or not less than 10 years if no additional mammograms are performed at the facility, or longer if mandated by State or local law. 42 U.S.C. 263b(f)(2)(G)(i)(I); 21 CFR 900.12(c)(4). The facility should make reasonable attempts to inform its former patients of how they can obtain their mammography records. Facilities should check with State or local agencies to determine ~~if their~~ whether State or local requirements are more stringent than those of MQSA. Note: Radiology practices and other medical facilities that still see patients but have permanently stopped performing mammography; may choose to keep the patients' medical records rather than transfer them to another facility ~~(unless the patient requests such a transfer)~~.

If option transfer of each patient's medical record (step 3) is not viable, facilities could store the medical records in a hospital, if appropriate, or make arrangements to warehouse the records. The facility should assure that there is a mechanism to release the films records to the appropriate entity when requested and that former patients are made aware of that mechanism. It should be noted that if no one else is willing to accept the records, the facility remains responsible for them. Under MQSA, facilities will not be held responsible for maintenance of examinations performed before October 1, 1994; however, State and local regulations may require otherwise.

Once the facility ceases operation, the MQSA certificate should no longer be displayed. The facility may file or destroy its MQSA certificate.

Due to the fact that some facilities have not followed the above recommendations, FDA has received inquiries from patients complaining that their mammography facility has closed, that they were not informed, and that they cannot find out where or how to gain access to their mammography records. For this reason, FDA requests that a facility that plans to stop performing mammography notify its Certifying Agency of how it intends to fulfill its obligations with respect to medical records. Such information may be sent to:

FDA/CDRH/OCER/DMQRP

Attention: Closed Facility Notification of Records Retention
1350 Piccard Drive, HFZ-240
Rockville, MD 20850

10903 New Hampshire Avenue
WO66-4621
Silver Spring, MD 20993

Facilities certified by States may send the above information to:

State of Illinois
Office of Radiation Safety
Division of Registration and Certification
~~Department of Nuclear Safety~~
1035 Outer Park Drive
Springfield, IL 62704
217-785-9974

State of Iowa
Mammography ~~Accreditation~~ Certification Program
Bureau of Radiological Health
Iowa Department of Public Health
Lucas State Office Bldg., 5th Floor
321 East 12th Street
Des Moines, Iowa 50319
515-281-3478

State of South Carolina
Mammography Certification Program
Department of Health and Environmental Control
Bureau of Radiological Health
~~Division of Electronic Products~~
2600 Bull Street
Columbia, SC 29201
803-545-4400

State of Texas
Texas Department of State Health Services
Mammography Certification Program
Machine Source Group
P.O BOX 149347
Mail Code 2835
Austin, TX 78714-9347
512-834-6688, Extension 2245

The following question and answer is being modified in Accreditation and Certification/Full Field Digital Mammography Certification Extension Program

Question 9: Which FFDM units can be accredited by which accreditation bodies?

The American College of Radiology has been approved to accredit the General Electric Senographe 2000D, General Electric Senographe DS, Fischer SenoScan, Lorad/Hologic Selenia, [Selenia S and Selenia Dimensions 2D](#), Siemens Mammomat Novation DR and [Novation S](#), General Electric Senographe Essential, and Fuji Computed Radiography FFDM units.

The State of Arkansas has been approved to accredit the Lorad/Hologic Selenia, [Selenia S and Selenia Dimensions 2D](#), General Electric Senographe 2000D, General Electric Senographe DS, General Electric Essential, [Siemens Mammomat Novation DR and Novation S](#), and Fuji Computed Radiography FFDM units.

The State of Iowa has been approved to accredit the General Electric Senographe 2000D, General Electric Senographe DS, General Electric Senographe Essential, Lorad/Hologic Selenia, [Selenia S and Selenia Dimensions 2D](#), [Siemens Mammomat Novation DR and Novation S](#), and Fuji Computed Radiography FFDM units.

The State of Texas has been approved to accredit the General Electric Senographe 2000D, General Electric Senographe DS, General Electric Senographe Essential, Fischer SenoScan, Lorad/Hologic Selenia, [Selenia S and Selenia Dimensions 2D](#), Siemens Mammomat Novation DR [and Novation S](#), and Fuji Computed Radiography FFDM units.

The following is being modified in Additional Mammography Review and Patient Notification/AMR General Guidance

AMR General Guidance for Additional Mammography Review

Background

The Food and Drug Administration (FDA) developed this Additional Mammography Review (AMR) guidance to inform facilities of possible ~~FDA~~ actions when [FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health. Information that could cause FDA to suspect that quality may have been compromised could include:](#)

1. [An MQSA inspections with a level 1 inspection observation show a Level 1 finding](#) for phantom image testing
2. [An MQSA inspection with a level 1 inspection observation for](#) ~~or~~ interpreting physician qualifications-
3. [Extensive failures to comply with the equipment quality assurance requirements under 21 CFR 900.12\(e\)](#)
4. [Evidence or information obtained from a facility's accreditation body or from physician, patient, or technologist complaints regarding a quality problem at the facility](#)

5. Evidence that records demonstrating compliance with the quality standards under 21 CFR 900.12 have been falsified
6. Performance of mammography without an MQSA certificate

A Level 1 finding inspection observation represents a deviation from MQSA standards that may seriously compromise the quality of mammography services offered by the facility. FDA has determined that these specific Level 1 findings, as well as the other examples listed above, are indicators that serious quality problems may be present at the facility and require further evaluation. An assessment of the quality of mammograms produced by the facility is performed to assess ~~should indicate~~ whether any of the equipment problems noted above that resulted in the Level 1 phantom image finding have affected clinical image quality. A Level 1 finding observation for the phantom image test exists when the score is less than 3 fibers, less than 2 speck groups, and/or less than 2 masses. Regarding interpreting physician qualifications, an assessment of mammograms and mammography reports may indicate whether failure to meet specific personnel standards has affected the quality of mammographic interpretations findings. If FDA determines that the problems rise to the level of a significant risk to human health, FDA may require the facility to notify patients and their referring physicians of the deficiencies, the potential harm resulting, appropriate remedial measures, and such other relevant information as FDA may require.

~~In addition to these two specific inspection findings, other problems could result in FDA requiring AMR for a facility. For example, evidence or information may be obtained from a facility's accreditation body or patient or physician complaints that could convince FDA to require an AMR. In the case where serious quality problems are suspected at a facility, FDA may require that the facility undertake an investigation of the impact of these findings on the clinical images produced by the facility or of the interpretations rendered by the interpreting physician. If FDA determines that the problems rise to the level of a significant risk to human health, FDA may require the facility to undertake patient/physician notification.~~

This authority is stated as follows (21 ~~C.F.R.~~ CFR 900.12(j)):

Additional Mammography Review and Patient Notification

- (1) *If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.*

- (2) *If FDA determines that the quality of mammography performed by a facility, whether or not certified under Sec. 900.11, was so inconsistent with the quality standards established in this section as to present a significant risk to individual or public health, FDA may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as FDA may require. Such notification will occur within a timeframe and in a manner specified by FDA.*

There are two specific types of AMR identified in the regulations and this policy. ~~These are AMR Conducted by the Facility (AMRFAMROE) and They are an~~ AMR ~~C~~conducted by the facility's Aaccreditation Bbody which we refer to as an (AMRAB) and an AMR conducted by another entity which we refer to as an AMROE. Under AMRAB, the facility's accreditation body is asked to conduct the AMR. Under ~~AMRFAMROE~~, FDA works with the facility to identify a qualified reviewing interpreting physician(s) to perform the AMR. The physician(s) is subject to FDA approval.

Facilities subject to an AMR may also be subject to other regulatory and enforcement actions by FDA, for example a Directed Plan of Correction (DPC) to correct violations in a timely manner or a patient and physician notification. See 42 U.S.C. 263b(h) and (i) for other actions, including civil money penalties, or suspension or revocation of certification, that FDA may impose on facilities.

~~Under AMRAB, the facility's accreditation body is asked to conduct the AMR. This policy does not prevent FDA from taking legal actions against facilities, in addition to AMR, where the use of an MQSA sanction may be necessary to compel a facility to comply with FDA regulatory requirements. As an example, FDA may issue a Directed Plan of Correction (DPC) to a facility to address serious problems at the facility. The DPC may require the facility to take specific corrective actions. 42 U.S.C. 263b(h)(1)(A). FDA may require the facility to notify patients and/or their referring physicians of facility problems, in the event the AMR indicates mammography quality problems are present that would justify such a notification.~~

Note: The interpreting physician(s) conducting the image review for AMRAB AMRF or AMROE AMRAB should not have a relationship with the facility, ~~conduct the review when it would~~ or otherwise be have a conflict of interest ~~for them to do so, or when they have a bias in favor of or against the facility.~~ Before the facility's accreditation body (AB) conducts AMRAB, the AB may require reimbursement of its expenses for the AMRAB. In this case, the AB should notify the facility accordingly, including an of the estimated of the cost and other relevant information, such as whether payment must be received to conduct the AMRAB. ~~The AB may also require payment~~ prior to the start of the AMRAB.

If a facility has a Level 1 phantom image finding or a Level 1 interpreting physician finding, FDA may require the facility to undergo an AMR. Because the AB already has procedures and personnel in place for performing AMRs, this type of AMR will generally

be the preferred method. However, if FDA considers it appropriate, it may propose an ~~AMRF~~AMROE, or accept a facility's proposal for an AMROE. In an AMROE, FDA would specify ~~The facility would then provide FDA with specific details as to~~ how the AMR would be conducted (including timeframes), how the patient exams would be selected, and the qualifications of the reviewing proposed interpreting physician(s) (including the physician's specialized training in evaluating clinical image quality). FDA would work with the facility to identify an acceptable reviewing physician(s). If an AMROE acceptable to FDA cannot be arranged ~~FDA does not approve the facility's proposal~~, the facility must undergo AMRAB.

Evaluations of Inspection Findings Leading Observations that May Lead to an AMR and Patient and/ Physician Notification:

- All level 1 observations for phantom image ~~test results at Level 1 will be~~ testing are confirmed through a second review by an ~~the~~ MQSA auditor or an FDA MQSA inspector (or by the State, if the State has a thorough phantom image quality assurance (QA) program in place). For those cases where there are no second reviewers available, the Division of Mammography Quality and Radiation Programs (DMQRP) will ~~provides~~ the second review.
- After confirmation of the level 1 observation that a physician was not board certified and did not have initial training in mammography and/or never had a valid license to practice medicine or the license to practice medicine was revoked, FDA will evaluate the findings to ~~determines~~ whether an AMR is appropriate based on the seriousness of the violations.
- After confirmation of the Level 1 finding inspection observation(s), ~~a Warning or Untitled Letter may be sent to~~ FDA may notify the facility in writing that it must undergo AMR.
- The ~~Warning or Untitled AMR~~ Letter ~~should~~ advises the facility that it must is required to undergo an AMR, that it will may be responsible for the cost of the AMR, and that further details (including how the AMR will be conducted whether an AMRF or AMRAB will be required) will follow in a letter from FDA and/or the AB. The type (AMRAB or AMRF~~AMROE~~) and scope of the AMR are will be determined by FDA (usually after consultation with the facility's AB).
- If the results of the AMR indicate that the quality of mammographic images or interpretations at the facility was so inconsistent with the quality standards as to represent a significant risk to human health, FDA may require the facility to undertake a patient and referring physician notification ~~of patients and/or referring physicians.~~

- If the results of the AMR do not indicate a significant risk to human health, FDA will evaluate the results of the AMR to determine if additional follow-up or monitoring is necessary.
- FDA also assesses whether to take other regulatory and enforcement actions, as needed.

Approved Alternative Standards/Requirements

All the approved alternative standards can be found on the following webpage:

<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Regulations/ucm110880.htm>

The following question and answer is being added to Equipment/X-Ray Film

Citation:

900.12(b)(11): X-ray film. The facility shall use X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

Question 2: Are we required to use a specific type of laser film when printing full field digital images?

While there is a requirement in 21 CFR 900.12(b)(11) that the x-ray film used for screen-film mammography be designated as appropriate for mammography, there is no similar requirement for the laser film used to print full field digital mammography hardcopy images. However, FDA recommends that facilities use laser film compatible with the printer being used, and designated for FFDM use by the laser film manufacturer or recommended by the FFDM manufacturer. Under 21 CFR 900.12(e)(6), laser film used for hardcopy must produce images of final interpretation quality that pass the applicable QC tests listed in the FFDM manufacturer's QC manual.

The following question and answer is being added to CMS (Formerly HCFA)/Centers for Medicare and Medicaid Services (CMS) (formerly HCFA) Reimbursement As It Relates to MQSA Certification

Question 2: If our facility is having difficulty being reimbursed by Medicare for mammography services, whom should we contact?

The answer to this question is available on the following webpage:

<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/ConsumerInformation/ucm113956.htm>

The following question and answer is being modified in Medical Records and Reports/Communication of Results to Patients

Citation:

900.12(c)(2)(i),(ii): *Communication of mammography results to the patients. Each facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.*

(i) *Patients who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section within 30 days, in addition to the written notification of results in lay terms.*

(ii) *Each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated.*

Question 2: What criteria will FDA use to determine that facilities meet the MQSA requirements for providing lay summaries and mammography reports to their patients and health care providers?

One way to meet the requirements for providing lay summaries and mammography reports is for facilities to ~~can either:~~ have ~~Provide~~ written ~~documentation describing the~~ procedures for all of the following:

- providing (sending or giving) the written lay summary to patients within 30 days of the examination.
- providing the mammography report to the health care provider (or the patient, if self referred) within 30 days of the examination.
- communicating the results of positive (suspicious or highly suggestive of malignancy) examinations to patients and health care providers as soon as possible (FDA recommends as guidance, within 5 and 3 business days of the date of interpretation, respectively). This communication may be verbal or written. If verbal, it must be followed by a written lay summary and mammography report provided within 30 days of the examination.

AND either

1. Demonstrate to the inspector that:

- the facility is notifying patients and health care providers of positive examinations as soon as possible (FDA recommends as guidance, within 5 and 3 business days of the date of interpretation, respectively). In the case of verbal communication, this may be done by documenting such communication in the mammography report or in logs. In the case of written communication, see next two bulleted items.
- the facility is providing written mammography reports. This may be done by having copies of the mammography report available within 30 days of the examination (positive mammography reports should be available within 3 business days of the date of interpretation).
- the facility is providing written lay summaries. This may be done by having copies of the lay summary available within 30 days of the examination (positive lay summaries should be available within 5 business days of the date of interpretation). If the facility does not keep copies of the patients' lay summaries, it may document such communication in the

mammography report, or in logs, or by stating in the facility's Quality Assurance (QA) manual that the lay summary is provided within the appropriate time frames.

OR

2. For facilities with computerized reporting systems, provide the inspector with a list or print-out documenting that all lay summaries and mammography reports have been sent out within the 30 day timeframe and that all positive results have been communicated, either verbally or by means of the written report, to patients and health care providers as soon as possible (FDA recommends within 5 and 3 business days of the date of interpretation, respectively).

The following question and answer is being modified in Medical Records and Reports/Communication of Results to Providers

Citation:

900.12(c)(3)(i),(ii): Communication of mammography results to health care providers. When the patient has a referring health care provider or the patient has named a health care provider, the facility shall:

- (i) Provide a written report of the mammography examination, including the items listed in paragraph (c)(1) of this section, to that health care provider as soon as possible, but no later than 30 days from the date of the mammography examination; and*
- (ii) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.*

Question 2: What criteria will FDA use to determine that facilities meet the MQSA requirements for providing lay summaries and mammography reports to their patients and health care providers?

One way to meet the requirements for providing lay summaries and mammography reports is for facilities to ~~can either~~ have ~~Provide~~ written documentation describing the procedure for all of the following:

- providing (sending or giving) the written lay summary to patients within 30 days of the examination.
- providing the mammography report to the health care provider (or the patient, if self referred) within 30 days of the examination.
- communicating the results of positive (suspicious or highly suggestive of malignancy) examinations to patients and health care providers as soon as possible (FDA recommends as guidance, within 5 and 3 business days of the date of interpretation, respectively). This communication may be verbal or written. If verbal, it must be followed by a written lay summary and mammography report provided within 30 days of the examination.

AND either

- 1. Demonstrate to the inspector that:
 - the facility is notifying patients and health care providers of positive examinations as soon as possible (FDA recommends as guidance, within 5 and 3 business days of the date of

interpretation, respectively). In the case of verbal communication, this may be done by documenting such communication in the mammography report or in logs. In the case of written communication, see next two bulleted items.

- the facility is providing written mammography reports. This may be done by having copies of the mammography report available within 30 days of the examination (positive mammography reports should be available within 3 business days of the date of interpretation).

- the facility is providing written lay summaries. This may be done by having copies of the lay summary available within 30 days of the examination (positive lay summaries should be available within 5 business days of the date of interpretation). If the facility does not keep copies of the patients' lay summaries, it may document such communication in the mammography report, or in logs, or by stating in the facility's Quality Assurance (QA) manual that the lay summary is provided within the appropriate time frames.

OR

2. For facilities with computerized reporting systems, provide the inspector with a list or print-out documenting that all lay summaries and mammography reports have been sent out within the 30 day timeframe and that all positive results have been communicated, either verbally or by means of the written report, to patients and health care providers as soon as possible (FDA recommends within 5 and 3 business days of the date of interpretation, respectively).

The following questions and answers are being added to Medical Records and Reports/Communication of Results to Patients and Medical Records and Reports/Communication of Results to Providers

Questions 24 and 7: Are there any additional issues we should be aware of when providing mammography results to referring healthcare providers and patients?

FDA has occasionally identified problems with the methods that some facilities use to provide mammography results to referring healthcare providers and patients. While the vast majority of facilities have adequate written standard operating procedures (SOPs) regarding the provision of mammography reports and lay summaries to referring healthcare providers and patients, some facilities do not track or monitor the issuance of the reports and/or lay summaries. Consequently, some referring healthcare providers and patients are not receiving their examination results or are not receiving them in a timely manner.

MQSA allows facilities to develop or use a procedure and tracking system that works best for them. Facilities should monitor their systems to ensure that their policies and procedures are being followed. FDA supports the use of computer tracking and paper or patient log systems to assist in tracking timely issuance of medical reports and lay summaries. Some radiology computer reporting systems can track individual reports and generate summary reports indicating when a mammography report or lay summary has been issued or is overdue. By routinely checking these summary reports, facilities can ensure that all mammography results have been issued in a timely manner. FDA encourages facilities (1) to check with their computer support vendors to determine whether their software can generate these types of

reports, and (2) to routinely assess their system(s) to ensure that these systems consistently document issuing mammography lay summaries and reports to all patients and their referring healthcare providers within the required timeframe.

Facilities that fax or email medical reports and/or lay summaries should have policies and procedures in place to ensure that, if any faxes or emails are reported as “delivery failure,” the reports and lay summaries are re-sent in a timely manner.

Questions 25 and 8: If a mammogram is interpreted as “Suspicious” or “Highly Suggestive of Malignancy” (a positive mammogram) the mammography report and lay summary are to be provided as soon as possible. Previously issued guidance mentions 3-5 days. Is that measured from the date of the mammogram or the date the mammogram was interpreted as positive?

The 3-5 day time period should start from the date that a facility interprets the mammogram as positive. In guidance we state that a facility should notify referring healthcare providers and patients within 3-5 days and that the facility should be able to justify its actions if it takes longer. Some facilities have incorrectly interpreted this guidance as referring to 3-5 days from the date of the performance of the mammogram rather than 3-5 days from the date the mammogram is interpreted as being positive.

Because the regulations do not identify when a facility is required to read the mammogram (only that the mammography report and lay summary must be sent within 30 days after the mammogram is performed), the facility should use the mammography report date, not the mammogram exam date, to determine if it has made reasonable attempts to communicate the positive mammogram results as soon as possible.

Example: A facility performs a mammogram on 10/1/2007 which is read and interpreted on 10/12/2007. The mammography assessment for this mammogram is Suspicious (a positive mammogram). The facility mails both the patient lay summary and the mammography report on 10/14/2007. The facility has met the requirement to make reasonable attempts to communicate the positive mammogram results as soon as possible because it has provided the mammography report and the patient lay summary within two days of making the assessment that the mammogram was positive. Furthermore, it has met the requirement that the mammography report and the patient lay summary be provided within 30 days of the date of the examination.

The following question and answer is being added to Personnel/General/Attestation - Acceptable Uses for Personnel Requirements

Applicable Citations:

900.12(a)(1)(ii)(B): All interpreting physicians shall maintain their qualifications by meeting the following requirement: Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were

completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period. This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice.

900.12(a)(1)(ii)(C) Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new mammographic modality.

900.12(a)(1)(iv)(B): Interpreting physicians who fail to meet the continuing education requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

900.12(a)(2)(iii)(A) and (C): Continuing Education Requirements:

(A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

(C) At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.

900.12(a)(2)(iii)(D): Requalification. Radiologic technologists who fail to meet the continuing education requirements of paragraph (a)(2)(iii)(A) of this section shall obtain a sufficient number of continuing education units in mammography to bring their total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

900.12(a)(3)(iii)(A): Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately

preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

900.12(a)(3)(iii)(C) Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under paragraph (a)(3)(i) or (a)(3)(ii) of this section, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality.

900.12(a)(3)(iv)(A): Medical physicists who fail to maintain the required continuing qualifications of paragraph (a)(3)(iii) of this section may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications as follows: (A) Medical physicists who fail to meet the continuing educational requirements of paragraph (a)(3)(iii)(A) of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 3 years.

Question 1: My initial mammography training documentation does not specify whether the training was in screen-film or full field digital. Will I have to go back to my training program to get additional documentation or will I be able to attest to which mammographic modality I was trained in?

While personnel generally cannot attest to initial training, in cases where the documentation meets the regulatory requirement but is deficient in identifying the mammographic modality, FDA will accept an attestation.

Citation:

900.12(a)(1)(ii)(A): All interpreting physicians shall maintain their qualifications by meeting the following requirement: Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. The facility will choose one of these dates to determine the 24-month period.

Question 9: I am qualified to interpret screen-film mammograms independently but I also interpreted some FFDM mammograms while under direct supervision. Can I count those FFDM mammograms toward my continuing experience requirement?

Yes.

The following questions and answers are being added to Personnel/Interpreting Physician/ Interpreting Physician Initial Experience

Citation:

900.12(a)(1)(i)(D): The interpreting physician shall have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

Question 3: I am a physician who wishes to become initially qualified as an interpreting physician. I completed my three months of initial mammography training in screen-film mammography and read 240 mammograms during the last six months of the residency program under direct supervision but all the examinations were performed on a full field digital mammographic (FFDM) unit. Does this satisfy the regulatory requirement?

Yes. While FDA recommends that personnel obtain initial experience using the same mammographic modality as used for the initial qualifications, the regulations do not specifically require it. Therefore, examinations read for the initial experience requirement do not have to be in the same mammographic modality as examinations read for the initial qualification.

Question 4: I am the physician in question 3. Once I've completed my initial requirements, can I independently read both screen-film and FFDM examinations?

No. Because your initial training was only in screen-film, under MQSA you are qualified to read only screen-film examinations independently. In order to read FFDM examinations, you will need to obtain and document eight hours of training in FFDM. 900.12(a)(1)(ii)(C).

The following questions and answers are being added to Personnel/Interpreting Physician/Interpreting Physician New Mammographic Modality Training

Citation:

900.12(a)(1)(ii)(C): Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a mammographic modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new mammographic modality.

Question 11: I am a physician who wishes to become initially qualified as an interpreting physician. I completed my three months of initial mammography

training in screen-film mammography and read 240 mammograms during the last six months of the residency program under direct supervision but all the examinations were performed on an FFDM unit. Does this satisfy the regulatory requirement?

Yes. While FDA recommends that personnel obtain initial experience using the same mammographic modality as used for the initial qualification, the regulations do not specifically require it. Therefore, examinations read for the initial experience requirement do not have to be in the same mammographic modality as examinations used for the initial qualification.

Question 12: I am the physician in question 11. Once I've completed my initial requirements, can I independently read both screen-film and FFDM examinations?

No. Because your initial training was only in screen-film, under MQSA you are qualified to read only screen-film examinations independently. In order to read FFDM examinations, you will need to obtain and document eight hours of training in FFDM. 900.12(a)(1)(ii)(C).

The following is being added at the end of the discussion section of Personnel/Interpreting Physician/Reestablishing the Interpreting Physician Continuing Experience Requirement

Citation:

900.12(a)(1)(iv)(A)(1)(2) and (3): Interpreting physicians who fail to meet the continuing experience requirements of paragraph (a)(1)(ii)(A) of this section shall:

- (1) Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or*
- (2) Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.*
- (3) The interpretations required under paragraph (a)(1)(iv)(A)(1) or (a)(1)(iv)(A)(2) of this section shall be done within the 6 months immediately prior to resuming independent interpretation.*

When an interpreting physician (IP) fails to meet the continuing experience requirement of reading 960 mammograms in the "previous 24 months," the regulation requires that he or she not read mammograms independently until he or she re-qualifies. The IP can re-qualify by reading, within a 6-month period under direct supervision, either 240 mammograms or the balance needed to bring the total to 960. FDA considers the "previous 24 months" to begin from the facility inspection date, or the date of the most recent calendar quarter preceding the inspection, or any date in between.

When a facility is inspected within the 6-month period following the date the IP re-qualified, FDA does NOT intend to cite the facility if the IP has not read a total of 960 mammograms for the previous 24 months. We consider this a 6-month exemption period. However, if a facility is inspected any time after the 6-month exemption period has expired (even one day after) and the IP has not read a total of 960 mammograms for the previous 24 months, FDA DOES intend to cite the facility. In summary, as long as the IP has read at least 960 mammograms by the facility's next inspection, the IP is compliant with MQSA regulations.

Example #1: An IP has been interpreting mammograms for more than two years and is hired by a new facility on 9/3/2007. The IP has read only 150 mammograms since 7/1/2005. She reads 240 mammograms under direct supervision by 9/25/2007. The facility is inspected on 1/15/2008. At the time of the inspection, this IP has read 590 mammograms, which includes the 240 under supervision, since 7/1/2005. Should the facility be cited?

No, because the IP's continuing experience requirement falls under the 6-month exemption period, which expires on 3/24/2008.

Example #2: This same facility is inspected on 4/15/2008 and the IP has read 790 mammograms, which includes the 240 under supervision, since 4/1/2006. Should the facility be cited?

Yes, because the 6-month exemption period after requalification has passed and the IP has not read the required 960 mammograms.

Example #3: This same facility is inspected on 4/15/2008 and the IP has read 960 mammograms, which includes the 240 under direct supervision, since 4/1/2006, but the IP had read only 600 mammograms by 3/31/08 (a date after the 6-month exemption period). Should the facility be cited?

No, because the IP has read the required 960 mammograms by the date of the inspection.

The following question and answer is being added to Personnel/Medical Physicist/Medical Physicist Continuing Experience

Citation:

900.12(a)(3)(iii)(B): Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(3)(i) and (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards this requirement.

Question 11: I am qualified to perform screen-film surveys independently but also performed some FFDM surveys while under direct supervision. Can I count those FFDM surveys toward my continuing experience requirement?

Yes.

The following questions and answers are being added to Personnel/Medical Physicist/Medical Physicist Initial Experience

Citation:

900.12(a)(3)(i)(B)(3): Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (a)(3)(i) and (a)(3)(iii) of this section.

Question 8: I am a physicist who wishes to become initially qualified as a medical physicist. I completed my 20 contact hours of initial mammography training in screen-film mammography and performed one facility and ten unit surveys under direct supervision but all the surveys were performed in a full field digital mammographic facility. Does this satisfy the regulatory requirement?

Yes. While FDA recommends that personnel obtain initial experience using the same mammographic modality as used for the initial qualification, the regulations do not specifically require it. Therefore, surveys performed for the initial experience requirement do not have to be in the same mammographic modality as surveys performed for the initial qualification.

Question 9: I am the physicist in question 8. Once I've completed my initial requirements, can I independently perform both screen-film and FFDM surveys?

No. Because your initial training was only in screen-film, under MQSA you are qualified to perform only screen-film surveys independently. In order to perform FFDM surveys, you will need to obtain and document eight hours of training in FFDM. 900.12(a)(3)(iii)(C).

Question 10: I am a physicist who wishes to become initially qualified as a medical physicist. I completed 10 contact hours of initial mammography training in screen-film mammography and performed one facility and ten unit surveys under direct supervision. I wish to count the time spent performing these surveys toward the 20 contact hour requirement. All of the surveys were performed in a full field digital mammographic facility. Is this acceptable and am I qualified to independently perform both screen-film and FFDM surveys?

Medical physicists (MP) may count the time they spent in the actual performance of surveys to be used toward satisfying the survey contact hour training requirement. As guidance, however, FDA recommends that MPs not count more than four hours for each facility survey and two hours for each unit survey toward the required total hours of training. Once an MP completes the facility and unit surveys, the MP is qualified to perform screen film surveys independently but not necessarily FFDM surveys. In order for the MP to also perform FFDM surveys independently, the training program will have to supply the MP with additional documentation showing that at least eight hours of experience/training was in FFDM. 900.12(a)(3)(iii)(C).

The following questions and answers are being added to Personnel/Medical Physicist/Medical Physicist New Mammographic Modality Training

Citation:

900.12(a)(3)(iii)(C): Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic modality other than one for which the physicist received training to qualify under paragraph (a)(3)(i) or (a)(3)(ii) of this section, the physicist must receive at least 8 hours of training in surveying units of the new mammographic modality.

Question 10: I am a physicist who wishes to become initially qualified as a medical physicist. I completed my 20 contact hours of initial mammography training in screen-film mammography and performed one facility and ten unit surveys under direct supervision but all the surveys were performed in a full field digital mammographic facility. Does this satisfy the regulatory requirement?

Yes. While FDA recommends that personnel obtain initial experience using the same mammographic modality as used for the initial qualification, the regulations do not specifically require it. Therefore, surveys performed for the initial experience requirement do not have to be in the same mammographic modality as surveys used for the initial qualification.

Question 11: I am the physicist in question 10. Once I've completed my initial requirements, can I independently perform both screen-film and FFDM surveys?

No. Because your initial training was only in screen-film, under MQSA you are qualified to perform only screen-film surveys independently. In order to perform FFDM surveys, you will need to obtain and document eight hours of training in FFDM. 900.12(a)(3)(iii)(C).

Question 12: I am a physicist who wishes to become initially qualified as a medical physicist. I completed 10 contact hours of initial mammography training in screen-film mammography and performed one facility and ten unit surveys under direct supervision. I wish to count the time spent performing these surveys toward the 20 hour requirement. All of the surveys were performed in a full field digital

mammographic facility. Is this acceptable and am I qualified to independently perform both screen-film and FFDM surveys?

Medical physicists (MP) may count the time they spent in the actual performance of surveys towards satisfying the survey contact hour training requirement. As guidance, however, FDA recommends that MPs not count more than four hours for each facility survey and two hours for each unit survey toward the required total hours of training. Once an MP completes the facility and unit surveys, the MP is qualified to perform screen film surveys independently but not necessarily FFDM surveys. In order for the MP to also perform FFDM surveys independently, the training program or trainer will have to supply the MP with additional documentation showing that at least eight hours of experience/training was in FFDM. 900.12(a)(3)(iii)(C).

The following question and answer is being added to Personnel/Radiologic Technologist/Radiologic Technologist Continuing Experience

Citation:

900.12(a)(2)(iv)(A): Continuing experience requirements. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of April 28, 1999, whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

Question 11: I am qualified to perform screen-film mammograms independently but also performed some FFDM mammograms while under direct supervision. Can I count those FFDM mammograms toward my continuing experience requirement?

Yes.

The following questions and answers are being added to Personnel/Radiologic Technologist/Radiologic Technologist Mammography Specific Training

Citation:

900.12(a)(2)(ii)(A)(B) and (C): Mammography requirements. All mammographic examinations shall be performed by radiologic technologists who meet the following mammography requirements: Have, prior to April 28, 1999 qualified as a radiologic technologist under paragraph (a)(2) of this section of FDA's interim regulations of December 21, 1993, or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

- (A) *Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;*
- (B) *The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and*
- (C) *At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams.*

Question 14: I am a technologist who wishes to become initially qualified as a radiologic technologist. I completed my 40 hours of initial mammography training in screen-film mammography and performed 25 mammograms under direct supervision but all the examinations were performed on a full field digital mammographic (FFDM) unit. Does this satisfy the regulatory requirement?

Yes. While FDA recommends that personnel obtain initial experience using the same mammographic modality as used for the initial qualification, the regulations do not specifically require it. Therefore, examinations performed for the initial experience requirement do not have to be in the same mammographic modality as examinations performed for the initial qualification.

Question 15: I am the technologist in question 14. Once I've completed my initial requirements, can I independently perform both screen-film and FFDM examinations?

No. Because your initial training was only in screen-film, under MQSA you are qualified to perform only screen-film examinations independently. In order to perform FFDM examinations, you will need to obtain and document eight hours of training in FFDM. 900.12(a)(2)(iii)(E).

Question 16: I am a technologist who wishes to become initially qualified as a radiologic technologist. I completed 27.5 hours of initial mammography training in screen-film mammography and performed 25 mammograms under direct supervision. I wish to count the time spent performing these mammograms toward the 40 hour requirement. All of the examinations were performed on a full field digital mammographic unit. Is this acceptable and am I qualified to independently perform both screen-film and FFDM examinations?

In previously issued guidance, we stated that training programs or facilities may include the actual time spent performing supervised examinations toward the 40 hour total. As guidance, however, FDA recommends that no more than 12.5 hours of the required 40 come from performing examinations. Once you complete the 25 mammograms, you are qualified to perform screen film mammograms independently but not necessarily FFDM mammograms. In order for you to also perform FFDM mammograms independently, the training program or mammography facility will have to supply you with additional documentation showing that at least eight hours of experience/training was in FFDM. 900.12(a)(2)(iii)(E).

The following questions and answers are being added to Personnel/Radiologic Technologist/Radiologic Technologist New Mammographic Modality Training

Citation:

900.12(a)(2)(iii)(E): Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic modality other than one of those for which the technologist received training under paragraph (a)(2)(ii)(C) of this section, the technologist shall have at least 8 hours of continuing education units in the new modality.

Question 12: I am a technologist who wishes to become initially qualified as a radiologic technologist. I completed my 40 hours of initial mammography training in screen-film mammography and performed 25 mammograms under direct supervision but all the examinations were performed on a full field digital mammographic unit. Does this satisfy the regulatory requirement?

Yes. While FDA recommends that personnel obtain initial experience using the same mammographic modality as used for the initial qualification, the regulations do not specifically require it. Therefore, examinations performed for the initial experience requirement do not have to be in the same mammographic modality as the examinations performed for the initial qualification.

Question 13: I am the technologist in question 12. Once I've completed my initial requirements, can I independently perform both screen-film and FFDM examinations?

No. Because your initial training was only in screen-film, under MQSA you are qualified to perform only screen-film examinations independently. In order to perform FFDM examinations, you will need to obtain and document eight hours of training in FFDM. 900.12(a)(2)(iii)(E).

Question 14: I am a technologist who wishes to become initially qualified as a radiologic technologist. I completed 27.5 hours of initial mammography training in screen-film mammography and performed 25 mammograms under direct supervision. I wish to count the time spent performing these mammograms toward the 40 hour requirement. All of the examinations were performed on a full field digital mammographic unit. Is this acceptable and am I qualified to independently perform both screen-film and FFDM examinations?

In previously issued guidance, we stated that training programs or facilities may include the actual time spent performing supervised examinations toward the 40 hour total. As guidance, however, FDA recommends that no more than 12.5 hours of the required 40 come from performing examinations. Once you complete the 25 mammograms, you are qualified to perform screen film mammograms independently but not necessarily FFDM

mammograms. In order for you to also perform FFDM mammograms independently, the training program or mammography facility will have to supply you with additional documentation showing that at least 8 hours of the 12.5 hours of experience/training was in FFDM. in order to demonstrate compliance with 900.12(a)(2)(iii)(E).

The following is being added at the end of the discussion section of Personnel/Radiologic Technologist/Reestablishing the Radiologic Technologist Continuing Experience Requirement

Citation:

900.12(a)(2)(iv)(B) Requalification. Radiologic technologists who fail to meet the continuing experience requirements of paragraph (a)(2)(iv)(A) of this section shall perform a minimum of 25 mammography examinations under the direct supervision of a qualified radiologic technologist, before resuming the performance of unsupervised mammography examinations.

When a radiologic technologist (RT) fails to meet the continuing experience requirement of performing 200 mammograms in the “previous 24 months,” the RT must not perform mammograms independently until the RT re-qualifies. The RT can re-qualify by performing 25 mammograms under direct supervision. FDA considers the “previous 24 months” to begin from the facility inspection date, or the date of the most recent calendar quarter preceding the inspection, or any date in between.

When a facility is inspected within the 6-month period following the date the RT re-qualified, FDA does NOT intend to cite the facility if the RT has not performed a total of 200 mammograms in the previous 24 months. **We consider this the 6-month exemption period.** If the facility is inspected any time after the 6-month exemption period has expired (even 1 day after) and the RT has not performed a total of 200 mammograms in the previous 24 months, FDA DOES intend to cite the facility. In summary, as long as the RT has performed at least 200 mammograms by the facility's next inspection, the RT is compliant with MQSA regulations.

Example #1: An RT has been performing mammography for more than two years and is hired by a new facility on 9/3/2007. The RT has performed only 100 mammograms since 9/1/2005. The RT performs 25 mammograms under direct supervision by 9/25/2007. The facility is inspected on 1/15/2008. At the time of the inspection, this RT has performed 150 mammograms, which includes the 25 under supervision, since 9/1/2005. Should the facility be cited?

No, because the RT’s continuing experience requirement falls under the 6-month exemption period, which expires on 3/24/2008.

Example #2: This same facility is inspected on 4/15/2008 and the RT has performed 175 mammograms, which includes the 25 under supervision, since 4/1/2006. Should the facility be cited?

Yes, because the 6-month exemption period after requalification has passed and the RT has not performed the required 200 mammograms.

Example #3: This same facility is inspected on 4/15/2008 and the RT has performed 200 mammograms, which includes the 25 under direct supervision, since 4/1/2006, but the RT had performed only 175 mammograms by 3/31/08 (a date after the 6-month exemption period). Should the facility be cited?

No, because the RT has performed the required 200 mammograms by the date of the inspection.

The following questions and answers are being added to Quality Assurance/Equipment/Air Kerma Calibration

Citation:

900.12(e)(12): Calibration of air kerma measuring instruments. Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every 2 years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of ± 6 percent (95 percent confidence level) in the mammography energy range.

Question 4: Must my air kerma measuring instrument be calibrated to all the target filter combinations I encounter during surveys and MEEs? Also, how does this calibration requirement affect kVp and dose measurements?

While the above regulation requires that all air kerma measuring instruments be calibrated to a standard that is traceable to the National Institute of Standards and Technology (NIST), the regulation does not specify the target filter combination to be used. Currently, all air kerma measuring instruments are typically calibrated in the mammography kVp range using only one target filter combination, such as molybdenum/molybdenum (Mo/Mo), even if the instrument is used with other combinations such as tungsten/silver (W/Ag) or tungsten/rhodium (W/Rh). In addition, NIST currently does not have the ability to provide calibration standards for W/Ag or W/Rh target filter combinations in the mammography kVp range. Consequently, while FDA continues to require that all air kerma measuring instruments be calibrated to a NIST-traceable standard for at least one target filter combination in the mammography x-ray range, FDA does not intend to enforce such calibration requirement with respect to W/Ag or W/Rh beams.

It is well known that the energy response for ionization chamber-based air kerma measuring instruments is typically flat in the 20-40 kVp range. For solid-state air kerma measuring instruments however, the energy response is not flat and because of this, the air kerma readings from these instruments may need to be adjusted by an appropriate

correction factor. The correction may already be handled internally by the instrument or you may need to contact the instrument manufacturer for the correction factor.

Question 5: Most non-invasive kVp meters are only calibrated for Mo/Mo and Mo/Rh beams and therefore give inaccurate kVp readings when used with FFDM units that only have W/Ag or W/Rh target/filter combinations. How should I compensate for this error when doing surveys and MEEs on such units?

The kVp value needs to be measured under one target/filter combination for which the kVp meter is calibrated (e.g., Mo/Mo, Mo/Rh, etc.). However, if the mammography unit has only a W/Ag or W/Rh target/filter combination, the measurement results must be appropriately corrected. FDA believes that the issue of inaccurate non-invasive kVp measuring instruments is one that ultimately is best resolved by the kVp instrument manufacturers and the medical physicists. Until this matter is resolved, FDA has the following suggestions for the equipment scenarios listed below:

kVp Measurements

Scenario 1. If you are using a kVp meter that has been manufacturer-certified for W/Ag and W/Rh beams and a mammography-calibrated ion chamber, you may accept the measurement results and record them in the medical physicist survey or mammography equipment evaluation (MEE).

Scenario 2. If your kVp meter has not been manufacturer-certified for W/Ag and W/Rh beams and you are using a mammography-calibrated ion chamber, you should include a correction factor in your kVp measurements. This correction factor may be obtained from the kVp meter manufacturer, or by working with the mammography unit’s service engineer (by comparing the engineer’s manufacturer-approved measurements during machine installation with your non-invasive meter results). You may also use this correction factor when performing MEEs or surveys using this kVp meter/ion chamber combination on other FFDM units by the same manufacturer that also have W/Ag or W/Rh target filter combinations.

Scenario 3. If your kVp meter has not been manufacturer-certified for W/Ag and W/Rh beams and you are using a separate solid-state probe, then you should follow Scenario 2 for kVp Measurements.

The table below gives a summary of the action needed under each of the three Scenarios discussed above.

<u>kVp Measurement of W/Ag and W/Rh Beams</u>				
<u>Scenario</u>	<u>kVp Meter</u>	<u>Air Kerma Instrument</u>	<u>Action</u>	<u>Correction Factor</u>
<u>1</u>	<u>Certified by manufacturer</u>	<u>Ion chamber calibrated for</u>	<u>Accept measurement</u>	<u>N/A</u>

	<u>for W/Ag and W/Rh</u>	<u>mammography</u>		
<u>2</u>	<u>Not certified by manufacturer for W/Ag and W/Rh</u>	<u>Ion chamber calibrated for mammography</u>	<u>Apply correction factor to kVp measurements</u>	<u>Obtain from kVp meter manufacturer or develop by comparing engineer's manufacturer-approved measurements during machine installation with your kVp meter</u>
<u>3</u>	<u>Not certified by manufacturer for W/Ag and W/Rh</u>	<u>Solid state probe</u>	<u>Apply correction factor to kVp measurements</u>	<u>Obtain from kVp meter manufacturer or develop by comparing engineer's manufacturer-approved measurements during machine installation with your kVp meter</u>

HVL Assessments

Scenario 1. If you are using an integrated solid state instrument (one that automatically measures kVp, HVL, and dose) and the instrument is manufacturer-certified for W/Ag and W/Rh, you may accept the measurement results and record them in the medical physicist survey or MEE.

Scenario 2. If you are using an integrated solid state instrument that is not manufacturer-certified for W/Ag or W/Rh, you should determine the HVL using exposure measurements in the standard manner. You may then use this HVL value with the appropriate dose conversion table that is provided in the FFDM manufacturer's QC manual to estimate the dose. Determine from the manufacturer of the dosimetry device if the exposure readings need to be corrected as aluminum is added to the beam. If so, then apply the correction factors applicable to each reading. It may be necessary to determine a typical correction factor by intercomparison with a mammography-calibrated ion chamber; this factor may then be used in the future. If the estimated dose is above 2.7 milligray (270 mrad), you should determine the actual HVL with a mammography-calibrated ion chamber and then use the actual HVL value to estimate the dose using the same conversion table provided in the QC manual.

Scenario 3. If your kVp meter has not been manufacturer-certified for W/Ag and W/Rh beams and you are using a separate solid-state probe, you should follow Scenario 2 for HVL Assessments.

The table below gives a summary of the action needed under each of the three scenarios discussed above.

<u>HVL Assessments of W/Ag and W/Rh Beams</u>				
<u>Scenario</u>	<u>kVp Meter</u>	<u>Air Kerma Instrument</u>	<u>Action</u>	<u>Correction Factor</u>
<u>1</u>	<u>Integrated solid state instrument (measuring kVp, HVL, and dose) certified by manufacturer for W/Ag and W/Rh</u>		<u>Accept measurement</u>	<u>N/A</u>
<u>2</u>	<u>Integrated solid state instrument (measuring kVp, HVL, and dose) NOT certified by manufacturer for W/Ag and W/Rh</u>		<ul style="list-style-type: none"> • <u>Apply correction factor to exposure</u> • <u>Calculate HVL in standard manner</u> • <u>Use corrected kVp with estimated HVL from dose table (in FFDM manufacturer's QC manual) to see estimated dose (see scenario 2 for more info)</u> 	<u>Obtain from kVp meter manufacturer or develop by comparing engineer's manufacturer-approved measurements during machine installation with your kVp meter</u>
<u>3</u>	<u>Not certified by manufacturer for W/Ag and W/Rh</u>	<u>Separate solid state probe</u>	<ul style="list-style-type: none"> • <u>Apply correction factor to exposure</u> • <u>Calculate HVL in standard manner</u> <u>Use corrected kVp with estimated HVL from dose table (in FFDM manufacturer's QC manual) to see estimated dose (see scenario 2 for more info)</u> 	<u>Obtain from kVp meter manufacturer or develop by comparing engineer's manufacturer-approved measurements during machine installation with your kVp meter</u>

Modification to the table in Quality Assurance/Equipment/Annual Physics Survey, Quality Assurance/Equipment/Mammography Equipment Evaluations, and Quality Assurance/Equipment/Use of Test Results

Table: Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs

For any adjustment, change, or repair not listed in the table below, or if the facility is unsure as to whether the full extent of the adjustment, change, or repair qualifies as a major repair, the facility should consult its their medical physicist to determine the proper extent of his or her involvement in evaluating the item.

<u>Item</u>	<u>Major Repair</u>	<u>Medical Physicist Involvement</u>
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Automatic Exposure Control		
AEC replacement	Y	MP conducts evaluation in person
Thickness compensation internal* adjustment	N	MP oversight
AEC sensor replacement	Y	MP conducts evaluation in person
AEC circuit board replacement	Y	MP conducts evaluation in person
Density control – internal* adjustment	N	MP oversight
Bucky (New to Facility) Replacement		
AEC sensor also replaced	Y	MP conducts evaluation in person
AEC sensor not replaced	N	MP oversight
FFDM detector also replaced	Y	MP conducts evaluation in person
FFDM detector not replaced	N	MP oversight
Cassette Replacement		
Same screen speed	N	MP involvement optional oversight
Faster screen speed	N	MP oversight
Slower screen speed where the dose increase may exceed 3.0 mGy for the standard breast	Y	MP conducts evaluation in person
Collimator		
Replacement	Y	MP conducts evaluation in person
Reassembly with blade replacement	Y	MP conducts evaluation in person
Adjustment	N	MP oversight
Compression Device		
Pressure adjustment	N	MP involvement optional
Thickness scale accuracy adjustment but only if it affects AEC performance	N	MP oversight
Repair of auto decompression	N	MP involvement optional
Compression Paddle		
Paddle (new to facility) replacement	N	MP oversight
Deflection adjustment	N	MP oversight
Adjustment due to extension beyond allowable limit, or visibility on images	N	MP oversight
Darkroom		
Repair of light leaks	N	MP involvement optional

Safe light change	N	MP involvement optional
Film Type/Speed Change	N	MP oversight
Processor		
Chemistry type change	N	MP involvement optional
Fixer/Developer replacement	N	MP involvement optional
Installation	Y	MP conducts evaluation in person
Reassembly	Y	MP conducts evaluation in person
Replenishment rate adjustment	N	MP involvement optional
Roller replacement	N	MP involvement optional
X-ray Unit		
kVp, mA or time internal* adjustments	N	MP oversight
High voltage generator replacement	Y	MP conducts evaluation in person
X-ray tube replacement	Y	MP conducts evaluation in person
Filter replacement	Y	MP conducts evaluation in person
Installation	Y	MP conducts evaluation in person
Reassembly	Y	MP conducts evaluation in person
Manufacturer's software modifications (see approved alternative standard)	Y	MP conducts evaluation in person
FFDM detector replacement or repair	Y	MP conducts evaluation in person
FFDM Display (monitor)/Printer Replacement	Check FFDM manufacturer's QC manual	Follow FFDM manufacturer's QC manual

* Internal adjustments refer to equipment adjustments that typically cannot be made by the operator

The following question and answer is being modified: Question 2 in Quality Assurance/Equipment/Dosimetry – Annual Quality Control Test and Question 18 in Quality Assurance/Equipment/Phantom Image – Weekly Equipment Quality Control Tests

Questions 2 and 18: We are using an FDA cleared single-use cushion pad when performing mammograms on some of our patients. Do we have to include the pad when performing the phantom and dose QC tests?

When performing the weekly and annual phantom and dose tests, you must simulate as closely as possible your typical clinical conditions. 21 CFR 900.12(e)(2)(i), (e)(5)(vi). Thus, if you are not using a cushion pad for more than half the majority of your patients,

you do not have to include the cushion pads when performing the phantom and dose QC tests.

However, if you are using a cushion pad for more than half the majority of your screen-film patients, you must include the cushion pads when performing these weekly phantom and annual phantom and dose QC tests in order to simulate as closely as possible your typical clinical conditions (21 CFR 900.12(e)(2)). If you routinely use the cushion pad on both the bucky and the compression paddle, you must use 2 two layers of the cushion pad when performing the phantom and dose QC tests. While not a regulatory requirement, FDA recommends that the pads also be included when performing AEC testing. When used clinically, the cushion pad is a single use device. Because of this, QC testing with the cushion pad in place is most appropriate when performing the phantom and dose tests. Therefore the facility does not have to include the cushion pad when performing other QC tests.

For FFDM units, we recommend that you perform QC tests, such as the phantom test, under clinical conditions. However, we can only REQUIRE that a facility include the pad during the test(s) when the manufacturer's QC manual specifies a pad be present during QC testing. The unit manufacturer's QC manual defines the test conditions for the phantom image and other QC tests because, under 21 CFR 900.12(e)(6), "...the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer."

The following question and answer is being added to Quality Assurance/Equipment/Compression Device Performance - Semiannual Quality Control Tests

Citation:

900.12(e)(4)(iii)(A)(B): Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(iii) Compression device performance.

(A) A compression force of at least 111 newtons (25 pounds) shall be provided.

(B) Effective October 28, 2002, the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 200 newtons (45 pounds).

Question 3: Is tapping the foot control of the initial power drive compression device more than once acceptable when testing initial power drive performance in computer-controlled compression devices?

The initial power drive on some mammography units (e.g., Siemens Mammomat) is designed with a built-in sensor that terminates the pressure applied to the paddle once the system's software algorithm determines that additional force will not achieve further thickness reduction.

This design is intended to maximize patient comfort while achieving optimum compression. When such a device is pressed against a hard surface (such as a bathroom scale), the sensor, recognizing that very little or no compression has been achieved by the

applied force up to that point, terminates the pressure before the maximum force can be achieved. When performing the compression test with such a device, the person conducting the test (i.e., radiologic technologist or medical physicist) may have to press the foot pedal more than once to accurately measure the maximum force.

Failure to do so may lead the person conducting the test to report an artificially low maximum compression force. This could lead to an inappropriate failure of the initial power drive compression device quality control test.

The following questions and answers are being added to Quality Assurance/Equipment/ Other Modalities Quality Control Tests

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 5: As a medical physicist is there anything I need to be aware of regarding laser printer mammography equipment evaluations (MEE)?

Some medical physicists are not including appropriate testing of the laser printer in their survey/MEE reports to the facility. There seems to be confusion about the required MEE testing of a laser printer: (1) before it is first put into clinical use; (2) following reassembly; or (3) after major repairs vs. the routine quality control QC testing of the laser printer after it is placed into clinical use. In some cases, the medical physicists did not test the laser printer at all, did inappropriate testing, or did appropriate testing but did not include documentation of the tests in the facility survey/MEE report. Therefore, FDA is clarifying the applicable MQSA requirements.

The regulations at 21 CFR 900.12(e)(6) require that all test procedures be conducted as specified in the QC manual of the FFDM system manufacturer. Some of these QC manuals specify both periodic QC (daily, weekly, or annual) and MEE testing for the laser printer while others do not address the subject and refer the user to the laser printer manufacturer's QC manual.

A table summarizing the laser printer test procedures in the current FFDM manufacturer QC manuals is available on the following webpage:

<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/ucm219622.htm>

Some of FFDM QC manuals do not specifically address the laser printer MEE testing requirements when first installed, reassembled, or after having undergone a major repair. They instead instruct operators to follow the applicable printer QC manual. Hence, the facility or medical physicist has to obtain this information from the laser printer manufacturer. In some cases, the QC manuals only address the interface between the FFDM unit and the laser printer. They do not address the basic requirement that the laser printer, before it is used clinically for mammography, has to be operating as designed by the laser printer manufacturer. Because the MEE requires that both the interface and basic requirements be checked, the medical physicist may have to consult both the FFDM manufacturer's QC manual and the laser printer QC or operator's manual to determine which tests are required to assure that the laser printer is functioning properly before being used clinically.

Some medical physicists incorrectly assume that simply scoring a laser printed phantom image satisfies all the requirements of the laser printer MEE. However, in most cases, simply scoring a phantom would be unacceptable under the applicable manual(s). To avoid unnecessary follow-ups by MQSA inspectors or facility citations, we urge all medical physicists to review the FFDM manufacturer's QC manual and, where necessary, the laser printer QC or operator's manual to determine the appropriate testing. Medical physicists must clearly document the testing of the laser printer in their reports.

Question 6: We do not have a QC manual for our printers or monitors. What QC testing should we perform on our printers and monitors?

Under 21 CFR 900.12(e)(6), facilities using a mammographic modality other than screen-film must follow a quality control program that is "substantially the same as the quality assurance program recommended by the image receptor manufacturer." While all FFDM manufacturers have QC manuals, in some cases, the QC manual instructs the facility to test monitors and printers according to the component's QC manual. In these cases, it is the responsibility of each facility to ensure that it obtains and follows the component's QC manual for its monitors and printers.

Question 7: We have FFDM units from different manufacturers, each with its own QC manual. The manuals have different recommendations for QC testing of our printers and monitors. What QC testing should we perform on our printers and monitors?

For facilities that are using FFDM units from different manufacturers, each with its own QC requirements for printers and monitors, there may be uncertainty regarding which QC tests must be performed on these components. The following three examples should help facilities decide.

- a. Each FFDM manufacturer's QC manual requires that the same test be done, but at different time frequencies. In this case facilities should perform the test at the more stringent frequency.

b. Each FFDM manufacturer's QC manual requires that different but equivalent tests be done. In this case facilities may perform only one of the tests at the more stringent frequency. The medical physicist should provide a written statement for the facility's quality control records, indicating that, in his or her opinion, the two tests are equivalent.

c. Each FFDM manufacturer's QC manual requires that different tests (not equivalent) be done. In this case facilities should perform each test at the frequency required in the respective FFDM manufacturer's QC manual.

Question 8: An FFDM unit is located in a satellite facility of a main hospital, and the review work station (RWS) and hard copy printer are located at the main hospital. The FFDM manufacturer quality control manual instructions call for making a final decision on whether the phantom image test passes by scoring the image either from the RWS or from a printed image. How can the inspector score the image correctly if the RWS and printer are not onsite during the inspection?

What follows is the recommended procedure for the inspector. The inspector:

1. asks the technologist to expose the phantom and produce an image. The inspector scores the phantom image on the acquisition work station (AWS) and, if the image passes, enters the information into the inspection software and closes out the inspection. If the image does not pass, the inspector:

2. asks the technologist to expose the phantom a second time to produce another image. The inspector scores this second phantom image on the AWS and if the image passes, closes out the inspection as in step #1 above. If the image does not pass, the inspector asks the satellite facility to send both phantom images to the hospital. Hospital personnel are instructed to print a hardcopy of both images and mail the images to the inspector. The inspector scores the images. This process should be accomplished within 5 days. The completed inspection is then downloaded to the FDA and a summary report is sent to the facility.

Question 9: What testing do the various FFDM manufacturers require for a new unit mammography equipment evaluation (MEE)?

A table summarizing FFDM manufacturer's testing requirements for new unit mammography equipment evaluations is available on the following webpage:

<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114138.htm>

Question 10: Is there a list that shows the laser printers that have been cleared for mammography by the FDA? If not, how can I determine if FDA has cleared a given laser printer for mammography use?

No. Although FDA has cleared many printers for FFDM use through the 510(k) process, FDA does not keep a list of cleared printers, other than what is available in FDA's 510(k)

database at <http://www.fda.gov/cdrh/510khome.html#database>. You can search this database by product code, device name, applicant name, decision date, and other elements, including a simple word search. Another way to find out whether a particular printer has been cleared for FFDM use is to check the device's labeling or to have the printer manufacturer provide you with written documentation showing that the printer has been cleared by FDA for FFDM.

Question 11: We are an FFDM certified facility but have now decided to have our mammography examinations read off-site at another already certified facility. This process entails the use of a review workstation and laser printer (accessory components) that are new to our facility. We know that we have to perform a Mammography Equipment Evaluation (MEE) on these accessory components prior to clinical use. However, since the accessory components have already undergone an MEE and are currently being used at the other facility, do they have to undergo a new MEE or can we use their original MEE or a subsequent annual physics survey instead?

For MEE tests that are specific to the accessory component, such as the SMPTE pattern, monitor luminance, and room illumination for the review workstation, the SMPTE pattern for the laser printer, and other component-specific tests that may be listed in the component's QC manual, you can use the test results from previous annual physics surveys or MEEs as long as those tests were performed within the last 14 months. For those MEE tests that evaluate the performance of the whole imaging chain and help to ensure that all the system components are compatible with one another, such as the phantom image and other tests that may be listed in the FFDM manufacturer's or accessory component's QC manual, FDA interprets 21 CFR 900.12(e)(10) to mean that you cannot use prior tests. The medical physicist must perform these MEE tests on the accessory components prior to using the components in patient examinations.

Question 12: We are adding an FFDM unit to our already certified digital facility. We know that we have to perform an MEE on the unit prior to clinical use. However, since our review workstation and laser printer (accessory components) have already undergone an MEE and are currently being used with our first unit, do they have to undergo a new MEE or can we use their original MEE or a subsequent annual physics survey instead?

Same answer as in Question 11.

Question 13: We are applying to become a new FFDM certified facility. We know that we have to perform an MEE on the unit prior to clinical use. However, we will have our examinations read off-site using a review workstation and laser printer (accessory components) that are currently located at another certified facility. Those accessory components have already undergone an MEE as part of the other

facility. Do these accessory components have to undergo a new MEE or can we use their original MEE or a subsequent annual physics survey instead?

Same answer as in Question 11.

Question 14: Our facility has five FFDM units (not all of the same model or from the same manufacturer), two laser printers (not the same model or from the same manufacturer) and four review workstations (not all of the same model or from the same manufacturer). We run clinical images through all the accessory components interchangeably. Do we have to perform periodic QC testing (e.g., weekly phantom image test) on all possible combinations of units with the printers and review workstations?

If the facility's medical physicist provides the facility with documentation that the FFDM units and accessory components are matched (see below), then the facility may perform its periodic QC tests using any review workstation or laser printer, as long as each accessory component is tested at its recommended frequency. For example, if the QC manual specifies performing the phantom image test on a weekly basis, the facility may produce a phantom image using each of its x-ray units and evaluate them on any review workstation or laser printer at least once each week of use. One mechanism by which the medical physicist can consider the FFDM units and the accessory components to be matched is for the medical physicist to initially perform and obtain passing results for all applicable QC tests through all possible combinations. (In this scenario each accessory component must be operating within its own pre-established action limits set forth in the applicable QC manual.) 21 CFR 900.12(e)(6). This method will reduce the number of QC tests that must be performed. Note: At least one example of each required QC test must be evaluated using each accessory component at the required periodic frequency. 21 CFR 900.12(e)(6).

Question 15: We have a screen-film unit that we are converting to FFDM-computed radiography (CR) use. We know that we have to perform a Mammography Equipment Evaluation (MEE) on the CR system prior to clinical use. However, since the unit underwent an MEE when it was first installed and has had subsequent testing as part of the annual physics survey does it have to undergo a new MEE or can we use its original MEE or a subsequent annual physics survey instead?

For those tests that are unit specific and independent of the computed radiography (CR) system, FDA interprets 21 CFR 900.12(e)(10) to mean that you may use the test results from previous annual physics surveys or MEEs as long as the tests were performed within the last six months. For those MEE tests that evaluate the performance of the whole imaging chain and help to ensure that all the system components are compatible, such as the phantom image, and other tests that may be listed in the CR manufacturer's QC manual, FDA interprets 21 CFR 900.12(e)(10) to mean that you cannot use prior tests.

The medical physicist must perform these MEE tests on the accessory components prior to using the components in patient examinations.