

## Compliance Guidance

# The Mammography Quality Standards Act Final Regulations Document #1

**Document issued on: March 19, 1999**

This document supersedes document Draft Compliance Guidance August 27, 1998



**U.S. Department Of Health And Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health**

**Inspection Support Branch  
Division of Mammography Quality  
and Radiation Programs  
Office of Health and Industry Programs**

# Preface

## Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Charles Finder, Division of Mammography Quality and Radiation Programs, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Charles Finder at 301-594-3332.

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# Compliance Guidance<sup>1</sup>

## The Mammography Quality Standards Act

### Final Regulations Document #1

#### Background

The Mammography Quality Standards Act was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the *Federal Register*. The final regulations will become effective **April 28, 1999**, and will replace the interim regulations (58 FR 67558 and 58 FR 67565) which, under MQSA, currently regulate mammography facilities.

The FDA is planning a variety of efforts to educate the public about the final regulations. These efforts include making presentations at key professional meetings and providing written materials to the public. The currently available written documents include the *Small Entity Compliance Guide* (October 1997), a quarterly newsletter *Mammography Matters*, and an Internet home page (<http://www.fda.gov/cdrh/dmgrp.html>). The latest edition of “*What a Mammography Facility Should Do to Prepare for the MQSA Inspection*” (June 1995 with a July 1996 addendum) is currently being revised to reflect the changes that will occur under the final regulations.

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<sup>1</sup> This document is intended to provide guidance. It represents the Agency’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. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

## **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) (Pub. L. 102-539). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations. This guidance uses a question-and-answer format to provide information about how FDA will implement its mammography program under the regulations and MQSA.

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 the state or local authorities regarding their requirements.

## Personnel - General

**Question:** Under the interim regulations, personnel were allowed to attest to training, education, or experience that was earned before October 1, 1994. Under FDA's final regulations, will this still be allowed? What about attestation for training or experience earned between October 1, 1994 and April 28, 1999?

**Answer:** In general, personnel may continue to attest to training, education, and experience earned before October 1, 1994, except for the three month training alternative to board certification for physicians. Attestation also may not be acceptable for board certification, licensure, or State approvals. FDA generally does not intend to accept attestation for training, education, or experience obtained after October 1, 1994, including training, education, and experience for personnel qualifying after April 28, 1999.

**Question:** Are there any exceptions for attestation for education or training earned after October 1, 1994?

**Answer:** FDA may continue to accept a limited form of attestation beyond October 1, 1994, in situations where the education or training provider does not specifically document that the education or training offered at a meeting, or other educational opportunity, was in mammography. For example, to use continuing medical education (CME) or continuing education units (CEU), the interpreting physician, radiologic technologist, or medical physicist should provide:

1. Documentation from the CME/CEU provider of the total number of CME/CEU he or she earned at the meeting.
2. Documentation (for example, meeting agendas) showing the number of hours he or she could have earned in mammography at the meeting.

If an individual provides such documentation, FDA may then accept attestation (using FDA's recommended form or a form with similar elements) to the number of CME/CEU in mammography he or she actually earned at the meeting. The above policy applies only in cases where there are opportunities to earn CME/CEU in several fields at the same event. If the meeting or other educational opportunity is limited to mammography, then all that would be needed is documentation from the provider of the number of CME/CEU earned. This limited form of attestation also may be accepted for continuing medical education requirements for other subjects related to breast disease.

### **21 CFR 900.2(o)**

*Direct supervision means that: (1) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records; or (2) During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting*

*the survey.*

**Question:** Under what conditions may students, trainees, interns, or residents work at facilities (interpreting mammograms, performing mammographic examinations, or conducting medical physicist surveys) to obtain knowledge and experience prior to meeting the appropriate initial qualifications?

**Answer:** Personnel in training may work at facilities as long as they are under the direct supervision of a qualified individual.

**21 CFR 900.12(a)(1)(ii)**

- (A) *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.*
- (B) *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.*

**21 CFR 900.12(a)(2)(iii)(A)**

*Continuing education requirements. 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.*

**21 CFR 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 MQSA inspection or the last day of the calendar quarter or any date in between the two. The facility will choose one of these dates to determine the 24-month period.*

**21 CFR 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 in 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.*
- (B) *Continuing experience. Following the second 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 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 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:** Is the date when an individual must begin meeting the continuing experience and continuing education requirements based on the date on which he or she initially qualifies under the MQSA regulations? How does one determine this date and why is this so important?

**Answer:** Yes, the date an individual must begin meeting the continuing experience and continuing education requirements is the date on which personnel have completed all of their initial requirements and are allowed to practice independently at mammography facilities (interpreting mammograms, performing mammographic examinations, or conducting medical physicist surveys). This is used as the starting date for evaluating continuing experience and continuing education requirements.

The starting date for evaluating continuing experience for interpreting physicians has been either October 1, 1994 or the date on which someone initially qualifies, whichever is later. For radiologic technologists and medical physicists, this date is April 28, 1999 (the effective date of the final regulations) or the date on which someone initially qualifies to work independently, whichever is later.

The starting date for evaluating continuing education for interpreting physicians, radiologic technologists, and medical physicists has been either October 1, 1994 or the date on which someone initially qualifies, whichever is later.

**Question:** Does the date on which personnel initially qualify to work independently ever change, due to personnel taking time off after they qualify or if they re-qualify when they are found to be deficient for either continuing experience or continuing education?

**Answer:** No. If personnel take time off from work after initially qualifying to work independently, it does not change the date on which they initially qualified. If someone fails to meet the requirement for continuing experience or continuing education, their original qualification date also stays the same.

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

**Answer:** 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 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 be acceptable toward meeting the continuing education requirement.

**Question:** If an individual publishes a paper in mammography, is it acceptable to use that paper for continuing medical education? How many units may that individual obtain?

**Answer:** Credit may be obtained for continuing medical education by publishing a paper if an organization that grants continuing medical education units awards credits or units to an individual for such publications. The organization must decide the number of units that may be awarded.

**Question:** Under the final regulations, if less than 24 months have passed since an interpreting physician, radiologic technologist, or medical physicist has initially qualified to work independently, will they still be evaluated for continuing experience during an inspection? What about continuing medical education if less than 36 months have passed since initial qualification?

**Answer:** If less than 24 months have passed since personnel have initially qualified, insufficient time has passed to cite the facility during an inspection for any failure of these personnel to meet continuing experience requirements. Similarly, in the case of the continuing medical education, inspectors cannot cite the facility for failure of these personnel until 36 months have passed since the individual initially qualified. However, inspectors will try to draw the attention of facilities to situations in which it appears that personnel will not be likely to fulfill continuing education and experience requirements in a timely manner.

**Question:** Under FDA's interim regulations, when personnel were found deficient for not having at least 15 CME/CEU credits in the previous 36 months, they were given up to 90 days to obtain this education while continuing to work at a mammography facility without direct supervision. Will this 90-day period be continued after FDA's final regulations take effect on April 28, 1999?

**Answer:** No, FDA does not intend to apply this policy after April 28, 1999. Also, any part of a 90-day extension period that might have extended beyond April 28, 1999 will terminate on April 28, 1999.

**Question:** If personnel, such as interpreting physicians, radiologic technologists, or medical physicists do not start working directly in mammography after meeting all their initial requirements, but decide to start working at a mammography facility later, what must they do to make sure they are in compliance with MQSA? What should facilities do before allowing new personnel, including locum tenens or those personnel who have left the facility but returned later, to provide mammography services?

**Answer:** Personnel who have not worked in mammography for two years or more after meeting the initial requirements may need to work under direct supervision when they return to mammography, if they do not meet the continuing experience or continuing education requirements. While under direct supervision, these personnel should obtain the necessary continuing experience and CME/CEU to requalify before resuming independent work in mammography. A facility may be cited during an inspection if such personnel work without direct supervision prior to obtaining sufficient hours of CME/CEU and continuing experience to meet the continuing requirements. Similarly, facilities should check to see that all new personnel meet all the appropriate requirements prior to letting them provide mammographic services independently. If these personnel are working independently and do not have the required continuing experience and CME/CEU, the facility may be cited for these problems.

**21 CFR 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.*

**21 CFR 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.*

**21 CFR 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:** What are examples of new mammographic modalities? What types of training would be acceptable as training in new mammographic modalities?

**Answer:** The term **mammographic modality** refers to a technology for radiography of the breast. Examples are screen-film mammography and xeromammography. An example of a new mammographic modality that may be available in the near future is digital mammography. Personnel whose training pertained solely to screen-film mammography would be required to obtain 8 hours of training in digital mammography, if they are to begin providing services or interpretations using this modality after April 28, 1999. However, if those personnel started using this modality before April 28, 1999, this 8 hour training requirement would not apply.

New modality training can be in many forms, including, but not limited to, residency training, special training courses, continuing medical education, and training provided by the manufacturer. For interpreting physicians, this does not have to be Category I continuing medical education.

**Question:** Some personnel may receive some training in full-field digital mammography as part of their initial qualifications. In addition to counting toward their initial requirements, can this training also be applied to the eight hour new modality training requirement?

**Answer:** Yes. They may use this training in digital mammography to count toward the eight hour new modality training.

**Question:** Some personnel may receive continuing medical education (CME/CEU) in full-field digital mammography as part of the CME/CEU requirement. Can they also use this toward meeting the initial eight hour new modality training requirement?

**Answer:** Yes. They may use this CME/CEU in full-field digital mammography to count toward the eight hour new modality training.

## **Personnel - Retention of Personnel Records**

### **21 CFR 900.12(a)(4)**

*Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility should not be discarded until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the MQSA personnel requirements.*

**Question:** If a facility has personnel who only worked for a week or two and are now no longer with the facility, should the records for these individuals be retained and, if so, for how long?

**Answer:** Yes. Their records (as with all other MQSA regulated personnel) must be retained until the facility's next annual MQSA inspection has been completed and FDA has determined that the facility is in compliance with the MQSA personnel requirements.

# Interpreting Physician

## **21 CFR 900.2(o)**

*Direct supervision means that: (1) During joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the patient's records;. . .*

**Question:** What does it mean for a physician to be under the direct supervision of a qualified interpreting physician? Does the supervising physician have to sit next to the physician being supervised when he or she reads and interprets the film? Whose name goes on the report, the supervising physician or the physician being supervised?

**Answer:** The supervising physician need not be present during initial reading and interpretation. Direct supervision for an interpreting physician means that during the joint interpretation of mammograms, the supervising interpreting physician reviews, discusses, and confirms the diagnosis of the physician being supervised. The physician being supervised should not provide final results to patients or referring physicians without prior confirmation from the supervising physician. Since each mammography report must be signed by a qualified interpreting physician, the name of the supervising interpreting physician must be on the report as the interpreting physician.

## **21 CFR 900.12(a)(1)(iii)(A)**

*Those physicians who qualified as interpreting physicians under paragraph (a)(1) of this section of FDA's interim regulations prior to April 28, 1999, are considered to have met the initial requirements of paragraph (a)(1)(i) of this section. They may continue to interpret mammograms provided they continue to meet the licensure requirement of paragraph (a)(1)(i)(A) of this section and the continuing experience and education requirements of paragraph (a)(1)(ii) of this section.*

**Question:** An interpreting physician has been practicing under FDA's interim regulations and has met all of the initial and continuing requirements under those regulations. Will he or she have to go back and get additional mammography training to meet the requirements after April 28, 1999, the effective date for the new regulations?

**Answer:** No, the interpreting physician will not have to obtain additional initial training to continue reading and interpreting mammograms after April 28, 1999. However, after April 28, 1999, if the physician wants to begin reading and interpreting mammograms produced by a mammographic modality (such as digital mammography) in which he or she has not been trained, the physician will need to get at least 8 hours of training in the new mammographic modality. For continuing medical education, only Category I may be counted toward meeting the requirement after April 28, 1999 and at least six credits must be obtained in each mammographic modality used by the interpreting physician in his or her practice.

**21 CFR 900.12(a)(1)(i)(B)(2)**

*Have had at least 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.*

**Question:** A physician is not board certified in radiology and had less than three months of training in mammography during his or her residency in radiology. Since residency, the physician has had many hours of continuing medical education. Can these continuing education units be added to the training in residency to satisfy the initial three month training requirement?

**Answer:** FDA considers that three months of training in mammography is equivalent to 420 hours of training (35 hours per week x 12 weeks). The physician should determine how many hours of training were received during the residency and add them to the hours of continuing education to determine if he or she meets this total. However, all of the three months of training must be documented formal training, which cannot include self-study programs without an instructor. The training in radiation physics should constitute no more than 90 of the 420 hours.

**21 CFR 900.12(a)(1)(i)(C)**

*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 the 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.*

**Question:** A physician is not board certified in radiology and did not have any training in mammography during residency, but has acquired 80 hours of category I continuing education in mammography over the last two years. The physician would like to begin reading mammograms. What else must the physician do before he or she can read mammograms independently?

**Answer:** This physician has met the 60 hours of documented medical education requirement, but must meet all other initial requirements (licensure, board certification or three months training, and initial experience) prior to beginning independent interpretation. The 60 hours of education obtained for this requirement can also be used toward meeting the three month training requirement. Since the physician is not board certified, he or she must document a total of three months of training in mammography. Since FDA considers these three months to be equivalent to 420 hours of training, the physician should get 340 additional hours of training in mammography, thereby fulfilling both of these requirements.

**21 CFR 900.12(a)(1)(ii)(B)**

*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.*

**Question:** After April 28, 1999, interpreting physicians must earn Category I continuing medical education (CME). If a facility is inspected one year after this date, will all 15 of a physician's CME credits that were earned in the previous 36 months have to be Category I?

**Answer:** No. Any CME credits earned prior to April 28, 1999 may be either Category I or II. Credits earned after April 28, 1999 must be Category I. Category II credits earned prior to April 28, 1999 can be counted toward the required 15 credits as long as they were obtained within the 36 month period as measured back from the date of the current inspection.

**Question:** If a facility uses locum tenens interpreting physicians, and the locum tenens is not working at the facility when it is inspected, must the facility have their continuing experience and continuing medical education updated quarterly or continuously, like the other (regular) interpreting physicians?

**Answer:** No. The facility is only responsible for demonstrating that these interpreting physicians are qualified at the time they begin work at the facility. However, if the facility wishes to bring that physician back at a later date to work as a locum tenens, the facility may need to get updated documentation on the physician's continuing medical education and continuing experience, to verify that the individual has met all of the requirements on the day they start working again for the facility. Facilities should keep in mind that if a locum tenens physician (or technologist) is working at the facility on the day of the inspection, all their qualifications will be checked as if they were a permanent employee of the facility.

**21 CFR 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:** There is a new requirement for eight hours of training for any new mammographic modality before an interpreting physician may begin independently interpreting mammograms produced by this new mammographic modality. If the physician did not have this training during

residency, would it have to be Category I continuing education? What about applications training from the manufacturer of the new mammographic modality?

**Answer:** The initial eight hours training in the new mammographic modality does not have to be Category I training. FDA intends to accept applications training from the manufacturer in the new mammographic modality. Other examples of training in the new mammographic modality could include manufacturer's instruction materials, residency training, or special training courses.

**21 CFR 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.*

**Question:** An interpreting physician teaches the same ten-hour course to residents in mammography every year. Can the physician count this for 30 hours of continuing education over a 36 month period?

**Answer:** No. FDA considers teaching in a residency program as equivalent to Category I continuing education. However, the physician may only count the ten hours (ten units) of this training once in a 36-month period toward meeting the requirement of having 15 Category I continuing medical education units in mammography.

**21 CFR 900.12(a)(1)(iii)(B)**

*Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from paragraph (a)(1)(i)(D) of this section.*

**Question:** A radiology resident had a mammography rotation more than a year (but less than two years) prior to graduation from his or her residency program. During this rotation, the resident read over 400 mammographic exams under supervision over a four-month period. The resident will take the board examination one month before the end of the residency, which will be the earliest he or she is qualified to take the exam. The residency will end in June 1999. Does the resident still have to read an additional 240 mammographic examinations within a 6-month period to qualify as an interpreting physician?

**Answer:** If the resident passes this board examination, he or she would not need to read an additional 240 examinations.

**21 CFR 900.12(a)(1)(iv)**

*Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:*

- (A)** *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 a qualified interpreting physician, or*
  - (2)** *Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of a qualified 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 six months immediately prior to resuming independent interpretation.*

Question: A physician only read 80 mammographic examinations independently in the 24 months prior to the facility's inspection. If the physician reads 240 examinations within six months under the direct supervision of a qualified interpreting physician to requalify, can he or she resume reading mammography film independently? Is there anything else the physician needs to be concerned about with respect to his or her continuing experience?

Answer: If the physician reads 240 examinations within six months under the direct supervision of a qualified interpreting physician, he or she can resume interpreting examinations independently. However, at the time of the next MQSA inspection at any facility where the physician interprets mammograms, he or she must have read 960 mammographic examinations during the 24 months immediately preceding the date of that facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. If not, the facility may be cited due to the physician failing to meet the continuing experience requirement and the physician may have to re-qualify again (see exemption - next question).

Question: Under the interim regulations, FDA would not make adverse findings for the continuing experience requirement for any interpreting physician within six months of his or her requalification. Will FDA continue this approach under the final regulations? Will FDA use a similar approach for radiologic technologists?

Answer: Yes to both questions. Upon completing the continuing experience requalification process, FDA will treat interpreting physicians and radiologic technologists as compliant with the continuing experience requirement for a period of six months after completing the requalification process. Those not fully meeting the continuing experience requirement by the end of the six month deadline may have to repeat the requalification process.

FDA allows interpreting physicians and radiologic technologists this six month period so they can provide mammography services independently without being subject to multiple adverse findings related to their continuing experience. Without this six month period, individuals who work at more

than one facility could be the subject of such adverse findings at each facility that employs them, even though they have complied with the requalification process. Personnel who are in either the requalification process or in this six month period should provide written documentation of their status to all the facilities at which they provide mammography services in order to preclude further inspection problems. Medical physicists are treated differently because their requalification process causes them to fully meet their continuing experience requirement. A similar approach for the continuing education requirement is also not needed because the continuing education requalification process causes all personnel to fully meet this requirement.

**Question:** A physician had over three months of training in mammography during residency, and has been reading and interpreting mammograms at a facility for several years. He or she has now passed the ABR certification exam. Will this change the starting date for the physician's continuing experience and continuing medical education?

**Answer:** No. If the physician has met the initial qualification requirements under either of the two alternatives for interpreting physicians and then obtains additional qualifications, his or her original date of meeting the initial qualifications does not change.

# Radiologic Technologist

## 21 CFR 900.2(n)

*Direct supervision means that: . . . or (2) During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.*

**Question:** What does it mean to be under the direct supervision of a qualified radiologic technologist?

**Answer:** For the performance of a mammography examination, direct supervision means that the supervisor is present to observe and correct, as needed, the performance of the trainee. This requires that the supervisor be in the examination room itself during the time the examination is being conducted. The goal of direct supervision is to provide reasonable assurance that any mistakes made by the trainee are corrected before harm is done to patients.

## 21 CFR 900.12(a)(2)(i)

*General requirements.*

**(A)** *Be licensed to perform general radiographic procedures in a State; or*

**(B)** *Have general certification from one of the bodies determined by FDA to have procedures and requirements adequate to ensure that radiologic technologists certified by the body are competent to perform radiologic examinations;*

**Question:** A technologist was originally certified for general radiological procedures under the American Registry of Clinical Radiography Technologists (ARCRT). He or she is now registered with the American Registry of Radiologic Technologists (ARRT). Is the technologist qualified to perform mammography under the new final regulations?

**Answer:** Yes, as long as the technologist maintains his or her registration with the ARRT and meets the other requirements in the final regulations.

## 21 CFR 900.12(a)(2)(ii)

*Mammography requirements. Have, prior to April 28, 1999, qualified as a radiologic technologist under paragraph (a)(2) of this section 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:** A radiologic technologist was qualified under the interim regulations using his or her many years of experience performing mammography. He or she stopped working as a technologist in August 1996, but now wishes to work again in mammography. The technologist never obtained the specific training in mammography required by October 1, 1996 under FDA's interim regulations. Under FDA's final regulations, could the technologist be exempt from the new requirements for initial mammography training?

**Answer:** No. If the technologist has not obtained the specific training in mammography required by the interim regulations, then on the effective date of the final regulations (April 28, 1999), he or she must meet the new requirements for initial mammography training (items (A), (B), and (C) above).

**Question:** Under FDA's interim regulations, there were several courses that FDA had indicated would meet the specific training in mammography requirement. For new technologists, will FDA continue to accept these courses as adequate initial training under the final regulations?

**Answer:** For technologists qualifying after April 28, 1999, the training must have at least 40 contact hours of instruction and include the performance of a minimum of 25 examinations under the direct supervision of a qualified radiologic technologist. Most of the training programs accepted by FDA under the interim regulations do not meet these conditions. However, the individual can still use credits from these courses toward meeting the 40 hours required under the final regulations.

**Question:** Under the interim regulations, FDA accepted certain specific State certificates in mammography as meeting the specific training in mammography requirement. For new technologists, will FDA continue to accept State certificates in mammography as adequate initial training under the final regulations?

**Answer:** To meet the final regulations, the requirements for the State certificate would have to involve at least 40 contact hours of instruction and include the performance of a minimum of 25 examinations under the direct supervision of a qualified radiologic technologist to completely meet the mammography training requirement under the final regulations. The technologist should check with the appropriate State agency to see what the State certificate covers.

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

**Answer:** 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.

**21 CFR 900.12(a)(2)(iii)**

- (A) *Continuing education requirements. 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) *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.*

**Question:** For physicians, there is Category I and II continuing medical education (CME). For technologists, there are Category A and B continuing education units (CEU). Under the final regulations, physicians can only count Category I CME to meet their requirements. Will technologists be similarly restricted to counting only Category A CEU?

**Answer:** No. There is no distinction in the regulations between Category A and B CEU for technologists. Either is acceptable under the final regulations, but must be appropriately documented.

**21 CFR 900.12(a)(2)(iv)**

*Continuing experience requirements. (A) 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 MQSA inspection or the last day of the calendar quarter or any date in between the two. The facility will choose one of these dates to determine the 24-month period.*

**Question:** A technologist works in a small facility with a limited number of patients and several mammography technologists, so meeting the 200 examination requirement over a 24-month period will be difficult. If he or she assists another technologist while performing an examination, can both technologists count the exams they perform together?

**Answer:** Yes, as long as both technologists are present with the patient during the examination, are both directly involved in positioning of the patient, and both evaluate the resulting images from the examination. For an instructor directing a student in the positioning of the patient and approving this positioning prior to the x-ray exposure, both the instructor and the student can count the examination.

**21 CFR 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.*

Question: Under the interim regulations, FDA would not make adverse findings for the continuing experience requirement for any interpreting physician within six months of his or her requalification. Will FDA continue this approach under the final regulations? Will FDA use a similar approach for radiologic technologists?

Answer: Yes to both questions. Upon completing the continuing experience requalification process, FDA will treat interpreting physicians and radiologic technologists as compliant with the continuing experience requirement for a period of six months after completing the requalification process. Those not fully meeting the continuing experience requirement by the end of the six month deadline may have to repeat the requalification process.

FDA allows interpreting physicians and radiologic technologists this six month period so they can provide mammography services independently without being subject to multiple adverse findings related to their continuing experience. Without this six month period, individuals who work at more than one facility could be the subject of such adverse findings at each facility that employs them, even though they have complied with the requalification process. Personnel who are in either the requalification process or in this six month period should provide written documentation of their status to all the facilities at which they provide mammography services in order to preclude further inspection problems. Medical physicists are treated differently because their requalification process causes them to fully meet their continuing experience requirement. A similar approach for the continuing education requirement is also not needed because the continuing education requalification process causes all personnel to fully meet this requirement.

# Medical Physicist

## **21 CFR 900.2(n)**

*Direct supervision means that: . . . or (2) During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.*

**Question:** What does it mean to be under the direct supervision of a qualified medical physicist?

**Answer:** For the performance of a medical physicist survey, direct supervision means that the supervisor is present to observe and correct, as needed, the performance of the trainee. This requires that the supervisor be in the room during the time the survey is being conducted. The goal of direct supervision is to provide reasonable assurance that any mistakes made by the trainee are corrected before harm is done to patients.

## **21 CFR 900.2(ii)**

*Physical science means physics, chemistry, radiation science (including medical physics and health physics), and engineering.*

**Question:** There are a variety of sub-specialties and corresponding degrees listed within the definition of physical science. Do they all meet the requirements for a physical science degree or only certain ones?

**Answer:** Degrees that are in one of the specialties or sub-specialties of physics, chemistry, and engineering meet the requirements for a physical science degree. All sub-specialties in radiation science that involve study or use of radiation may be considered as a radiation science degree and thus a physical science degree.

## **21 CFR 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:*

### **21 CFR 900.12(a)(3)(i)**

*Initial Qualifications*

- (A) *Be State licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics survey; and*
- (B) (1) *Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics;*

- (2) *Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and*
- (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:** Are medical physicists who were board certified, State licensed, or State approved prior to April 28, 1999, exempt from having to meet the new requirements regarding their degree, semester hours of physics, and training on conducting surveys? What about survey experience?

**Answer:** No. All medical physicists, including those who were board certified, State licensed, or State approved prior to April 28, 1999, must meet the new requirements of either 900.12(a)(3)(i) initial qualifications or 900.12(a)(3)(ii) alternative initial qualifications regarding their degree, semester hours of physics, training on conducting surveys, and initial survey experience. There is no blanket "grand-parenting" of medical physicists who qualified prior to April 28, 1999.

**Question:** Assuming that boards that certify medical physicists already check on educational requirements, such as the type of degree and/or amount of physics the board-examination candidates must have prior to taking their examination, would inspectors need to check on this type of documentation?

**Guidance:** Prior to April 28, 1999, FDA plans to check with the boards designated by FDA to certify medical physicists and with the States that grant licenses or approval to ascertain what evaluations these boards or States perform when certifying, approving, or licensing medical physicists. If the board or State has in place or has had in place a mechanism that FDA believes sufficiently assures that the medical physicist has the required physical science degree and/or the required semester hours in physics, inspectors will not need to check on this documentation for those physicists.

**21 CFR 900.12(a)(3)(i)(B)(2)**

*Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities.*

**21 CFR 900.12(a)(3)(ii)(B)(2)**

*Forty contact hours of documented specialized training in conducting surveys of mammography facilities.*

**Question:** All medical physicists must have specialized training in conducting surveys of mammography facilities. What type of training can be used to meet this requirement? Can CME/CEU credits be counted to meet this requirement or does it have to be formal, academic

training? Can CME/CEU be used to meet both the "15 CME/CEU in 36-month" requirement and also to meet this "specialized training in conducting surveys" requirement?

**Answer:** Various types of training may be used to meet the requirement of having specialized training in conducting surveys, including CME/CEU, formal academic training, or other types of training programs. However, not all CME/CEU may be acceptable for this survey training. FDA accepts any CME/CUE credits or units related to the diagnosis or treatment of breast disease or to other areas that will aid medical physicists in improving the quality of the survey as acceptable toward meeting the continuing education requirement for physicists. The survey training should be specifically related to technical or quality assurance topics pertinent to mammography facility surveys.

Physicists who are qualified prior to April 28, 1999 and obtain their survey training prior to this date may count the survey training for both continuing education and the "specialized training in conducting surveys" requirement. However, physicists who qualify after April 28, 1999 may only use the survey training to meet their initial requirements and may not use the training for continuing education.

**21 CFR 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:** Prior to October 27, 1997, physicists who qualified through the degree, training and experience option had to have two years of experience in conducting performance evaluations of mammography equipment. Will this experience meet the initial experience requirement under the final regulations?

**Answer:** Only if the evaluations included at least ten units and also a complete facility survey (including the evaluation of technologist quality control records).

**21 CFR 900.12(a)(3)(ii) Alternative Initial Qualifications**

- (A) *Have qualified as a medical physicist under paragraph (a)(3) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and*
- (B) *Prior to the April 28, 1999, have:*
  - (1) *A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,*
  - (2) *Forty contact hours of documented specialized training in conducting surveys of mammography facilities, and*

- (3) *Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 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. The training and experience requirements must be met after fulfilling the degree requirement.*

**Question:** A physicist was performing facility surveys prior to April 28, 1999, with a bachelor's degree in physics. His or her State approval is still current after April 28, 1999. Is this degree acceptable toward meeting the alternative initial requirement?

**Answer:** Yes. The degree would be acceptable as meeting part of the initial qualifications. The physicist would also need to document that he or she has the experience of conducting surveys on at least 20 mammography units and one complete facility survey (including the evaluation of the technologist quality control records), as well as having had 40 contact hours of documented specialized training in conducting surveys of mammography facilities.

**Question:** A State-approved medical physicist has been conducting medical physicist surveys under the interim regulations. He or she has well over 40 contact hours of documented specialized training in conducting surveys of mammography facilities and has performed dozens of facility surveys. However, the physicist does not currently have a physical science degree but will obtain a bachelor's degree in physics by April 28, 1999. Will his or her survey experience count?

**Answer:** No. The experience and survey training must be met after fulfilling the degree requirement for those physicists expecting to qualify with a bachelor's degree.

**Question:** Prior to October 27, 1997, physicists who qualified through the degree, training and experience option had to have two years of experience in conducting performance evaluations of mammography equipment. Will this experience meet the initial experience requirement under the final regulations?

**Answer:** Only if the evaluations included at least 20 units and also a complete facility survey (including the evaluation of technologist quality control records).

**21 CFR 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 in 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.*

**Question:** May medical physicists count general medical physics continuing education not related to mammography or general continuing education in mammography unrelated to medical physics?

**Answer:** Yes. All continuing education credits related to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography, may be acceptable toward meeting the continuing education requirement. Diagnostic medical physics continuing education not directly related to mammography or general continuing education in mammography unrelated to medical physics would also be acceptable. However, physicists must make sure they obtain continuing education appropriate to each mammographic modality evaluated by them.

**21 CFR 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 paragraph (a)(3)(i) or (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 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 the total mammography unit survey requirement.*

**Question:** Can a medical physicist count surveys of the same facility and same unit more than once in the previous 24 month period toward meeting the continuing experience requirement?

**Answer:** A medical physicist can count two annual surveys of the same facility within a 24-month period to meet this requirement as long as the surveys are at least ten months apart. The same mammography unit may be surveyed more than once per year to meet the six unit requirement, as long as these unit surveys are at least 60 days apart.

# Equipment

**General:** Facilities are required to accredit all of their x-ray units used for mammography by submitting both clinical and phantom images for each such unit to the accreditation body as specified in 900.4(c)(4)(i) and 900.4(d)(4).

**Question:** Are all regulated mammography units in the facility required to be accredited and, if so, what documentation is necessary to establish that this has been done?

**Answer:** Yes. The facility should have documentation showing that each unit has been accredited by the accreditation body or, for new units, showing that the unit has passed an equipment evaluation or medical physicist's survey and that the application for accreditation of the unit has been submitted. There are three cases where the units in use in the facility may not need to be accredited: 1) the unit is a "loaner" while repairs to the facility's unit are taking place (limited to 30 days without extenuating documentation), 2) the unit is installed in the facility for evaluation prior to purchase (limited to not more than 90 days), or 3) the unit is an experimental one installed and used under an Investigational Device Exemption (IDE) as described in the Safe Medical Devices Act of 1990 or other FDA approved research protocol. The requirements for accreditation of these units is dependent on the rules of the facility's accreditation body. Note that under both 1) and 2) the unit still must have passed an equipment evaluation or survey and each such unit will be tested by the MQSA inspector, regardless of its accreditation or ownership status.

## **21 CFR 900.12(b)**

- (1) *Prohibited equipment. Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in Sec. 1020.31(f)(3) of this chapter.*
- (2) *General. All radiographic equipment used for mammography shall be specifically designed for mammography and shall be certified pursuant to Sec. 1010.2 of this chapter as meeting the applicable requirements of Secs. 1020.30 and 1020.31 of this chapter in effect at the date of manufacture.*

**Question:** If an x-ray unit is sold for several uses including mammography and nonmammography applications, may it be used for mammography?

**Answer:** Yes, as long as the equipment meets all of the applicable MQSA requirements. Equipment designed specifically for mammography, because of its unique characteristics, may be useful for nonmammography procedures and such use is not prohibited under MQSA. The requirements in 900.12(b)(1) and (2) do not preclude mammography equipment being advertised, sold, and used for other purposes. They simply require that the design has been optimized for mammography.

**21 CFR 900.12(b)(3)** *Motion of tube-image receptor assembly. (i) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion. (ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.*

**Question:** What motion requirements must the tube-image receptor assembly meet?

**Answer:** There is no specific range of motion that the assembly must provide. However, once fixed in any operating position intended by the equipment design, it must remain fixed in that position, even during power failure.

**21 CFR 900.12(b)(4)(i)**

*Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.*

**Question:** How many cassette/image receptor (IR) sizes must the facility have for each x-ray unit?

**Answer:** As a minimum requirement, the facility must have at least one 18x24 cm cassette and one 24x30 cm cassette for each mammography x-ray unit in the facility and each of these must be capable of properly functioning with their respective units. The facility may use additional sizes if desired.

**21 CFR 900.12(b)(4)(ii)**

*Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.*

**Question:** How many moving grid sizes must facilities have for each x-ray unit?

**Answer:** Facilities must have on hand at least one 18x24 cm and one 24x30 cm moving grid mechanism for each mammography x-ray unit in the facility. In addition, if the facility uses image receptor sizes other than the 18x24 and the 24x30 sizes, the facility must have moving grid mechanisms matched to each of these additional sizes. Each of these must be capable of properly functioning with their respective units. Note that a single, large grid assembly that is capable of accepting multiple sized cassettes is not sufficient to meet this requirement. The reason for not allowing the use of the single large grid assembly is the problem such an assembly causes when trying to adequately position small breasted patients.

**21 CFR 900.12(b)(4)(iii)**

*Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.*

**Question:** Can a facility keep the grid in place but position the cassette on top of the patient support (to prevent the grid from interfering with the image) and meet the intent of the regulation?

**Answer:** Yes, however, under these conditions the system must still be capable of providing magnification within the specified range. A facility meets the requirement if it has a written procedure for (or can demonstrate that the system has the capability of) conducting mammography with and without a grid between the image receptor and the x-ray source and such a practice does not cause the system to fail any other applicable requirement. A medical physicist may be consulted regarding the appropriateness of the technique.

**21 CFR 900.12(b)(5)(i)**

*All systems shall have beam-limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.*

**Question:** Do the regulations require that the x-ray unit have adjustable collimation on the chest wall edge of the x-ray beam?

**Answer:** No, but the beam must be capable of covering the chest wall edge of the image receptor.

**21 CFR 900.12(b)(5)(ii)**

*For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.*

**Question:** Are there illumination requirements applicable to the collimator light on mammography x-ray systems? If so, do they apply to all systems?

**Answer:** If the system is equipped with a light source to show the approximate size of the x-ray field or for positioning of the breast and this light passes through the x-ray beam-limiting device (collimator), then effective April 28, 1999 the above minimum light output requirement is applicable to that system. The regulation only specifies this requirement if such a collimator-light field combination is provided. The requirement is applicable to all such systems in use on that date or installed on or after that date.

**21 CFR 900.12(b)(6)(i)**

*Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.*

**Question:** In 900.12(b)(6)(i) what does the phrase “available for use by the operator” mean?

**Answer:** Noninterventional problem solving mammography x-ray systems are required to have the capability for magnification “available for use by the operator,” meaning that any necessary magnification devices must be present with such units to allow operator access to, and to facilitate the

use of, magnification procedures. The decision on whether to use the magnification still rests with the facility.

**21 CFR 900.12(b)(6)(ii)**

*Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.*

**Question:** A facility's x-ray unit has two magnification attachments that provide a magnification of 1.5 or 2.2, depending on which attachment is used. Other values specified in the regulation cannot be achieved using that unit. Must a facility purchase new attachments to cover the range, and does it mean that magnification at the 2.2 level must be discontinued?

**Answer:** No. The requirement is that the x-ray unit provide "at least one magnification value" from the specified range (in this case, the 1.5). The regulation does not prohibit the presence or use of other magnification settings.

**21 CFR 900.12(b)(7)**

- (i) *When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.*
- (ii) *When more than one target material is provided, the system shall indicate, prior to exposure, the pre-selected target material.*

**Question:** For x-ray systems with multiple focal spot sizes and target materials that are automatically selected by the system, how is it possible for the system to indicate the selected focal spot or target material before the exposure is taken?

**Answer:** When used in the automatic mode the system cannot show before the exposure, the actual values used during the exposure, but some values must exist before the exposure can begin. These pre-exposure values are set either by the technologist, by the unit, or by default. The unit must indicate these pre-exposure values, either on the unit or at the operator position, prior to the exposure and then indicate the actual values used during the exposure, as required in 900.12(b)(7)(iii). The indication must be clear and legible and can be achieved in any manner that provides the required information in an unambiguous fashion.

**21 CFR 900.12(b)(7)(iii)**

*When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.*

**Question:** A facility's x-ray unit has automatic exposure control of the mAs but does not automatically select the focal spot or the target material. Are the requirements of 900.12(b)(7)(iii) applicable to that unit?

**Answer:** No.

**21 CFR 900.12(b)(8)**

*Compression. All mammography systems shall incorporate a compression device.*

**Question:** Although all mammography systems are required to have a compression device, their use does not appear to be required. Is this true?

**Answer:** Yes. FDA's regulations do not prescribe use by the technologist. However, use of the system without adequate compression should be reserved only for those special procedures in which compression can not or should not be applied; FDA believes that adequate compression should be used for all other mammography as an aid in providing uniform tissue thickness and reducing patient motion.

**21 CFR 900.12(b)(8)(i)**

*Application of compression. Effective October 28, 2002, each system shall provide: (A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and (B) Fine adjustment compression controls operable from both sides of the patient.*

**Question:** A facility's x-ray units have compression devices operated by a single foot control on each unit. Does the foot control meet both the "hands-free" requirement and the "operable from both sides" requirement, even if each unit only has one foot control? Must the facility purchase a second control for each in order to meet the "operable from either side" requirement?

**Answer:** The system described may meet the regulations, but individual evaluation is necessary. The foot control does meet the "hands-free" portion of the requirement. If the single foot control is operable from both sides of the patient, then it would meet the full requirement. However, if the control is permanently mounted so that an operator can activate it from only one location, then it would not meet the requirement, therefore requiring that an additional "hands-free" control be incorporated into the system. Note that the "fine adjustment control" is not required to be a "hands free" device. Any method of activation, including a "foot control" could be used as the "fine adjustment compression control" required by this section. If there are additional questions, the facility should consult with its medical physicist before the October 28, 2002 deadline.

**21 CFR 900.12(b)(8)(ii)(A)**

*Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to the requirements of paragraphs (b)(8)(ii)(D) and (b)(8)(ii)(E) of this section.*

**Question:** A facility has two identical x-ray units, both of which have the capability to use multiple cassette/image receptor sizes. Would it be permissible to have both equipped with the 18x24 cm cassette-grid-compression paddle combination and have only one 24x30 cm cassette-grid - compression paddle combination that could be used on either unit on an as-needed basis? Additionally, must the facility provide the “spot compression” paddles referred to in the regulation?

**Answer:** No, to both questions. A facility must have on hand at least one cassette-grid-compression paddle combination of each of the 18x24 cm and 24x30 cm sizes to equip each mammography x-ray unit in the facility. “Spot compression” paddles are not required.

**21 CFR 900.12(b)(8)(ii)(B)**

*Except as provided in paragraph (b)(8)(ii)(C) of this section, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.*

**Question:** Must the compression paddle remain parallel to the patient support table when no compression is being applied?

**Answer:** No. The requirement for the paddle to be parallel is only applicable when compression is applied. Once the diagnostic range of compression is reached the paddle should be parallel to the support table and not deflect from parallel by more than 1.0 cm when compression is applied. .

**Question:** First, a facility’s mammography unit has a compression paddle on which the plastic plate itself does not flex but the mounting is worn and allows the plate to tilt when under compression. Would this meet the intent of the regulation? Second, in addition to standard mammography, interventional procedures (such as wire placements) are performed using an accredited, conventional mammography x-ray unit. The special paddles provided for this purpose will not meet this requirement. Must the facility purchase new paddles for this application that will meet the specification?

**Answer:** No, to both questions. First, if the system was designed to have the plate remain flat and parallel, then the situation you describe would not meet the intent of the regulation and the worn part(s) must be repaired or replaced. Second, the regulations do not currently cover interventional procedures so accessory devices used solely for such procedures, even when they are used on accredited units, are not required to meet the regulations.

**21 CFR 900.12(b)(8)(ii)(C)**

*Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.*

**Question:** What is the intent of the requirement that these paddles “meet the manufacturer’s design and maintenance specifications”?

**Answer:** Conventional paddles are designed to provide essentially flat compression across the breast to yield a uniform thickness of tissue for the mammographic study. However, some systems incorporate paddles designed to provide uniform compression pressure rather than thickness. Such systems must continue to operate consistent with their design over the life of the unit. This requirement simply states that the facility must maintain the system to the manufacturers' specifications.

**21 CFR 900.12(b)(8)(ii)(D)**

*The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.*

**Question:** The chest wall edge of the compression paddle on our system is generally straight but “slightly wavy.” Will this meet the requirement?

**Answer:** Yes. The intent of the regulation is that the chest wall edge be generally straight as opposed to curved to fit the general chest wall shape. Some older paddles/compression cones were formed to a curved shape at the chest wall edge and this section was included to prevent their use.

**21 CFR 900.12(b)(8)(ii)(E)**

*The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.*

**Question:** If the image of the chest wall edge of some of a facility’s “spot compression” paddles appears on the mammograms during these special procedures, would this be a violation of the regulations?

**Answer:** No. 900.12(b)(8)(ii)(E) is only applicable to full sized compression paddles when used with their matching image receptors.

**21 CFR 900.12(b)(9)(i)**

*Manual selection of milliamperere seconds (mAs) or at least one of its component parts (milliamperere (mA) and/or time) shall be available.*

**Question:** Would an x-ray unit with both a manual mode and an automatic exposure control mode assure that the mAs selection requirement is met?

**Answer:** Yes. If the system has a manual mode, then the selection of the mAs or a component part (mA or time) will be available to the operator. A properly functioning manual mode would ensure that the requirement is satisfied.

**21 CFR 900.12(b)(9)(ii)**

*The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.*

**Question:** When used in manual mode a facility's x-ray unit displays kVp, mA, and time before the exposure. When in AEC mode, the display usually changes from the preset indications after the exposure. Does this meet the requirement?

**Answer:** Yes.

**21 CFR 900.12(b)(9)(iii)**

*Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.*

**Question:** Are there any specific requirements for the mechanism of the display required by 900.12(b)(9)(iii)?

**Answer:** No. Under a separate FDA performance standard, the Diagnostic X-ray Performance Standard, the display must be clear, legible, and visible to the operator at the unit or the operator control location. The actual mechanism can be achieved in any manner that provides the required information in an unambiguous fashion.

**21 CFR 900.12(b)(10)(i)**

*Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.*

**Question:** A facility only performs screening mammography and does not do any magnification or diagnostic studies. Does this requirement mean that the facility must have the AEC set up to function in every mode where it is capable of operating, even though it may never be utilized in that mode in that facility?

**Answer:** The intent of the regulation is to ensure that the AEC mode is operable in all equipment configurations used clinically. One way is to have the AEC mode operable in all the configurations provided by the system. An alternative method is to ensure that the system will not be used in those modes without an operable AEC. This can be accomplished by placing a label on the unit's control panel listing the system configurations that cannot be used and by referencing these non-operational configurations in the facility's quality assurance records.

**21 CFR 900.12(b)(10)(ii)**

*The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.*

**Question:** A facility's x-ray unit has a single detector that may be moved to any of three positions along the chest wall to nipple midline of the breast. It cannot be placed under all areas of the breast. Would this meet the intent of the regulation?

**Answer:** Yes. It is not necessary that the detector be mobile over the entire area of the breast.

**21 CFR 900.12(b)(10)(ii)(A)**

*The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.*

**Question:** On the facility's x-ray unit, the indication of the detector size and position options is projected onto the input surface of the compression paddle. However, when the paddle is moved up and down, the indicated detector size does not change with distance. Is this an acceptable indication under 900.12(b)(10)(ii)(A)?

**Answer:** Yes. The size and positions indicated at the input surface should be indicative of the size and positions of the detector in the plane of the detector. Compliance could be achieved by representations permanently marked on the paddles or by a projected image that approximates the size and position of the detector.

**21 CFR 900.12(b)(10)(ii)(B)**

*The selected position of the detector shall be clearly indicated.*

**Question:** A facility's unit indicates the selected position of the detector by the relative position of the adjustment lever located on one side of the unit and is only visible from that side of the unit. Does this meet the regulation?

**Answer:** Yes. The relative position of the selector would be an adequate display of the detector position, and this display need be visible from only one location.

**Question:** The position of the AEC detector is indicated by a knob under the bucky that can be felt but not seen. Does this satisfy the requirement of being "clearly indicated?"

**Answer:** Yes.

**21 CFR 900.12(b)(10)(iii)**

*The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.*

**Question:** How much variability from the “normal” optical density setting must the system provide?

**Answer:** The regulations do not specify the range of variability that must be provided; only that some variability be available.

**21 CFR 900.12(b)(11)**

*The facility shall use X-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.*

**Question:** What does “designated by the film manufacturer as appropriate for mammography” mean, and how does the facility establish that they meet this requirement?

**Answer:** This simply means that the film manufacturer has established that the properties of the film are appropriate for mammography and markets it for such purposes, not that the film must be sold only for mammography. One mechanism to establish compliance would be to have documentation from the manufacturer, such as advertising material or specific literature, that clearly identifies the film and its intended use.

**21 CFR 900.12(b)(12)**

*The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.*

**Question:** How can the facility establish the match between the film and the screen output?

**Answer:** The facility is responsible for matching the sensitivity of the film with the spectral output of the screen. Examples of acceptable methods to establish compliance would be to provide documentation from the screen and/or film manufacturer, such as advertising material or specific literature, that clearly identifies the appropriateness of the combination or specifies the screen output and the film sensitivity showing a match between them. Otherwise, the facility should independently show that matching has been established. Facility personnel should contact their medical physicist for additional advice and assistance, if necessary.

**21 CFR 900.12(b)(13)**

*For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.*

**Question:** How does the facility establish the developing equivalency specified for different processing chemicals?

**Answer:** A facility must either have documentation from the chemical manufacturer/supplier or the film manufacturer showing that the processing chemicals being used provide results consistent with the film manufacturer's processing specifications, or the facility must establish that the film performance is sensitometrically equivalent to films developed according to the film manufacturer's specific recommendations. Facility personnel should contact their medical physicist for additional advice and assistance.

**21 CFR 900.12(b)**

- (14) *The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.*
- (15) *Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.*

**Question:** Are there any specific requirements concerning the viewing conditions for screen-film mammograms?

**Answer:** Yes. Facilities where screen-film mammograms are interpreted or reviewed for comparison, must provide **both** hot lights and masking devices to the interpreting physicians. Any device that blocks light not required for viewing and interpretation of the image would meet the masking requirement. Although not required, it is recommended that hot lights and masking devices be available for technologists to aid in their evaluation of clinical and quality control films.

## Medical Records

### **21 CFR 900.12(c)(1)(iv)**

*[The report shall contain] Overall final assessment of findings, classified in one of the following categories:*

*(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);*

*(B) "Benign:" Also a negative assessment;*

*(C) "Probably Benign:" Finding(s) has a high probability of being benign;*

*(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;*

*(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant;*

### **21 CFR 900.12(c)(1)(v)**

*In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and*

### **21 CFR 900.12(c)(1)(vi)**

*Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible, even if the assessment is negative or benign.*

**Question:** What categories must be shown on mammography reports for final assessments of findings?

**Answer:** Only one of the following final assessment categories must appear on the mammography report: "Negative," "Benign," "Probably benign," "Suspicious," "Highly suggestive of malignancy," or "Incomplete: Need additional imaging evaluation." Furthermore, the report must contain recommendations for additional action(s), when appropriate.

**Question:** If the assessment category is "incomplete" and the patient is referred for additional testing such as ultrasound or MRI to complete the diagnosis, must the facility revise the original report if, as a result of this referral, the assessment is changed to one of the other categories?

**Answer:** No. However, if the other test is covered under MQSA (e.g., mammographic coned or magnification views), the facility performing these views must issue a report reflecting the final assessment.

### **21 CFR 900.12(c)(2)**

*Communication of mammography results to the patient. This section of the regulations as published on October 28, 1997 has been superseded by the Mammography Quality Standards Reauthorization*

Act of 1998, which requires that a summary of the written report shall be sent directly to all patients in terms easily understood by a lay person.

*(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:** What constitutes an acceptable system for notifying patients of examination results?

**Answer:** Facilities must provide a summary of the results of the mammographic examination written in lay terms to all patients within 30 days (patients who do not have a health care provider must also receive the mammographic report within 30 days). Furthermore, when the mammography report assessment is “Suspicious” or, “Highly suggestive of malignancy,” the lay summary results and recommended course of action must be communicated as soon as possible. FDA believes that communication of suspicious or highly suggestive results can ordinarily be accomplished within five working days. One way to achieve this is through direct verbal communication with the patient; however, this does not obviate the need to also send written communication within 30 days. In the case of exams where the assessment is “Incomplete, Need additional imaging evaluation” FDA recommends that facilities communicate this (verbally or in writing) to the patient as soon as possible so as to avoid delays in patient work-up. FDA’s concern is that an effective communication system exists. The details of such a system are left to the facility and should be individualized to address the facility’s specific situation. A system that works well for one facility and its patients may not work well for another. Some examples of sample lay summary letters can be found in the Agency for Health Care Policy and Research’s Publication No. 95-0632 **Quality Determinants of Mammography**, pages 44-50 (may be obtained by writing to AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907). One example of an acceptable system for patient communication would be through the use of the U.S. mail. Confirmation of the receipt of these results would not be required.

**Question:** What are the requirements for notification of examination results to women who have a primary health care provider?

**Answer:** Women who have a primary health care provider must be given or sent the written lay summary within 30 days of the examination. Furthermore, when the assessment is “Suspicious” or, “Highly suggestive of malignancy,” the results must be communicated as soon as possible (ordinarily accomplished within five working days).

**Question:** What are the requirements for notification of examination results to women who do not have a primary health care provider?

**Answer:** Women who do not have a primary health care provider must be given or sent both the written mammography report and the written lay summary within 30 days of the examination.

Furthermore, when the assessment is “Suspicious” or, “Highly suggestive of malignancy,” the results must be communicated as soon as possible (ordinarily accomplished within five working days).

**Question:** Our facility currently gives the patient the examination results verbally. Will this meet the patient communication requirements under the final regulations?

**Answer:** No. While FDA encourages this type of communication, Congress’ intent was for patients to get a permanent record of their results. Therefore, any verbal communication must be supplemented with written communication.

**Question:** Will giving the referred patient a written lay summary of results at the time of the examination satisfy the patient communication requirements under the final regulations?

**Answer:** Yes.

### **21 CFR 900.12(c)(3)**

*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:** What are the requirements for notification of examination results to the referring health care provider?

**Answer:** Communication of all results to the referring health care provider must be done within 30 days by a written report.

In addition, when there are “Suspicious” or “Highly suggestive of malignancy” results, the facility must also make reasonable attempts to communicate the results to the referring health care provider or a responsible designee as soon as possible. “Suspicious” or “Highly suggestive of malignancy” results should be communicated to the health care provider within three working days, using either a written report or documented verbal communication. If this is achieved through direct verbal communication with the health care provider, this does not obviate the need to also send written communication within 30 days. In the case of exams where the assessment is “Incomplete, Need additional imaging evaluation,” FDA recommends that facilities communicate this to the health care provider as soon as possible so as to avoid delays in patient work-up. FDA’s concern is that an effective communication system exists. The details of such a system are left to the facility and should be individualized to address the facility’s specific situation. A system that works well for one facility and its health care providers may not work well for another. One acceptable system for health care

provider communication would be through the use of the U.S. mail. Confirmation of the receipt of these results would not be required.

**21 CFR 900.12(c)(4)(ii)**

*[The facility] 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;*

**21 CFR 900.12(c)(4)(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.*

**Question:** What should a facility do if a patient (or someone acting on her behalf) requests permanent or temporary transfer of mammograms and/or reports? Who should pay for it? What recourse does the patient have if the facility overcharges for the transfer or refuses to cooperate?

**Answer:** The facility must transfer the original mammograms and copies of the patient's reports to the patient's designated recipient upon such written request by the patient (or someone acting on her behalf). Facilities should be aware that the Federal Law pertaining to transfer of original mammograms supercedes any conflicting State or Local requirements. The mammograms and reports may be sent to a medical institution, a health care provider, or to the patient. If the designated recipient is not available, the facility should work with the patient (or someone acting on her behalf) to designate an alternate destination. The facility may charge a fee for this service but it must not derive a financial profit from it. If the facility overcharges for the transfer or refuses to transfer the records, the patient may inform the FDA via the Facility Hotline # 1/800-838-7715 or by writing to the following address: FDA, P.O.Box 6057, Columbia MD 21045-6057.

## Quality Assurance - General

### **21 CFR 900.12(d)(1)(i)**

*Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of paragraphs (d) through (f) of this section. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.*

**Question:** What are the responsibilities of the lead interpreting physician?

**Answer:** In general, the lead interpreting physician must ensure that the quality assurance program, including personnel assignments, all equipment quality control tests, records, and corrective actions, the annual physicist's survey, and medical audit and outcomes analysis, meet the required standards. He or she must ensure that the individuals he or she has assigned to quality assurance tasks are qualified to perform these tasks and that their performance is adequate.

Regarding medical outcome audits, he or she must either review and discuss the audit results with the other interpreting physicians or assign this task to another interpreting physician (the reviewing interpreting physician). For facilities with only one interpreting physician, that person will be the lead interpreting physician.

### **21 CFR 900.12(d)(1)(ii)**

*Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall:*

- (A)** *Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and*
- (B)** *Participate in the facility's medical outcomes audit program.*

**Question:** What are some examples of corrective actions that facilities may include in the procedures to be followed by interpreting physicians when they see images of poor quality? What constitutes participation in medical audits?

**Answer:** Examples of corrective actions and procedures that interpreting physicians must follow regarding poor quality images would be providing feedback to technologists and physicists on image optical density and contrast, patient motion and other artifacts, compression, technique factors, and positioning. Participation in medical audits means either being designated (as the reviewing interpreting physician) with responsibilities for analyzing and discussing medical audit outcome data with other interpreting physicians, or discussing this data with the lead or reviewing interpreting physician.

**21 CFR 900.12(d)(1)(iii)**

*Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the reports described in paragraphs (e)(9) and (e)(10) of this section.*

**Question:** What are the responsibilities of the medical physicist regarding quality assurance?

**Answer:** The medical physicist is responsible for performing the facility's annual survey (which includes all the annual quality control tests specified in 900.12(e)(5), the phantom image quality test, the other (new) mammographic modality tests, as well as evaluation of the quality control tests and results that are normally conducted by the QC technologist), and providing the facility with a report of the annual survey. He or she is also responsible for mammography equipment evaluations (when applicable).

**21 CFR 900.12(d)(1)(iv)**

*Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of paragraph (e) of this section.*

**Questions:** 1) What are the responsibilities of the quality control (QC) technologist regarding the quality assurance program and what are some examples of ways in which "other personnel" can become qualified to perform QC tasks, and 2) what documentation is needed for such actions?

**Answers:**

1) The quality control (QC) technologist is responsible for all quality assurance duties not assigned to the lead interpreting physician or the medical physicist. Normally, he or she is expected to perform these duties, but may also assign other qualified personnel or may train and qualify others to do some or all of the tests. When these duties are assigned to others, the QC technologist retains the responsibility to ensure they are performed in accordance with the regulations.

"Other personnel qualified" means persons with technical training appropriate for the task(s) assigned to them. Examples include a radiological technologist qualified under MQSA, a technologist who is trained to do the QC test(s) by the QC Technologist, or other persons appropriately trained to do the task(s) and supervised by the QC technologist. A receptionist or a secretary whose sole qualification is to copy documents, type, or answer the phone is not included under "other" qualified personnel.

2) Acceptable documentation of appropriate training includes facility records (if done in-house), or certificates or letters from the training organization, or formal training sessions provided to such individuals, identifying the person who gave the training, subject matter, date, and length of training.

## Quality Assurance - Records

### 21 CFR 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. These 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:** What quality assurance (QA) records must be maintained? Where and for how long?

**Answer:** The facility must maintain quality assurance (QA) records that show:

- 1) Personnel Responsibilities: qualified mammography personnel assigned appropriate QA tasks
- 2) Technique Charts/Tables: the mammography techniques and procedures used in conducting mammograms
- 3) QC test Records: including QC test procedures, test performance and monitoring, data analysis and timely corrective actions for each.
- 4) Procedures for safety and protection of patients and personnel.

These records must be maintained until the next annual inspection that would verify compliance or until an individual test has been performed two additional times at the required frequency, whichever is longer. Verifying compliance implies that if QC records for a given test were found to be deficient and the facility was cited during an annual inspection, these records must be kept until the facility corrects the problem to FDA's satisfaction. This also means that records for semi-annual tests may have to be kept longer than the period between two successive annual inspections, and records for annual tests must include the most recent two.

## Quality Control (QC) Tests - Other Than Annual

### 21 CFR 900.12(e)(1)

*Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.*

- (i)** *The base plus fog density shall be within + 0.03 of the established operating level.*
- (ii)** *The mid-density shall be within <plus-minus> 0.15 of the established operating level.*
- (iii)** *The density difference shall be within <plus-minus> 0.15 of the established operating level.*

### 21 CFR 900.12(e)(2)

*Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.*

- (i)** *The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.*
- (ii)** *The optical density of the film at the center of the phantom image shall not change by more than <plus-minus> 0.20 from the established operating level.*
- (iii)** *The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with Sec. 900.3(d) or Sec. 900.4(a)(8).*
- (iv)** *The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than <plus-minus> 0.05 from the established operating level.*

### 21 CFR 900.12(e)(3)

*Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:*

- (i)** *Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.*
- (ii)** *Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.*

### 21 CFR 900.12(e)(4)

*Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:*

- (i)** *Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.*
- (ii)** *Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.*

**(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).

**General:** The tests listed in Table 1 below are normally performed by (or fall under the responsibility of) the quality control (QC) technologist and must be performed according to the frequencies shown in the Table.

FDA recommends that the facility adopt and follow documented procedures for all QC tests. Examples of such procedures are given in the Radiologic Technologist's Section of the most recent version of the American College of Radiology (ACR) *Mammography Quality Control Manual* . However, a facility that uses such a manual must ensure that the procedures it adopts are consistent with the final regulations. For example, the phantom QC test, which is listed as a monthly test in the 1994 ACR manual, is a weekly test under the final regulations.

**Question:** What records must the facility keep for the daily, weekly, quarterly, and semi-annual quality control tests and what is considered acceptable documentation for each?

**Answer:** The required records and the acceptable documentation for each are listed in Table 1.

**Question:** What is the facility required to do if a test result falls outside the limits defined in the regulations?

**Answer:** The test results must fall within the listed acceptable limits in order to continue normal operations. Results outside these limits indicate the need for corrective action. This action depends on the test and does not necessarily mean that facilities have to cease examining patients. Specifically, facilities must not process mammograms when the processor parameters fall outside operating limits. Also, they must not use x-ray units when either the parameters that monitor phantom image QC or the compression force on the x-ray unit fall outside action limits. Likewise, facilities must not use a darkroom when the fog level exceeds the limit in that room, nor use cassettes that fail the screen-film contact test. In the case of darkroom fog, if the source of the fog is determined to be due to a safelight, then films can be processed with that safelight off until such time as the safelight problem has been corrected and the darkroom passes the fog test. With all other test failures, the equipment may continue to be used before corrective actions are performed but such actions must be carried out within 30 days of the test. This is summarized in Table 1.

**Question:** How many films (and what type) must be included in the repeat analysis test each quarter?

**Answer:** Repeat or reject films, must be included in the analysis. Repeat films are those that had to be redone (whether discarded or not) resulting in additional radiation exposure to the patient. Typical causes of repeat films include poor positioning, compression, contrast, artifacts, etc. and usually would not include those additional films taken to work-up true or suspected lesions, even if the patient was brought back to have the additional films taken. Reject films are those that are in the

mammography reject bin. They include those repeat films that have been discarded as well as any other mammography film that has been discarded. The regulations do not specify a minimum or maximum number of exams to be included in the analysis. To minimize the burden on high volume facilities, under the interim regulations FDA accepted the lesser of 250 patient examinations (about 1000 films) or whatever accumulated in the 90-day analysis period. Under the final regulations, FDA recommends that facilities continue to do this minimum during an uninterrupted period in the quarter, but also believes that it is beneficial to the facility to increase the number of exams included in the analysis as much as possible. Keep in mind that a larger sample generally will provide more reliable statistics, decrease the relative change in the percentage of repeats or rejects, and thus, may reduce the number of times corrective actions are needed to keep the change below 2%. If the repeat or reject rate, calculated as a percentage of the total films included in the analysis, changes by more than 2 percentage points from the rate determined the previous quarter, the cause of the change must be identified. For example, if the repeat or reject rate the previous quarter was 4 percent and this quarter it is 7 percent, the cause of the change must be identified. If the repeat or reject rate this quarter is 6 percent, no further action is needed.

**Question:** Are facilities required to do daily QC on the back-up processor (general purpose or dedicated for mammography) as they do on their primary mammography processor?

**Answer:** No, they are not. However, back-up processors used for mammography will be held to the same quality standards as the primary processor(s) used for mammography. It is the responsibility of the facility to assure that the processor is in control (monitored parameters are within the action limits) before processing any clinical images. One way to achieve this is to establish a baseline for any processor that might be used as a back-up for processing mammograms. Subsequently, on the day the back-up processor is needed, the daily processor QC tests should be performed prior to processing clinical images and if the test results fall outside the action limits, clinical images should not be processed until all problems have been fixed and the new test results show that the processor is in control.

**Question:** What about QC on mammography processors that are also used to develop films for copying mammograms and for laser films that are used in digital mammography?

**Answer:** Films that are used to copy mammograms (duplicating or copy films but not laser films) generally alter the performance of the processor by degrading the chemicals in the processor. This does not significantly affect processor performance if a small number of copies are made at a time. However, if a large number of copies is produced on a given day, FDA recommends that the daily processor QC tests be performed after the copies have been processed and prior to processing the clinical images.

**Question:** The regulations specify a minimum optical density of 1.2 at the center of the phantom image when exposed under typical clinical conditions. Is there an upper limit on this density and why does it have to be measured in the center of the phantom?

**Answer:** No, there is no specified upper limit. A trend has developed in recent years towards increasing the optical density of mammographic images, albeit at a somewhat higher dose, to take advantage of the resulting higher contrast. The amount of density increase will always be limited by the fact that the film contrast will peak (and so will the visibility of image details) before the density gets too high. Measurement of the optical density is specified to be in the center of the phantom because this location is most representative of the mean density and is easy to find consistently.

**Question:** What is an acceptable documentation for the phantom image QC? Is a table of values sufficient or should the facility plot the results?

**Answer:** While a table of 52 values (over a year) contains all the necessary information, it does not provide an easy way to analyze the results and detect trends for the background optical density and contrast. For this reason, FDA recommends that the facility plot the phantom scores, the measured optical density, and contrast values.

**Question:** What optical density (or range) should the facility use for the screen-film contact test and what is the criteria for determining pass or fail for a cassette?

**Answer:** The final regulations do not specify an optical density, range, or a pass-fail criteria because there has not been a consensus of expert opinion on these. If a facility follows the same criteria as in the interim regulations, namely a range of 0.70 to 0.80 for the density and fails a cassette for any poor contact area exceeding one centimeter, it would be acceptable. However, this does not preclude the facility from using other appropriate criteria.

**Table 1 - Quality Control Tests Other Than Annual**

<b>Test &amp; Frequency</b>	<b>Requirements for Acceptable Operation</b>	<b>Guidance for Acceptable Documentation Retention*</b>	<b>Timing of Required Corrective Action **</b>
<i>Processor QC-Daily</i>	<i>Established operating level for B+F, + up to 0.03 O.D.</i>	QC records (&charts) for the last 12 months or since the last inspection, whichever is longer. QC test films for the last 30 days	<i>Before any further clinical films are processed</i>
"	<i>Established operating level for MD, ± 0.15 O.D.</i>	"	"
"	<i>Established operating level for DD, ± 0.15 O.D.</i>	"	"
<i>Phantom QC-Weekly (7d)</i>	<i>Established operating level for O.D. at center of image ≥1.2 ± 0.20, but the minimum O.D must be ≥1.2 at any time.</i>	QC charts & records for the last 12 months or since the last inspection, whichever is longer. Phantom images for the last 12 weeks.	<i>Before any further examinations are performed using the x-ray machine.</i>
"	<i>Established oper. level for contrast, ± 0.05 O.D.</i>	"	"
"	<i>Minimum score of 4 fibers, 3 speck groups, 3 masses.</i>	"	"
<i>Fixer retention in film-Quarterly (90 d)</i>	<i>Below 5 micrograms per square cm of residual fixer.</i>	QC Records since the last inspection or for the past three tests, whichever is longer.	<i>Within 30 days of the date of the test</i>
<i>Repeat Analysis-Quarterly (90 d)</i>	<i>Operating level for repeat or reject rate is &lt; 2% change [up or down] from previous rate.</i>	"	"
<i>Darkroom Fog-Semi-annually (180 d)</i>	<i>OD ≤ 0.05</i>	QC Records since last inspection or for the past three tests, whichever is longer. Fog QC films from the previous three tests.	<i>Before any further clinical films are processed</i>
<i>Screen-Film Contact-Semi-annually (180 d)</i>	<i>All mammography cassettes used must be tested with a 40-mesh copper screen.</i>	QC records since last inspection or for the past three tests, whichever is longer. S-F contact QC films from the previous three tests.	<i>Before any further examinations are performed using the cassettes.</i>
<i>Compression Device Semi-annually (180 d)</i>	<i>Compression force ≥111 newtons (25 pounds).</i>	QC records since last inspection or for the past three tests, whichever is longer.	<i>Before examinations are performed using the compression device.</i>

\* Guidance regarding the length of time for which the facility is required to keep QC records was given earlier under 900.12(d)(2).

\*\* Refer to 900.12(e)(8)(ii)(A) or (B) as applicable.

## QC Tests - Annual

### 21 CFR 900.12(e)(5)

*Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:*

- (i)** *Automatic exposure control performance.*
  - (A)** *The AEC shall be capable of maintaining film optical density within <plus-minus> 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within <plus-minus> 0.30 of the average under phototimed conditions can be produced.*
  - (B)** *After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within <plus-minus> 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.*
  - (C)** *The optical density of the film in the center of the phantom image shall not be less than 1.20.*
- (ii)** *Kilovoltage peak (kVp) accuracy and reproducibility.*
  - (A)** *The kVp shall be accurate within <plus-minus> 5 percent of the indicated or selected kVp at:*
    - (1)** *The lowest clinical kVp that can be measured by a kVp test device;*
    - (2)** *The most commonly used clinical kVp;*
    - (3)** *The highest available clinical kVp, and*
  - (B)** *At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.*
- (iii)** *Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.*
  - (A)** *System Resolution.*
    - (1)** *Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 Cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.*
    - (2)** *The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.*
    - (3)** *When more than one target material is provided, the measurement in paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal spot for each target material.*
    - (4)** *When more than one SID is provided, the test shall be performed at SID most commonly used clinically.*

- (5) *Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.*
- (B) *Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1 in the Federal Register [Vol. 62, NO. 208, page 55990].*
- (iv) *Beam quality and half-value layer (HVL). The HVL shall meet the specifications of Sec. 1020.30(m)(1) of this chapter for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2 in the Federal Register [Vol. 62, NO. 208, page 55990]. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.*
- (v) *Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mA's shall not exceed 0.05.*
- (vi) *Dosimetry. The average glandular dose delivered during a single cranio-caudal 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.*
- (vii) *X-ray field/light field/image receptor/compression paddle alignment.*
  - (A) *All systems shall have beam-limiting devices that allow the useful X-ray beam to extend to or beyond the edges of the image receptor but by no more than 2 percent of the SID at the chest wall side.*
  - (B) *If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.*
  - (C) *The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.*
- (viii) *Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.*
- (ix) *System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.*
- (x) *Radiation output.*
  - (A) *The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milli Roentgen (mR) per second) when operating at 28 kVp in the standard*

*mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.*

- (B)** *The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.*
- (xi)** *Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:*
  - (A)** *An override capability to allow maintenance of compression;*
  - (B)** *A continuous display of the override status; and*
  - (C)** *A manual emergency compression release that can be activated in the event of power or automatic release failure.*

**General:** These tests and their regulatory requirements are summarized in Table 2 below. The test results must fall within the listed action levels. Results outside these action levels indicate the need for corrective action within the time periods specified in the table.

**Question:** Who in the facility must conduct the annual QC tests listed above?

**Answer:** These tests must be conducted by a qualified medical physicist (or someone in training under his or her direct supervision) as part of the annual survey. The test results and recommendations for corrective actions (if any) must be stated in the medical physicist's survey report.

**Question:** If the AEC fails, can a facility use manual techniques until the unit is fixed? Would it require the physicist to come and recheck it or if the repairman did so would that be satisfactory?

**Answer:** The answer to the first question is yes. According to 900.12(e)(5)(i)(A), if the physicist (or the facility) learns that the AEC cannot perform as required, the facility should first attempt to correct the problem by adjusting the density settings on the AEC. If that is unsuccessful, the facility may use manual mode technique charts. Manual mode would also be acceptable under the complete failure situation raised by the question. Hence, the facility can use manual techniques for 30 days while the non-functioning AEC is being repaired and can continue to use the unit on patients during this period. Regarding the second question, because the AEC is considered to be a major component of the mammography unit, the physicist must recheck the unit after the problem has been corrected in accordance with 900.12(e)(10).

**Question:** Is FDA in the process of amending regulation CFR 900.12(e)(5)(vii)(A) to allow the beam to extend within or beyond the 3 non-chest wall edges of the image receptor?

**Answer:** Yes. FDA has published a proposed amendment to make such a change. In the meantime, FDA has approved requests for alternative standards from several equipment manufacturers to make such a change.

**Table 2 - Annual Quality Control Tests**

<i>Test</i>	<i>Final Regulation Citation</i>	<i>Regulatory Action Levels</i>	<i>Required documentation</i>	<i>Timing of required corrective action*</i>
AEC	900.12(e)(5)(i)	<i>O.D. exceeds the mean by more than <math>\pm 0.30</math> (over 2-6 cm thickness range), or the phantom image density at center is less than 1.20</i>	<i>The two most recent survey reports.</i>	<i>Within 30 days of the date of the test.</i>
KVp	900.12(e)(5)(ii)	<i>Exceeds <math>\pm 5\%</math> of indicated or selected kVp C.O.V. exceeds 0.02</i>	"	"
Focal spot	900.12(e)(5)(iii)	<i>See table in regulations</i>	"	"
HVL	900.12(e)(5)(iv)	<i>See table in regulations</i>	"	"
Air Kerma and AEC reproducibility	900.12(e)(5)(v)	<i>Reproducibility C.O.V. exceeds 0.05</i>	"	"
Dose	900.12(e)(5)(vi)	<i>Exceeds 3.0 mGy (0.3 rad) per exposure</i>	"	<i>Before any further examinations are performed using the x-ray machine</i>
X-ray field / light field / compression device alignment	900.12(e)(5)(vii)	<i>Exceeds 2% SID at chest wall Paddle visible on image</i>	"	<i>Within 30 days of the date of the test</i>
Screen speed uniformity	900.12(e)(5)(viii)	<i>O.D. variation exceeds 0.30 from the maximum to the minimum</i>	"	"
System artifacts	900.12(e)(5)(ix)	<i>Determined by physicist</i>	"	"
Radiation output	900.12(e)(5)(x)	<i>Less than 4.5 mGy/sec (513 mR/sec)</i>	"	"
Automatic decompression control	900.12(e)(5)(xi)	<i>Failure of override or manual release</i>	"	"
Any applicable annual new modality tests	900.12(e)(6)	<i>To Be Determined</i>	"	<i>Before any further examinations are performed</i>

\* Refer to 900.12(e)(8)(ii)(A) or (B) as applicable.

**21 CFR 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:** What are the required quality control tests for new mammographic modalities?

**Answer:** Mammography systems with image receptor modalities other than screen-film must undergo periodic quality control tests following procedures that are recommended by the manufacturer of the mammographic modality. As is the case for screen-film QC, the facility must keep records of these tests and all applicable corrective actions for the longer of: last 12 months or since the last annual inspection which verifies compliance, or until the test has been done two additional times at the required frequency. Regardless of the mammographic modality, the mean glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom must not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. If the test results exceed the action level, corrective action must be taken within time frames as specified in Table 2 (where applicable) or as recommended by the manufacturer (for the new mammographic modality tests).

**21 CFR 900.12(e)(7)**

*Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of this section. In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.*

**Question:** How does a facility demonstrate satisfactory performance for mobile units after they are moved to a new location?

**Answer:** For those facilities with mobile units, each mammography unit must be tested after moving to a new examination location and before examining any patients to verify the adequacy of the image quality produced by each unit.

As an example of an acceptable test, a phantom image can be taken in the AEC mode (or the mode used clinically) after the move but prior to patient examination. This image is then either processed and evaluated at the mobile unit site (if possible), or processed off-site and evaluated to verify performance prior to examining patients. A passing score for this phantom image verifies that the unit is performing adequately after moving and before patient examination.

Another example is to (1) for a given kVp, record the mAs resulting from a phantom exposure (in the AEC mode or the mode used clinically); (2) compare that mAs to a standard mAs value previously established as ensuring output consistency; and (3) if the two readings are within + or - 5%, proceed with clinical examinations; otherwise take corrective actions to bring the two values within this limit

before proceeding with clinical examinations. A crucial follow-up to this test by the facility is to process (using a processor in control) and score the phantom image taken in step (1) at the earliest time available and before batch processing any of the clinical images. If this phantom fails because of any processing problems, the problems should be corrected prior to processing any of the clinical images.

Other tests designed by qualified personnel (the medical physicist should be consulted) could be acceptable but may have to be evaluated by the inspector on a case-by-case basis.

### **21 CFR 900.12(e)(8)**

*Use of test results.*

- (i) *After completion of the tests specified in paragraphs (e)(1) through (e)(7) of this section, the facility shall compare the test results to the corresponding specified action limits; or, for nonscreen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.*
- (ii) *If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:*
  - (A) *Before any further examinations are performed or any films are processed using a component of the mammography system that failed any of the tests described in paragraphs (e)(1), (e)(2), (e)(4)(i), (e)(4)(ii), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section;*
  - (B) *Within 30 days of the test date for all other tests described in paragraph (e) of this section.*

**Question:** How can the facility correct within 30 days a problem that may be found as a result of an annual test that is done by a physicist as part of the annual survey if the report is not provided to the facility before the 30 days are up (since the physicist has up to 30 days to provide the report)?

**Answer:** The facility is encouraged to work with the physicist to ensure that any problems found are fixed within the regulatory limit. One way to do this would be for the physicist to notify (preferably via a written list) the facility, immediately after the completion of the survey, of the tests that failed and the problems found, to enable the facility to correct the problem(s) within the 30-day limit.

# Medical Physicist's Annual Survey

## 21 CFR 900.12(e)(9)

### *Surveys.*

- (i) *At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test described in paragraph (e)(2) of this section.*
- (ii) *The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.*
- (iii) *The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.*
- (iv) *The survey report shall be sent to the facility within 30 days of the date of the survey.*
- (v) *The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.*

**Question:** What are the requirements of the annual survey?

**Answer:** Once a year, each facility must be surveyed by a medical physicist or by someone in training under his or her direct supervision. The survey will include:

- (1) performance of the annual tests described in the regulations (Table 2 above and the QC tests for other modalities, if applicable) and the weekly phantom image quality test;
- (2) review of the results of the QC tests conducted by the facility (Table 1 above), as well as of written documentation of any corrective actions taken and their results; and
- (3) a report, which must be provided to the facility within 30 days of the date of the survey, that includes a summary of the areas tested and reviewed and recommendations for necessary improvements.

The annual tests must be performed using technique factors and test conditions as stated in the regulations whenever those factors are specified. Otherwise, technique factors that are clinically used in the facility for which the annual survey is conducted should be used whenever possible. For test procedures that determine dose to the average breast, the same kVp value (within +/- 1 kVp of that used clinically for the average breast) must be used for measuring both the entrance skin exposure and the HVL.

The report must be dated and signed by (or contain the identification of) the medical physicist performing or supervising the survey and any other individual who performed or assisted in the survey. If the survey is done over a period of time, the dates of completion of the individual parts must be indicated in the report.

**21 CFR 900.12(e)(10)**

*Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is disassembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.*

**Question:** When are “additional mammography equipment evaluations” required and who must conduct the evaluations?

**Answer:** Whenever a new unit or processor is installed, disassembled and reassembled at the same or a new location, or major components are changed or repaired, an evaluation of the mammography unit or image processor is required. The medical physicist should decide which tests need to be performed following a particular repair, and should explain the rationale behind his or her decision. Examples of major changes or repairs that would call for equipment evaluations are: replacement of an x-ray tube, collimator, AEC unit, AEC sensor, or x-ray filter. For the processor, a total overhaul would be an example of a major repair. Routine preventive maintenance, pump replacement, replacement of the developer or fixer racks, replacement of the control board or changes in chemistry brand are not examples of major changes or repairs and would not require evaluation by a medical physicist.

This additional evaluation is needed to verify that all functions that may have been affected by the change or repair have been successfully restored even if a full survey had recently been completed. For a new unit, an equipment evaluation is needed before the unit is used on patients unless the unit has already undergone a full survey. In this situation, the facility must follow the accreditation body procedures. Keep in mind that under MQSA, the facility has the ultimate responsibility for ensuring image quality and patient safety. If changes or repairs to the system are anticipated, contact the facility’s accreditation body to inquire whether the change affects a major component and requires an evaluation.

The equipment evaluation must be performed by a qualified medical physicist or by an individual under the direct supervision of the medical physicist.

These evaluations will be used to determine whether the new or changed equipment meets the requirements of applicable standards in 900.12(b) and (e). All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. A facility should maintain documentation that shows the date(s) on which a mammography equipment evaluation was performed, who performed the evaluation, and that any identified problems were corrected before the equipment was used on patients. A facility must maintain this documentation until the next inspection that verifies compliance.

**21 CFR 900.12(e)(11)**

- (i) *The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness.*
- (ii) *The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.*

**Question:** What facility cleanliness measures are required under MQSA and what constitutes acceptable documentation of such measures?

**Answer:** MQSA does not specify cleanliness measures. However, the facility must establish and follow adequate protocols (such as those found in the latest ACR Mammography QC Manual) for darkroom, screen, and view box cleanliness. Acceptable documentation would be written procedures for performing the corresponding cleaning activities, with records showing that each was conducted at the designated frequency, and was followed by the appropriate corrective actions when needed.

**21 CFR 900.12(e)(13)**

*Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:*

- (i) *Comply with all applicable Federal, State, and local regulations pertaining to infection control; and*
- (ii) *Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or*
- (iii) *If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.*

**Question:** What infection control procedures are required under MQSA ?

**Answer:** Facilities must establish and follow a protocol for cleaning and disinfecting mammography equipment that has come in contact with blood or other body fluids or potentially infectious materials. MQSA inspectors will be looking for such a protocol or procedure that the facility is following. A sign-off sheet recording cleaning after each patient is not required. For additional guidance on this, refer to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030), any additional State and local regulations on this subject that may be applicable to the facility, and manufacturer's procedures specific to their equipment.

# Mammography Medical Outcomes Audit

## 21 CFR 900.12 (f)

*Quality assurance - mammography medical outcomes audit.*

*Each facility shall establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.*

**Question:** What are the basic elements of a mammography medical outcomes audit system?

**Answer:** The basic elements of a mammography medical audit system are: (1) a definition of positive mammograms requiring follow-up, (2) a method to follow-up positive mammograms, (3) a system to attempt to collect pathology results for all biopsies performed, (4) methods to correlate pathology results with the final assessment category indicated by the interpreting physicians, (5) a method to include any cases of breast cancer among patients imaged at the facility that subsequently became known to the facility, and (6) review of medical outcomes audit data for the aggregate of interpreting physicians as well as each individual interpreting physician at least once every 12 months.

**Question:** Is a facility required to purchase and use a computerized system to conduct the follow-up of positive mammograms and correlation with pathology reports?

**Answer:** No. A computerized tracking and follow-up system for follow-up of positive mammograms is not required under the MQSA final regulations. Paper or patient log systems can be used to conduct the required follow-up.

**Question:** Is a particular staff person required to conduct the follow-up for positive mammograms?

**Answer:** No. The regulations do not designate a specific staff person to conduct the follow-up for positive mammograms. The facility may specify that the reviewing interpreting physician conduct the follow-up, but this is not required under the MQSA final regulations. The facility may designate a single individual to take the lead on patient follow-up, and also identify a back-up person to conduct the follow-up during the designated lead person's absence. However, the lead interpreting physician is responsible for the facility's quality assurance program, which includes the mammography medical outcomes audit.

**Question:** Do the final regulations require specific calculations for the medical outcomes audit?

**Answer:** No. The final regulations do not require any specific calculations. However, some statistics that may be useful to the facility are the percent of exams interpreted as positive that have a

positive pathology report, and the percent of exams interpreted as positive that do not have a positive pathology report.

**Question:** Where can a facility obtain more information about medical outcomes audit programs?

**Answer:** A facility may obtain additional information about medical outcomes audit programs from a variety of sources, including the medical literature, the latest ACR Illustrated Breast Image Reporting and Data System Manual, the Agency for Health Care Policy and Research's Publication No. 95-0632 Quality Determinants of Mammography (may be obtained by writing to AHCPR Publications Clearinghouse, P.O. Box 8547, Silver Spring, MD 20907), and selected issues of the FDA's Mammography Matters (beginning with Volume 4, Issue 2). Be aware that non-FDA publications may suggest analyses and use definitions that are different from those required by the regulations.

### **21 CFR 900.12 (f) (1)**

*General requirements.*

*Each facility shall establish a system to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently became known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.*

**Question:** Which mammograms must be included in the medical outcomes audit system?

**Answer:** A facility must conduct follow-up for all patients with mammograms interpreted as "Suspicious" or "Highly suggestive of malignancy" and those recommended to have a biopsy. A facility is not required to follow-up other cases such as those recommended for short-term follow-up or ultrasound, or cases that are in the assessment category of "Incomplete, Need additional imaging evaluation", however, the facility may choose to follow these patients.

**Question:** How often should follow-up on surgical and/or pathology results be conducted for women with positive mammograms?

**Answer:** The regulations do not require that follow-up on surgical and/or pathology results for women with positive mammograms be conducted any more frequently than once per year. However, facilities should conduct follow-up on a routine basis in order to ensure that cases are not lost to follow-up.

**Question:** Will the FDA maintain the confidentiality of any patient's surgical and/or pathology results which may be seen during an inspection?

**Answer:** Yes. Inspectors will be checking to ensure that outcome results have been obtained by the facility and/or that there have been reasonable efforts made to obtain such results. The FDA-certified inspector will verify that a system exists to collect positive mammographic outcomes information. During typical inspections, inspectors may review patient's surgical/pathology results or individual or aggregate physician medical outcomes audit information but will not routinely record, copy or retain this information.

**21 CFR 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.*

**Question:** Should a facility perform an audit analysis more frequently than once per year?

**Answer:** Under the interim regulations, facilities were required to have a system to track their positive mammograms but the frequency of audit analysis was not specified. Under the final regulations, a facility must continue to track their positive mammograms and perform a medical outcomes audit analysis at least once per year. However, facilities may review their audit data at more frequent intervals if they believe it would be beneficial for their practice.

**21 CFR 900.12 (f) (3)**

*Reviewing interpreting physician.*

*Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results and for notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the followup.*

**Question:** Does the FDA require that the interpreting physician who reviews the medical outcomes audit data also be responsible for overall facility quality assurance?

**Answer:** No. The final regulations permit a facility to designate a person other than the lead interpreting physician as responsible for reviewing the medical outcomes audit data.

**Question:** Why is the data analyzed for the aggregate and then for each interpreting physician?

**Answer:** Aggregate medical outcomes audit data provide a picture of how the facility is detecting breast cancer among its patients. Individual analyses are also important to identify interpreting physicians who have results that are very different from the aggregate.

**Question:** How long must a facility maintain the medical outcomes audit data on positive mammograms, including the associated surgical and/or pathology reports?

**Answer:** For the purpose of MQSA, the medical outcomes audit (including the associated surgical and/or pathology reports) is considered part of a facility's internal quality assurance program. Therefore, the data should be maintained according to the quality assurance requirements. The applicable section of the regulations state that the records must be kept until the test has been performed two additional times at the required frequency. Since the audit analyses are required to be conducted at least once every 12 months, the audit data should be kept for an additional 24 consecutive months following the analysis. However, State laws may define the data as part of a patient's or facility's medical records, and may have more stringent requirements for the retention of this data. A facility may want to check with the State regarding its requirements.

# Mammographic Procedure and Techniques for Mammography of Patients with Breast Implants

## 21 CFR 900.12 (g)

*Mammographic procedure and techniques for mammography of patients with breast implants.*

## 21 CFR 900.12 (g)(1)

*Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.*

**Question:** Is a facility required to accept patients who have breast implants for mammographic examinations? If not, must the facility refer patients with implants to another facility that provides implant imaging services?

**Answer:** No. Facilities are not required to perform mammographic examinations of patients with breast implants. However, facilities must have a procedure to inquire whether the patient has breast implants prior to the actual mammographic exam. If the facility does not provide implant imaging services, it may refer the patient to other facilities who provide such services. However, the final regulations do not require that this referral be done.

**Question:** Can a facility inquire whether the patient has a breast implant at the time the appointment is being made, or immediately prior to the actual mammographic examination?

**Answer:** Either method is acceptable. The facility may inquire whether the patient has a breast implant at any time prior to the actual mammographic examination. Facilities without implant imaging expertise may want to identify breast implant patients at the time of scheduling so patients may be referred to facilities with such expertise.

**Question:** Do the regulations specify who at the facility is responsible for inquiring whether the patient has breast implants?

**Answer:** No. The facility designates the person(s) who will be responsible for this function.

**Question:** What type of documentation will the inspector accept as meeting the regulations regarding breast implant inquiries?

**Answer:** A written Standard Operating Procedure for inquiring whether the patient has breast implants will be sufficient to meet the requirements of 900.12(g)(1) during an inspection.

## 21 CFR 900.12 (g) (2)

*Except where contraindicated, or unless modified by a physician's directions, patients with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue.*

**Question:** Is a facility required to use any specific implant displacement technique when imaging patients with breast implants?

**Answer:** No. Because breast implant imaging techniques are evolving, FDA believes that it would be inappropriate to limit, by regulation, this imaging to only one technique.

# Consumer Complaint Mechanism

## 21 CFR 900.12 (h)

*Consumer complaint mechanism.*

*Each facility shall:*

- (1) Establish a written and documented system for collecting and resolving consumer complaints;*
- (2) Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received;*
- (3) Provide the consumer with adequate directions for filing serious complaints with the facility's accreditation body if the facility is unable to resolve a serious complaint to the consumer's satisfaction;*
- (4) Report unresolved serious complaints to the accreditation body in a manner and time frame specified by the accreditation body.*

**Question:** How is a “serious complaint” defined?

**Answer:** A serious complaint is defined as a report of a serious adverse event, which means an event that significantly compromises clinical outcomes or one for which a facility fails to take appropriate corrective action in a timely manner. Examples of serious adverse events include: poor image quality, missed cancers, the use of personnel that do not meet the applicable requirements of 900.12 (a), and failure to send to the appropriate person(s) mammography reports or lay summaries within 30 days.

**Question:** If a facility is unable to resolve a consumer’s “serious complaint,” how is the complaint then handled?

**Answer:** If a facility is unable to resolve a serious complaint to the consumer’s satisfaction, the consumer may file the complaint with the facility’s accreditation body. The consumer should be able to obtain adequate directions from the facility for filing serious complaints with the accreditation body. Section 900.4(g), under accreditation body standards, established requirements for actions that accreditation bodies must take to resolve consumer complaints that have been referred to them. The final regulations do not prescribe any one particular method for accreditation bodies to use because FDA believes that flexibility will permit each accreditation body to establish a system that works best for the facilities it accredits and the patients they serve. The accreditation body and/or a consumer may forward a serious complaint to the FDA. FDA notes that nothing in the MQSA or the regulations precludes FDA or a State from investigating complaints.

**Question:** May consumer complaints be handled by a third party acting on behalf of the facility?

**Answer:** Yes. A third party may handle complaints for the facility if it is part of the facility’s written Standard Operating Procedures (SOP) for handling complaints. However, under MQSA, the facility

bears the ultimate responsibility for meeting the regulations related to the consumer complaint mechanism.

**Question:** Does the FDA require a specific format be used for the consumer complaint mechanism?

**Answer:** No. The facility may select or create its own format.

**Question:** Does the FDA require a specific system be used for the consumer complaint mechanism?

**Answer:** No. In addition, the system may be manual or computerized.

**Question:** What type of documentation will the inspector accept as meeting the regulations related to the consumer complaint mechanism?

**Answer:** The presence of a written Standard Operating Procedure (SOP) for collecting and resolving consumer complaints ordinarily will be an acceptable demonstration of compliance during an inspection.

**Question:** Is a facility required to maintain records of serious consumer complaints as outlined in the quality assurance record keeping requirements?

**Answer:** No. Quality assurance record keeping requirements do not apply to the maintenance of serious consumer complaint records (see next question).

**Question:** How long must a facility maintain records of serious consumer complaints?

**Answer:** The final regulations state that a facility must maintain a record of each serious complaint received by the facility for at least three years from the date the complaint was received.

## Additional mammography review and patient notification

### 21 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 any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a timeframe and in a manner specified by FDA.*

**Question:** Is an additional mammography review (AMR) used for the same purpose as the reviews that are performed for accreditation, reaccreditation, or random clinical image review?

**Answer:** No. AMR is performed in cases where FDA has reason to believe that mammography quality has been compromised and may present a serious risk to human health. An example of such a circumstance would be the detection of a Level 1 phantom image failure during an inspection.

**Question:** Who is responsible for performing an AMR?

**Answer:** Either an FDA-approved accreditation body or an entity approved by FDA may be responsible for performing an AMR.

**Question:** Where is an AMR performed?

**Answer:** Depending on the individual circumstances, this review may be conducted as an on-site evaluation at the facility or may be performed through the mail-in of films and/or other materials to the approved reviewing entity.

**Question:** Will the facility be responsible for patient notification that may result following the AMR?

**Answer:** Yes. If patient notification is among the necessary corrective actions, the facility will be required to notify patients of the identified problems, consult with FDA in developing the patient notification, and ensure that the appropriate audience is reached. The facility has the right to have a determination about patient notification reviewed within the agency.

**Question:** Where can a facility obtain more information about additional mammography review and patient notification?

**Answer:** FDA is developing further guidance regarding additional mammography review and patient notification. This document will be posted on the FDA CDRH website in the near future, and will be available upon request from the FDA. FDA will publish a Notice of Availability in the Federal Register and in Mammography Matters when the guidance is available.

## Changes in the Levels of Non-compliance (Findings)

Since the early days of MQSA inspections under the interim rule, FDA has adopted and used a three-tier system of inspection findings and has assigned three corresponding non-compliance levels as defined below:

**Level 1 (L1).** Level 1 is the most serious. It indicates a failure to meet a key MQSA requirement that may compromise the quality of mammography services performed at the facility. FDA reviews each L1 finding, and if confirmed, the facility receives a Warning Letter (WL) requiring a response from the facility within 15 working days regarding the necessary corrective action(s).

**Level 2 (L2).** In the absence of L1 findings, a Level 2 finding indicates that the facility meets all key MQSA requirements but fails to meet a significant mammography quality item. An L2 finding usually requires a response from the facility within 30 days regarding the necessary corrective action(s).

**Level 3 (L3).** In the absence of L1 and L2 findings, Level 3 findings indicate that the facility meets all major MQSA requirements with only minor problems. While the facility is expected to correct each non-compliance found in an MQSA inspection as soon as possible regardless of its level, it is not required to send a written response to FDA concerning a Level 3 non-compliance. Corrective actions regarding these are usually checked during the next annual inspection.

Based on inspection experience to date and feedback from the States and the mammography community, FDA has re-evaluated the finding level assignments to be implemented under the final rule and is intending: (1) to implement a new set of finding levels corresponding to new inspection questions, and (2) to restructure some of the existing finding levels in order to reflect a more realistic approach.

In accordance with FDA's good guidance practices, the Agency is making available for public comment, the following list of the new and changed finding levels FDA intends to implement, along with their corresponding inspection questions (as they appear on the inspection program used by MQSA inspectors). In general, whenever an inspection question is answered with a "no," a non-compliance or finding at the proposed level would be generated by the inspection software program. All Level 1 findings and all repeat findings at Level 1 and Level 2 will be reviewed to determine whether a Warning Letter or other request for corrective action is necessary.

The remaining inspection questions and corresponding levels of findings, which are not listed below, are not expected to change under FDA's implementation of the final regulations. Those questions were listed in the latest edition of "What a Mammography Facility Should Do to Prepare for the MQSA Inspection" (June 1995 with a July 1996 addendum), which is currently being revised to reflect the changes that will occur under the final regulations.

## A. New Questions and Finding Levels

<b>Inspection Subject &amp; Question</b>	<b>Finding Level</b>
<b>General</b>	
If a facility is operating with an expired certificate	L1
<b>X-Ray System</b>	
X-Ray unit prohibited for mammography?	L1
Does x-ray system include the following:	
- Image Receptors, moving grids & compression paddles for 2 sizes?	L2
- post-exposure display-AEC mode (focal spot & target material)?	L2
Unit Evaluation (by m. physicist) Done?	L2
Performance verification (for mobile units) after each move?	L2
<b>Quality Assurance (QA)</b>	
- S.O.P. for infection control?	L2
- S.O.P. for handling consumer complaints?	L2
<b>For Digital Mammography</b>	
Manufacturer recommended QC procedures followed?	L2
Monitor QC done per manufacturer's recommendation?	L2
Is the manufacturer recommended phantom used (with laser films)?	L2
<b>Medical Physicist's Survey</b>	
If the period between two successive surveys exceeds 14 months	L2
If the report does not identify the person who conducted the survey	L2
<b>Interpreting Physician's Qualifications</b>	
3 Months Training?	L1
60 CME hours?	L2
New modality training (if applicable)?	L2
<b>Technologist's Qualifications</b>	
40 supervised hours of training adequate?	L2
- specific mammography subject training?	L2
- 25 supervised exams?	L2
New modality training (if applicable)?	L2
Continuing Experience Adequate?	L2
<b>Medical Physicist's Qualifications</b>	
Masters in a physical science w/20 semester hours in physics?	L1
20 contact hours survey training?	L2
Survey experience (1 facility & 10 surveys)?	L2
<u>Under the Alternative Requirements:</u>	

Bachelors in a physical science w/10 semester hours in physics?	L1
40 contact hours survey training?	L2
Surveys experience? (1 facility & 20 surveys)	L2
New modality training (if applicable)?	L2
Continuing Experience Adequate?	L2
<b>Medical Audit and Outcome Analysis</b>	
Is outcome review done annually?	L2
Is there a designated reviewing I.P.?	L2

## B. Changes in Current Finding Levels

The following pertains to changes in finding level boundaries (for the same type of finding).

### 1. Dose to the average breast as represented by a 4.5 cm mammography phantom.

If the measured dose is greater than 350 mrad: (Values between 300 and 350 mrad are within the measurement uncertainty.)	L1
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### 2. Processing Evaluation - (S.T.E.P. test (PS) results)

#### Standard Processing

If PS is less than 80 but is greater than or equal to 65:	L2
If PS is less than 65:	L1

#### Extended Processing

If PS is less than 100 but is greater than or equal to 85:	L2
If PS is less than 85:	L1

### 3. Processor QC Charts (daily)

There are 3 types of findings in this area. Each type is discussed separately below:

**a- Percentage (%) missing.** The fraction of time when QC charting is not done (missed) is calculated as a % of the total number of days when mammography is practiced during the worst month of a 12-month period (or since the last inspection).

If % is greater than or equal to 30 (in the worst month):	L1
If % is less than 30 but is greater than or equal to 10 (in the worst month):	L2

**b- Number of consecutive days (cd) missed** in the 12-month period. This refers to the number of consecutive days without charting and could be within the same month or across 2 different months.

If # cd missed is greater than 4:	L1
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Id # cd missed is 2, 3, or 4: L2

**c- Number of days operated with the processor out-of-control (ool).** This refers to processing mammograms when any of the processor parameters is outside the action limits (+-0.15 for mid density (MD) and density difference (DD), 0.03 for B+F).

If # ool is greater than or equal to 4: L1

Id # ool is 2 or 3: L2

**d- Corrective Action documented?** L2

#### 4. Phantom Image QC (weekly)

Under the current interim regulations, this is a monthly requirement. It will become a weekly required test under the final regulations.

##### **a- Number of times without conducting phantom image QC**

If # of weeks missing (in worst consecutive 12-week period) is equal to or greater than 4: L1

If # of weeks missing is 2 to 3: L2

If # of weeks missing is 1: no finding

##### **b- Other phantom QC records/test conditions adequate?**

- Image taken at clinical setting?

- Operating Level BD > 1.20

- C/A (for L1 failures) before subsequent exams documented?

If the answer to any of the above is no: L2

#### 5. Medical Physicist's Survey

All findings associated with any of the physicist's QC tests and evaluation of the tech QC program are L3 findings except if any of the following tests are missing from the survey: L2

AEC performance, dose evaluation, phantom image quality, focal spot/system resolution, artifact evaluation, and new modality (if applicable).

#### 6. Medical Records

Five random reports are checked for having exam results and ID of the interpreting physician (I.P.).

If any number of (or all) the reports does not have results or I.P. name: L2