Guidance for Industry and FDA Staff

The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9

Document issued on: April 19, 2006

The draft of this document was issued on July 15, 2005

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OMB Control No. 0910-0580
Expiration Date: 03/30/2009
See additional PRA statement in Section V of this guidance.

C·D·R·H
Center for Devices and Radiological Health

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.fda.gov/dockets/ecomments. When submitting comments, please refer to Docket No. 2005D-0195. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Table of Contents

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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.

I. Introduction

On July 15, 2005, FDA published The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #9 Draft Guidance for public comment. During the public comment period, six respondents submitted a total of 38 comments. In addition, the National Mammography Quality Assurance Advisory Committee reviewed the Draft Guidance during its September 26-27, 2005 meeting and provided additional comments. FDA reviewed and considered all the comments and in response, FDA has modified the guidance as follows by:

1. Further clarifying Small Field Digital Mammography (SFDM) requirements
2. Adding the phrase “final interpretation quality” to the section on retention and transfer of Full Field Digital Mammography (FFDM) images
3. Clarifying the uses of digitized or compressed mammographic images
4. Clarifying that FFDM images used for final interpretation contain certain identifying information
5. Clarifying under what circumstances the 8 hours of new mammographic modality training can be included as part of other initial interpreting physician requirements
6. Further clarifying the table describing acceptability of the ARRT(M) certificate
7. Modifying the guidance regarding the testing of single use cushion pads
8. Modifying the table listing medical physicist involvement in certain FFDM repairs
9. Clarifying the conditions under which electronic Quality Control test data may be retained

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 various aspects of the final regulations implementing the Mammography Quality Standards Act (MQSA) (Public Law 102-539). This guidance document adds to and updates material in the Policy Guidance Help System (PGHS) in order to address recurring inquiries to CDRH about these issues. The PGHS is a computerized system accessible through FDA's web site that is intended to provide useful information to mammography facilities and their personnel on issues relating to MQSA. This guidance only addresses those portions of PGHS that are being revised. Portions of the system that are not being modified will not be discussed in this document.

This document provides guidance on the following issues:

1. Definitions of final interpretation and lossless and lossy digital compression
2. Use of Small Field Digital Mammography (SFDM) image receptors
3. Clarification relating to reestablishing processor operating levels
4. Impact of the Health Insurance Portability and Accountability Act (HIPAA) requirements on certain MQSA activities
5. Retention of medical outcomes audit records
6. Steps to take when patients do not wish to receive their lay summaries
7. Combining medical reports
8. The effect of film digitization and compression of Full Field Digital Mammography (FFDM) digital data on retention, transfer, and interpretation of mammographic images
9. Clarification of continuing education requirements
10. Use of foreign-trained physicians
11. Use of the American Registry of Radiologic Technologists ARRT(M) certificate to meet certain radiologic technologist requirements
12. Quality Control testing when using cushion pads on compression devices
13. Medical physicist involvement in certain FFDM repairs
14. Use of printers and monitors that were not specifically approved as part of an FFDM unit
15. Digitization of paper records and personnel documents

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.

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.

II. The Least Burdensome Approach

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

III. Background

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

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

The information in the PGHS has periodically been updated 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://list.nih.gov/cgi-bin/wa?SUBED1=mammography_cdrh-l&A=1 and following the directions there.

IV. Discussion of Revisions

This guidance revises certain aspects of the PGHS, which was last updated in October 2003. The PGHS is organized by broad subject matter areas (e.g., Equipment) which are immediately followed by related topics that address more specific issues (e.g., Image Receptor Sizes). Many of the pages in the PGHS begin with the regulatory citation related to the selected topic. After the citation, there is generally a discussion and/or series of questions and answers concerning the topic. This document will follow that same format. For purposes of this document, additions to the PGHS are shown as highlighted text (^+Example^-) while deletions are shown by strikethroughs (*+~~Example~~*-). The symbols ^+, ^-, *+, and *- have been added to enable computerized

text readers to identify the changes. Those portions of the PGHS that are not being revised will not be discussed in this document.

A. Definitions

The discussion in the PGHS concerning several topics listed under the "Definitions" heading is being revised as follows:

^+Final interpretation means the interpretation done by an MQSA-qualified interpreting physician that forms the basis for the mammography report required by 21 CFR 900.12(c).

Lossless compression refers to methods of digital data compression in which all the original data information is preserved and can be completely reconstituted.

Lossy compression refers to methods of digital data compression in which the original data information cannot be completely reconstituted.^-

Mammographic Modality

Citation:[1]

900.2(z): Mammographic Modality means a technology, within the scope of 42 U.S.C. 263b ^+[MQSA]^-, for radiography of the breast. Examples are screen-film mammography and xeromammography.

Discussion:

^+Question 5: What is Small Field Digital Mammography (SFDM) and is it a mammographic modality?

Small Field Digital Mammography (SFDM) refers to the use of a small digital image receptor (usually an add-on component to a film-screen system) to produce mammographic images. Because this small receptor cannot image the entire breast, it cannot generally be used for screening examinations and in almost all cases is limited to only a portion of the breast for either interventional or diagnostic purposes. When used for diagnostic purposes, SFDM is considered a subpart of the Full Field Digital Mammography (FFDM) mammographic modality. (See Question 6 below)

Question 6: Which MQSA requirements must SFDM meet in order to use it clinically?

If the SFDM receptor is part of a mammography unit that is used solely for interventional procedures, the unit and the receptor are excluded from all MQSA requirements.

If the SFDM receptor is part of a mammography unit that is used for mammography, either screening and/or diagnostic, then the unit and the SFDM receptor must meet the following MQSA requirements:

1. The unit must be accredited and certified (section 354(d)-(e) of the MQSA). The SFDM receptor does NOT have to undergo a separate accreditation or certification.
2. The SFDM receptor manufacturer must have obtained marketing clearance from FDA's Office of Device Evaluation for diagnostic mammography use of the SFDM receptor (21 CFR part 807, subpart E, 21 CFR 900.12(b)(1), (2)). This is usually stated in the labeling information in the receptor manual. If the facility is unsure whether the particular model of SFDM receptor it plans to use has received such clearance, it can contact the manufacturer.
3. Personnel must meet all applicable MQSA requirements (21 CFR 900.12(a)). For SFDM this means that, in addition to the basic requirements, personnel who only had training in film-screen mammography would need to have 8 hours of training in digital mammography (either FFDM or SFDM) prior to independently using the SFDM receptor clinically (21 CFR 900.12(a)(1)(ii)(C), (a)(2)(iii)(E), (a)(3)(iii)(C)). Personnel who already had 8 hours of training in FFDM would NOT have to obtain additional training.

[1] All citations to MQSA regulations in this draft guidance refer to Title 21 of the Code of Federal Regulations (21 CFR), Part 900, unless otherwise noted. Some citations have been paraphrased for easier readability.

Note: Personnel who use SFDM for diagnostic purposes prior to January 1, 2006 will be considered to have met the 8 hour requirement. Such personnel can attest to or document this experience.

4. Facilities must have the receptor pass a mammography equipment evaluation prior to initial use (21 CFR 900.12(e)(10)) and must follow the SFDM manufacturer's quality control manual with respect to periodic testing (21 CFR 900.12(e)(6)). The receptor must also be checked as part of the annual physics survey (21 CFR 900.12(e)(6), (9)).^-

B. Inspection

The discussion in the PGHS concerning the following topic listed under the "Inspection/Quality Control and Quality Assurance" heading is being revised as follows:

Reestablishing Processor Operating Levels *+~~Over the 5-Day Period~~*-

Discussion:

Question 2 [Repeated as question 7 under Quality Assurance/Equipment/Daily QC tests]: During the time a facility is establishing new operating levels ^+for a processor^- (typically done by performing a five-day data plot average): A) *+~~does~~*-^+Must^- the facility continue to plot the data on the processor chart? B) Is the facility exempt from having to stay within the old processor action limits during the *+~~five-day~~*- averaging period?

While establishing new operating levels ^+for a processor^- (during which time the facility can continue to process mammograms), the facility must continue to perform the daily processor QC tests (21 CFR 900.12(e)(1)) and should plot the data in the same manner it usually does. This may be done on the same graph as the previous data or on a different graph. In either event, this new data should be clearly identified as being derived during the establishment of the new operating levels, so that both the facility and the inspector are aware of the origins of this data. Because no operating level has yet been established, the facility is exempt from having to stay within any processor action limits during this *+~~five-day~~*- averaging period. During the *+~~five-day~~*- averaging period, the facility should daily perform and evaluate a phantom image as a means of monitoring image quality. ^+ Because phantom optical densities may also vary during this time period, the facility may limit its evaluation of the phantom image to the fiber/speck/mass scores. The facility is reminded that if the phantom image scores fall below the minimum requirement, the facility must cease performing mammography until the problem has been corrected. (21 CFR 900.12(e)(8)(ii)(A)) ^-

C. ^+Health Insurance Portability and Accountability Act (HIPAA)

The following discussion is being added to the PGHS under the new topic "Health Insurance Portability and Accountability Act (HIPAA)":

HIPAA and release of information for MQSA purposes

Discussion:

Implementation of the Health Insurance Portability and Accountability Act (HIPAA) has raised a number of issues with respect to mammography facilities that operate under the Mammography Quality Standards Act (MQSA). Three issues are arising with increasing frequency. The first concerns the protection of patient information during MQSA inspections. The second deals with whether other medical entities (e.g., referring physicians, pathology departments, surgeons) can release patient biopsy information to mammography facilities for purposes of their MQSA medical outcomes audit without obtaining patient authorization. The third deals with the transfer of medical records from one medical entity to another for treatment, payment, or healthcare operation purposes. The HIPAA regulations address these matters as follows:

Question 1: Can facilities release patient information to an MQSA inspector without patient authorization?

Yes. Sections 164.512(b) and (d) of the HIPAA regulations issued by the Department of Health and Human Services (DHHS) (45 CFR) allow a mammography facility to release patient information to an MQSA inspector without patient authorization because MQSA inspectors are performing health oversight activities required by law.

Question 2: Can medical entities such as referring physicians, pathology departments, and surgeons release patient biopsy information to mammography facilities for purposes of their MQSA medical outcomes audit without obtaining patient authorization?

Section 164.512(b) of the HIPAA regulations allows a covered entity (e.g., referring physician, pathology department, surgeon) to release patient biopsy information to a mammography facility for purposes of the MQSA medical outcomes audit without patient authorization because the disclosure: (1) is to a person subject to FDA jurisdiction; (2) concerns an FDA-regulated product or activity for which the mammography facility has responsibility; and (3) relates to the quality, safety, or effectiveness of the product or activity.

Question 3: Can a patient's medical records be transferred to another medical entity for treatment, payment, or healthcare operation purposes without obtaining patient authorization?

Section 164.506 of the HIPAA privacy regulations permits release of information for treatment, payment, or healthcare operation purposes without a specific patient authorization. Consequently the regulation allows a mammography facility to transfer medical records to another covered entity in most situations without a specific patient authorization. The Office of Civil Rights, the DHHS office with primary responsibility

for HIPAA implementation, has also stated that, "a covered health care provider may share protected health information with another health care provider for treatment purposes without a business associate contract." Additional information regarding HIPAA requirements can be found on the DHHS Website at http://www.hhs.gov/ocr/hipaa/.^-

D. Medical Outcomes Audit

The discussion in the PGHS concerning the topic listed under the "Medical Outcomes Audit/Frequency of Medical Outcomes Audit Analysis" heading is being revised as follows:

Citation:

900.12(f)(2): Frequency of audit analysis. The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999, whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

Discussion:

Question 2: How long must we maintain the records of our medical outcomes audit?
+~~The medical outcomes audit is a quality assurance record and as such must be maintained for at least 2 years. If the facility has obtained actual pathology reports, those should be maintained until the next annual inspection.~~- ^+For MQSA purposes, the medical outcomes audit (including the associated surgical and/or pathology reports) is considered part of a facility's quality assurance program. Therefore, the data must be maintained according to the quality assurance requirements. The analysis must be kept until subsequent analyses have been performed two additional times at the required frequency or until the next annual inspection has been completed and FDA has determined that the facility is in compliance with QA requirements, whichever is longer (21 CFR 900.12(d)(2)). Because the audit analysis is required to be conducted at least once every 12 months, the audit analysis must be kept for 24 months following its completion. If the facility has obtained actual pathology reports, these should be maintained until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements.

However, State laws may define the data as part of a patient's or facility's medical records, and may impose more stringent requirements for the retention of this data. A facility may want to check with the State regarding its requirements.^-

E. Medical Records and Reports

The discussion in the PGHS concerning several topics listed under the "Medical Records and Reports" heading is being revised as follows:

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 23: If a patient specifically asks the facility not to provide her with a lay summary, can the facility comply with her request?
If a patient specifically requests that no lay summary be sent to her, the facility may comply with the patient's request provided the facility adequately documents why it did not comply with the requirement in section 900.12(c)(2) to provide a lay summary. We recommend that the facility take all of the following actions:

1. Obtain from the patient a signed written statement indicating that she does not want to receive her lay summary. The facility should obtain from the patient a separate statement for each examination for which the patient says she does not want to receive a lay summary.
2. Maintain the patient’s signed written statement(s) until the facility’s next annual MQSA inspection.
3. Have the patient designate someone to receive the lay summary on her behalf, such as her physician or another responsible party.^-

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.

Discussion:

^+**Question 6 [Repeated as question 17 under Medical Records and Reports/Contents of Records and Reports]: Under new Centers for Medicare and Medicaid Services (CMS) guidelines, we can now charge for screening and diagnostic exams done on the same patient on the same day. Can we combine the two exams into one report or must we issue two separate reports?**

The facility has the option of issuing either separate reports or one combined report. If two reports are issued, each must contain its own overall final assessment (21 CFR 900.12(c)(1)(iv)). In either case, the facility can report the exam(s) on the same piece of paper.

If the facility decides to issue a single combined report, the facility needs to be aware of the following:

1. A combined report must contain a single overall final assessment for the two exams (21 CFR 900.12(c)(1)(iv)).
2. The combined report should make it clear that it is combining the results of the screening and diagnostic studies. This is especially important if questions arise about whether the exams were billed correctly.
3. Issuing a single combined report with a single final assessment may skew the facility's medical audit results.
4. Though some computerized reporting systems may consider this a single exam (rather than two), FDA would still allow facilities to count both exams toward meeting the continuing experience requirement.^-

Recordkeeping

Citation:

900.12(c)(4)(i),(ii): Recordkeeping. Each facility that performs mammograms:

(i) Shall (except as provided in paragraph (c)(4)(ii) of this section) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law; and

(ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or healthcare provider of the patient, or to the patient directly.

Discussion:

Question 4: [Repeated as question 4 under Medical Records and Reports/Transfer of Records] With the introduction of Full Field Digital Mammography, what constitutes a mammogram ^+for retention and transfer purposes^-, the digital data or the *+~~hard copy~~*-^+hardcopy^- film?

There are two sections of the recordkeeping requirement that are affected by the introduction of ^+full field^- digital mammography ^+(FFDM)^-. The first deals with retention of the mammography films. For purposes of film retention, the facility must maintain, in retrievable form, either the ^+original or lossless compressed full field^- digital data or *+~~hard copy~~*-^+hardcopy^- films ^+of final interpretation quality^- for the ^+time periods specified in the above regulation^-*+~~specified periods of time~~*-. ^+The second section affected by FFDM deals with transferring films.^- For purposes of transferring films, the facility must be able to provide the medical institution, physician, health^+care^- provider, patient or patient's representative, with *+~~hard copy~~*-^+hardcopy^- films of-*+~~primary~~*-^+final^- interpretation quality*+~~. Facilities may transfer~~*- ^+or, when it is acceptable to the recipient (e.g., a transfer between two FFDM facilities), with original or lossless compressed full field^- digital images electronically.

^+Question 5: Can a facility copy or digitize a film screen mammogram and use that copied or digitized image for retention purposes or final interpretation?

No. While not allowed for final interpretation, copied or digitized images of previously obtained mammograms may be used for comparison purposes if the interpreting physician deems that acceptable. However, such images cannot be used toward initial or continuing experience requirements.

We recommend that if copied or digitized images are used for comparison purposes that only copiers or digitizers approved or cleared by FDA's Office of Device Evaluation for such purposes be used. In addition, we recommend that phantom and clinical images produced by such copying or digitization pass all applicable quality control tests and be of such quality that if they were submitted, they would pass the facility's accreditation body's phantom and clinical image review process.

Question 6: Can a facility use lossless compression to store FFDM images for retention purposes?

Yes. Lossless compression accurately preserves all of the data from the original mammogram and therefore FDA permits images regenerated from lossless compressed data to be used in the same manner as the original mammogram.

Question 7: Can a facility use lossless compression to recreate FFDM images for final interpretation?

Yes. Lossless compression accurately preserves all of the data from the original mammogram and therefore FDA permits images regenerated from lossless compressed data to be used in the same manner as the original mammogram.

Question 8: Can a facility use lossy compression to store FFDM images for retention purposes?

No. Currently FDA does not permit images regenerated from lossy compressed data to be used in the same manner as the original mammogram.

Question 9: Can a facility use lossy compression to recreate FFDM images for final interpretation?

No. Currently FDA does not permit images regenerated from lossy compressed data to be used in the same manner as the original mammogram.

While not allowed for final interpretation, lossy compressed images of previously obtained mammograms may be used for comparison purposes if the interpreting physician deems that acceptable. However, such images cannot be used toward initial or continuing experience requirements.

We recommend that if lossy compressed images are used for comparison purposes that only algorithms approved or cleared by FDA's Office of Device Evaluation for such purposes be used. In addition, we recommend that phantom and clinical images produced by lossy compression pass all applicable quality control tests and be of such quality that if they were submitted, they would pass the facility's accreditation body's phantom and clinical image review process.^-

Transfer of Records

Citation:

900.12(c)(4)(ii),(iii): Each facility that performs mammograms:

(ii) Shall upon request by, or on behalf of, the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;

(iii) Any fee charged to the patients for providing the services in paragraph (c)(4)(ii) of this section shall not exceed the documented costs associated with this service.

Discussion:

Question 5: We have an FFDM unit and do not keep hardcopy of our exams (^+i.e.,^- we retain the images electronically). When patients request the release of their exam, we create a hardcopy for them. May we charge the patient for the cost of creating the hardcopy?

The facility may not charge for creating the first hardcopy version of the mammogram. However, if the patient requests *+~~a second~~*- ^+one or more additional hard copies^- *+~~copy~~*- of the mammogram, the facility may pass the costs of *+~~that reproduction~~*- ^+the additional hardcopies^-on to the patient.

^+ Question 6: Can a facility use lossless compression to transmit images to the patient or other medical institutions for final interpretation?

Yes, provided that such transmission is acceptable to the receiving party. Lossless compression accurately preserves all of the data from the original mammogram and therefore FDA permits images regenerated from lossless compressed data to be used in the same manner as the original mammogram.

Question 7: Can a facility use lossy compression to transmit images to the patient or other medical institutions for final interpretation?
No. Currently FDA does not permit images regenerated from lossy compressed data to be used in the same manner as the original mammogram.

While not allowed for final interpretation, lossy compressed images of previously obtained mammograms may be transferred to the patient or another medical institution to be used for comparison purposes if the interpreting physician deems that acceptable.

However, we recommend that if lossy compressed images are used for comparison purposes that only algorithms approved or cleared by FDA's Office of Device Evaluation for such purposes be used. In addition, we recommend that phantom and clinical images produced by lossy compression pass all applicable quality control tests and be of such quality that if they were submitted, they would pass the facility's accreditation body's phantom and clinical image review process.^-

Mammographic Image Identification
Citation:
900.12(c)(5)(i),(ii),(iii),(iv),(v),(vi),(vii): Mammographic image identification. Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:
(i) Name of patient and an additional patient identifier.
(ii) Date of examination.
(iii) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with 900.3(b) or 900.4(a)(8) shall be used to identify view and laterality.
(iv) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.
(v) Technologist identification.
(vi) Cassette/screen identification.
(vii) Mammography unit identification, if there is more than one unit in the facility.

^+Question 5: When we display a breast image on our monitor for final interpretation the identifying information is not displayed (view and laterality, technologist identification, patient name, etc.), but this information does appear on the hard copy film. Is this acceptable?
No. The above regulation requires that the identifying information be indicated on each mammographic image used for final interpretation, not just on the hard copy film. Work

stations used for final interpretation may allow the option for the interpreting physician to temporarily switch off the image identification information, provided that the standard or default setting shows the image identification information.^-

F. Personnel

The discussion in the PGHS concerning several topics listed under the "Personnel" heading is being revised as follows:

Personnel/General
Acceptable Subject Areas for the Continuing Education and Initial Training Requirements

Citations:

^+Interpreting physician requirements

900.12(a)(1)(i): Initial qualifications.

900.12(a)(1)(i)(B)(2) The interpreting physician shall have a minimum of 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of paragraph (a)(1) of this section.^-

900.12(a)(1)(i)(C): The interpreting physician shall have a minimum of 60 hours of documented medical education in mammography, which shall include: Instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and quality control in mammography. All 60 of these hours shall be category I and at least 15 of the category I hours shall have been acquired within 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution.

^+900.12(a)(1)(ii): Continuing experience and education.^-

* * *

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)(D): Units earned through teaching a specific course can be counted only once towards the 15 required by paragraph (a)(1)(ii)(B) of this section, even if the course is taught multiple times during the previous 36 months.

^+*900.12(a)(1)(iv): Reestablishing qualifications*.^-

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.

^+Radiologic Technologist requirements^-

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; and

900.12(a)(2)(iii)(A), (B), 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.

(B) Continuing education requirements. Units earned through teaching a specific course can be counted only once towards the 15 required in paragraph (a)(2)(iii)(A) of this section, even if the course is taught multiple times during the previous 36 months.

(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.

^+Medical Physicist requirements^-

900.12(a)(3): All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under paragraph (e) of this section shall meet the following:

* * *

900.12(a)(3)(i)(B)(2): Initial qualifications. Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities.

^+ *900.12(a)(3)(ii)(B)(2) Alternative Initial Qualifications. Prior to April 28, 1999, have … Forty contact hours of documented specialized training in conducting surveys of mammography facilities and, ….*^-

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)(iv)(A): Reestablishing qualifications. 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.

Discussion:

All continuing education credits (category I for interpreting physician^+s^-) related to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography, will be acceptable toward meeting the continuing education requirement.

Initial training must be in topics directly related to the regulated areas of mammography ^+as specified in the regulations above^-.

Question 1: Are there specific subject areas that are acceptable for continuing medical education and others that are not acceptable?

*+~~Except for credits in each mammographic modality used,~~ *-FDA does not require specific subject areas for continuing medical education in mammography. All continuing education units ^+(category I for interpreting physicians)^- related to the diagnosis or treatment of breast disease or to other areas that will aid facility personnel in improving the quality of mammography, *+~~may*~~ ^+will^- be acceptable toward meeting the continuing education requirement. ^+Also, because of the external pressures affecting mammography facilities that have caused facility closures and a decrease in the number of personnel performing mammography, topics such as medical malpractice and mammography billing and reimbursement are becoming increasingly important to the continued viability of many mammography facilities. Because of this, CME/CEU training in these areas may be accepted toward meeting the MQSA CME/CEU requirement. However, the number of credit hours in these topics should not constitute a majority of the 15 hour requirement.^-

Personnel – Interpreting Physician – Interpreting Physician Alternative to Board Certification

Citation:

900.12(a)(1)(i)(B)(2): The interpreting physician shall have a minimum of 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of paragraph (a)(1) of this section.

Discussion:

Formal training is a structured documented education program that includes mammographic interpretation, academic course work, and/or continuing medical education (course work and CME includes but is not limited to the topics listed in the citation above). *+~~Three months equals 12 weeks, which also equals 420 hours (35 hours x 12 weeks).*~~

Some of the ways that formal training ^+requirements^- may be met and documented include the following:

(1) A letter or other documentation from the physician's American or Canadian residency program documenting that the physician has met the 3 months of training in mammography. ^+For purposes of meeting the training requirements, FDA considers 3 months to equal 12 weeks, which also equals 420 hours (35 hours x 12 weeks).^- The 3 months of training can occur any time during the residency program and does not have to be in one continuous block of time. The letter can come from either the current officials or from those in authority at the time of the physician's residency. It *+~~must~~*-^+should^- come from a responsible residency program official who has the authority to sign for the department and *+~~must~~*-^+should^- indicate the signer's title (e.g. Chairman of Program, Director of Residency Education, Director of Mammography Section).

(2) Documented CME in mammography totaling 420 hours that may include certificates, letters, etc. These CME units must be category I as recognized by the Accreditation Council for Continuing Medical Education (ACCME), ^+the Accreditation Council for Graduate Medical Education (ACGME), the^- American Osteopathic Association Continuing Medical Education (AOA CME), ^+the^-American Medical Association Physician's Recognition Award (AMA PRA), state medical society, or equivalent.

(3) Documentation of successful completion of formal mammography training courses as recognized by the ACCME, ^+ACGME,^- AOA CME, AMA PRA, state medical society, or equivalent.

(4) Documentation of formal training in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection may be used to satisfy up to 90 hours of the total 420 hours training requirement.

(5) Documentation establishing that a combination of the physician's residency training, formal training, and CME total the equivalent of 3 months (420 hours).

Attestation may not be used to document that the interpreting physician satisfies the alternative to board certification.

^+**Question 3: Do the 3 months of mammography training have to be performed during the last two years of the residency program?**

No. The regulations do not establish a time frame for meeting this requirement. The 3 months of training could have occurred anytime during the residency program (or outside the residency program, see discussion above). However, the initial experience (240 exams) and initial medical education (60 hours) must be obtained within the specified timeframes of the person's starting date (21 CFR 900.12(a)(1)(i)(C)-(D)).

Question 4: Our facility would like to hire a physician to interpret mammograms who did not train in a U.S. or Canadian residency program. Are there any special conditions we need to be aware of?

Yes. There are 4 basic initial requirements for any physician to qualify to interpret mammograms under the MQSA final regulations (21 CFR 900.12(a)(1)). These requirements are:

1. Must have a valid State license to practice medicine.

2. Must be Board-certified in Diagnostic Radiology by an FDA-approved body or have 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography.

3. Must have 60 category I CME credits in mammography with at least 15 obtained in the 3 years immediately prior to qualifying as an interpreting physician.

4. Must have interpreted or multi-read, under direct supervision of an interpreting physician, the mammographic examinations from at least 240 patients in the 6 months immediately prior to qualifying as an interpreting physician.

With respect to foreign-trained physicians, special conditions may exist for some of the above requirements:

1. The physician will have to contact the State where he or she wishes to practice and satisfy all its requirements in order to obtain a State license to practice medicine.

2. The three Boards accepted by FDA are the American Board of Radiology, the American Osteopathic Board of Radiology, and the Royal College of Physicians and Surgeons of Canada. These Boards do not have reciprocity with foreign Boards. This leaves the alternative option of documenting three months of formal mammography training. In terms of residency training, FDA accepts American or Canadian training but does not recognize programs from other countries. To meet the training requirement, the physician in question could obtain the three months of mammography training once he or she arrives in the U.S. However there are 2 other approaches he or she could take. The first involves having an organization, such as an American or Canadian radiology residency program, the Accreditation Council for Graduate Medical Education (ACGME), the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association Continuing Medical Education (AOA CME), the American Medical Association Physician's Recognition Award (AMA PRA), or a State medical society, document that the foreign training was equivalent to that of an American or Canadian program. The second approach involves the mammography facility submitting a request for an alternative standard. The facility would have to perform a detailed comparison of the foreign training received by the physician to that given by an American or Canadian program and submit that evaluation to FDA. We would then review all the submitted documents and make a decision as to whether to accept or reject the alternative standard request. The general rules for submitting alternative standard requests can be found in our regulations at 21 CFR 900.18.

3. The 60 Category I CME hours can be included as part of the three months of training (see requirement #2 of the four basic initial requirements), although the facility will have to make sure that at least 15 hours were obtained in the 3 years prior to the physician's beginning independent interpretation in the US.

4. Because FDA only accepts initial and continuing experience obtained in MQSA-certified facilities and initial experience obtained in Canadian residency programs, the physician will have to meet the initial experience requirement (see requirement #4 of the four basic initial requirements) once he or she arrives in the U.S.

The facility should also be aware that if it has a Full Field Digital Mammography (FFDM) unit, the interpreting physician would have to obtain 8 hours of training in that mammographic modality prior to interpreting examinations produced by the facility's FFDM unit (21 CFR 900.12(a)(1)(ii)(C)). These 8 hours of training can be included as part of the three months of training (see requirement #2 of the four basic initial requirements) or, if Category I, as part of the 60 hours of CME (see requirement #3 of the four basic initial requirements).

Once the physician meets all of the above requirements, he or she would be permitted to independently interpret mammograms. Of course, the physician would also be responsible for meeting all continuing requirements when they become applicable.^-

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 6: *+~~For new technologists, what about the ARRT advanced certificate in mammography?~~*- Can *+~~this still~~*- ^+ the ARRT advanced certificate in mammography ^- be used to meet the initial training in mammography requirement?

*+~~The technologist may count this certificate as meeting 24 hours of the 40 hour training requirement. Hence, each technologist qualifying after April 28, 1999, who has passed~~

~~this examination, would need to get an additional 16 hours of training. The ARRT advanced certificate in mammography also did not include the performance of a minimum of 25 examinations under the direct supervision of a qualified radiologic technologist. The technologist would need to get this initial experience.~~*-

^+Because the standards for obtaining the ARRT(M) certificate have changed over time, the answer depends on when the ARRT(M) certificate was issued and whether the technologist is qualifying under the interim or final regulations.

Date ARRT(M) issued	Qualifying under Interim Regulations before 4/28/99	Qualifying under Final Regulations between 4/28/99 and 12/31/00	Qualifying under Final Regulations after 1/1/01
ARRT(M) issued before 1/1/01	Acceptable as fulfilling Initial Training requirements	Counts as 24 hours of the 40 hour requirement (includes necessary subject areas). Doesn't include 25 supervised exams or new mammographic modality training.	Counts as 24 hours of the 40 hour requirement (includes necessary subject areas). Doesn't include 25 supervised exams or new mammographic modality training.
ARRT(M) issued 1/1/01 or later	Not Applicable	Not Applicable	Acceptable as fulfilling Initial Training requirements (40 hours, includes necessary subject areas and 25 supervised exams). Doesn't include new mammographic modality training.

Also see Acceptable Documents for Radiologic Technologists in the PGHS for more detail.^-

G. Quality Assurance/Equipment

The discussion in the PGHS concerning several topics listed under the "Quality Assurance/Equipment" heading is being revised as follows:

Dosimetry ^+-^- Annual Quality Control Test

Citation:

900.12(e)(5)(vi): Dosimetry. The average glandular dose delivered during a single craniocaudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

^+Question 1: My facility uses two distinct groups of small size cassettes of different speed classes to image the standard breast. Must annual dose measurements be obtained for both groups of cassettes?
Yes, because both groups of cassettes are used to image the standard breast.

Question 2: [Repeated as question 18 under Quality Assurance/Equipment/Weekly Equipment Quality Control]: 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?
If you are not using a cushion pad for 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 the majority of your patients, you must include the cushion pads when performing the 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 layers of the cushion pad when performing the phantom and dose QC tests. 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.^-

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 the full extent of the adjustment, change, or repair, the facility should consult their medical physicist to determine the proper extent of his or her involvement in evaluating the item.

Item	Major Repair	Medical Physicist Involvement
Automatic Exposure Control		
AEC *+~~R~~*-^+r^-eplacement	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 *+~~r~~*-^+R^-eplacement		
Same screen speed	N	MP involvement optional
+~~Different~~- ^+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
+~~t~~-^+T^-hickness scale accuracy adjustment but only if it affects AEC performance	N	MP oversight
+~~r~~-^+R^-epair 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 change~~*-^+Type/Speed Change^-	N	MP oversight
~~*+Filter Replacement~~	~~Y~~	~~MP conducts evaluation in person*-~~
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 *+T*-^+t^-ube *+R*-^+r^-eplacement	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

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 2: Can a facility use printers and monitors that were not specifically approved as part of its FFDM unit?
FDA recommends that only printers and monitors specifically approved or cleared for FFDM use by FDA's Office of Device Evaluation be used. However, a facility may use other printers and monitors. Facilities need to ensure that all printers and monitors used by the facility with its FFDM unit comply with a quality assurance program that is substantially the same as that recommended by the FFDM manufacturer and pass the facility's accreditation body's phantom and clinical image review process. At the current time, no accreditation body reviews soft copy images so we recommend that the soft copy images be of such quality that if they were submitted they would pass the facility's accreditation body's phantom and clinical image review process.

Note: Each softcopy and hardcopy mammographic image used for final interpretation must indicate identifying information (view and laterality, technologist identification, patient name, etc.) (21 CFR 900.12(c)(5)).

Question 3: Can a manufacturer hook up a printer or monitor to its FFDM unit if the printer or monitor were not part of its original Pre-Market Approval (PMA)?
Manufacturers will need to check the exact wording of their PMA to see if this is allowed. However, the facility is not restricted by the PMA and may hook up and use printers and monitors other than those approved by FDA for use with the manufacturer's FFDM unit as long as they meet the requirements specified in question #2.^-

H. Quality Assurance/General

The discussion in the PGHS concerning the topic listed under the "Quality Assurance/General" heading is being revised as follows:

Quality Assurance Records

Citation:
900.12(d)(2): Quality assurance records. The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, protection, and employee qualifications to meet assigned quality assurance tasks, are properly maintained and updated. The quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

^+Question 8: How long must we maintain our quality assurance records for our FFDM unit?
While the test result records (documentation logs) must be maintained as described above, FDA realizes that maintaining a large number of QC test images may be overly burdensome. Therefore, similar to what is already allowed for film-screen, FDA will allow FFDM QC test images to be retained according to the following schedule:

Images produced from daily QC tests – previous 30 days
Images produced from weekly QC tests – previous 12 weeks
Images produced from monthly QC tests – until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements
Images produced from quarterly QC tests – until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements
Images produced from semi-annual QC tests – until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality

assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

Question 9: Can a facility digitize (scan) its paper QC records, MEE and annual physics survey reports, and personnel documentation, keep the digital data in a retrievable format, and then discard the original paper records?
Digitization and storage of paper QC records, MEE and annual physics survey reports, and personnel documentation is acceptable if the following conditions are met:

1. The digitized data is easily accessible for review by the inspector during MQSA inspections. Failure to have records available at the time of inspection may result in a citation.
2. The digitized record needs to look like the original paper record, including any handwritten signatures or annotations that may be on the original record.
3. The facility has the capability of printing a hardcopy from the digitized records. While this will not generally be necessary, the facility must retain this capability for those cases where the inspector needs to take a hardcopy for further evaluation or to verify or document a noncompliance.
4. The facility maintains the original paper charts and records of QC tests performed by the radiologic technologist. These original paper QC records must be maintained for the time frame required by the regulations.
5. For all other digitized records, the digitized data must be maintained for the time frame required by the regulations.

Note:

1. Records that require, but lack adequate identification of who performed the test, survey, etc., are not acceptable.
2. Some mammography units and QC test measurement devices are automated and electronically store the QC test data. In addition, some facilities may record their QC data on computer, rather than using handwritten charts or tables. In these cases, the facility may maintain either the electronic data or a hardcopy printout of the data. In such cases, conditions 1, 3, and 5 above apply.
3. State laws may impose more stringent requirements for the retention of these records. A facility may want to check with the State regarding its requirements.^-

V. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 8.5 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Division of Mammography Quality and Radiation Programs, Office of Communication, Education, and Radiation Programs (HFZ-240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332.

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in §900.12 have been approved under OMB Control No. 0910-0309.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0580 (expires 03/30/2009).