

1 **The Mammography Quality**
2 **Standards Act Final Regulations**
3 **Modifications and Additions to**
4 **Policy Guidance Help System #6;**
5 **Draft Guidance for Industry and**
6 **FDA**

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9
10 *Draft Guidance – Not for Implementation*

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12 **This guidance document is being distributed for comment purposes only.**
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs

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Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

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The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Draft Guidance for Industry and FDA

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 the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

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1 **Background**

2
3 The Mammography Quality Standards Act was signed into law on October 27, 1992, to establish
4 national quality standards for mammography. The MQSA required that to provide mammography
5 services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans
6 Affairs, must be accredited by an approved accreditation body and certified by the Secretary of
7 Health and Human Services (the Secretary) or by an approved State certification body. The
8 authority to approve accreditation bodies, State certification bodies, and to certify facilities was
9 delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA
10 final regulations in the *Federal Register*. The final regulations, under which mammography facilities
11 are currently regulated, became effective April 28, 1999. The FDA compiled all final guidance
12 related to MQSA into a computerized searchable Policy Guidance Help System in November
13 1998. The Policy Guidance Help System is available on the Internet at:

14 www.fda.gov/cdrh/mammography/robohelp/start.htm

15 This draft compliance guidance document contains proposed guidance to update the Policy
16 Guidance Help System. This document deals with new and previously issued guidance about the
17 Automatic Exposure Control (AEC) component of mammography units.

18
19 Guidance information is periodically updated. Individuals wishing to get automatic notification of
20 such updates may subscribe to our E-mail ListServ by visiting [http://list.nih.gov/cgi-](http://list.nih.gov/cgi-bin/wa?SUBED1=mammography_cdrh-l&A=1)
21 [bin/wa?SUBED1=mammography_cdrh-l&A=1](http://list.nih.gov/cgi-bin/wa?SUBED1=mammography_cdrh-l&A=1) and following the directions there.

22
23 **The Least Burdensome Approach**

24
25 We believe we should consider the least burdensome approach in all areas of medical device
26 regulation. This guidance reflects our careful review of the relevant scientific and legal requirements
27 and what we believe is the least burdensome way for you to comply with those requirements.
28 However, if you believe that an alternative approach would be less burdensome, please contact us
29 so we can consider your point of view. You may send your written comments to the contact person
30 listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on
31 CDRH's Ombudsman, including ways to contact him, can be found on the Internet at
32 <http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html>.

1 **Introduction**

2

3 This document is intended to provide guidance to mammography facilities and their personnel. It
4 represents the Food and Drug Administration's (FDA) current thinking on the final regulations
5 implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). The FDA
6 uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory
7 requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend
8 when referring to guidance. It is the responsibility of the facility to read, understand, and follow the
9 final regulations.

10

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

14

15

16

1 **Automatic Exposure Control (AEC) Performance Testing – Annual**
2 **Physics Survey and Mammography Equipment Evaluation**

3
4 *Citations:*

5
6 *900.12(e)(5)(i)(A)(B)(C): Annual quality control tests. Facilities with screen-film systems shall perform the*
7 *following quality control tests at least annually:*

8 (i) *Automatic exposure control performance.*

9 (A) *The AEC shall be capable of maintaining film optical density within ± 0.30 of the mean*
10 *optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the*
11 *kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If*
12 *this requirement cannot be met, a technique chart shall be developed showing appropriate*
13 *techniques (kVp and density control settings) for different breast thicknesses and compositions that*
14 *must be used so that optical densities within ± 0.30 of the average under phototimed conditions can*
15 *be produced.*

16 (B) *After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD)*
17 *within ± 0.15 of the mean optical density when thickness of a homogeneous material is varied over a*
18 *range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used*
19 *clinically in the facility.*

20 (C) *The optical density of the film in the center of the phantom image shall not be less than 1.20.*

21
22 *900.12(b)(10)(i),(ii)(A)(B),(iii): Automatic Exposure Control.*

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

26 (ii) *The positioning or selection of the detector shall permit flexibility in the placement of the detector*
27 *under the target tissue.*

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

30 (B) *The selected position of the detector shall be clearly indicated.*

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

33
34 **Question 1: What is meant by the terms “AEC”, “AEC mode”, “mean optical**
35 **density”, and “configuration”?**

36
37 In its Diagnostic X-ray Performance Standard, FDA defines an automatic exposure control (AEC)
38 as a device that automatically controls one or more technique factors in order to obtain a desired
39 quantity of radiation at a preselected location. Such a device would automatically terminate the
40 exposure when the selected quantity of radiation had been delivered. The AEC may control the
41 selection of target material, focal spot, filter material, time, mA, mAs, kVp or a combination of any
42 or all of these factors.

43
44 AEC mode refers to the type of AEC being used. Typically available AEC modes can range from
45 fixed kVp and mA (where the kVp and mA are selected by the operator and the time is varied by
46 the AEC), to fixed kVp (where the kVp is selected by the operator and the mAs is varied by the

1 AEC), to various AEC modes in which all factors are varied by the AEC. Some of the more
2 automated AEC modes are known by brand names such as BACE, OPDOSE, AUTO FILTER
3 and AOP.

4
5 Mean Optical Density (MOD) is defined as the average of the optical densities measured on the
6 images produced during the AEC performance test using phantom thicknesses of 2, 4, and 6
7 centimeters.

8
9 Examples of equipment configurations include contact (grid), magnification (nongrid), and various
10 target-filter combinations.

11
12 ***Question 2: Can we continue to use technique charts after 10/28/2002?***

13
14 Yes. Facilities should continue to develop and use technique charts for their clinical exams,
15 especially for AEC modes where kVp and other technique factors must be selected by the
16 technologist. The only place where the words “technique chart” appear in the regulations is in the
17 annual AEC performance test requirement. This regulation places a restriction on the use of a
18 portion of the technique chart (density control setting) when the medical physicist is performing the
19 AEC test after October 28, 2002. After that date, the medical physicist may not adjust the density
20 control setting while performing the AEC test in the 2 to 6 cm range. In other words, the medical
21 physicist may not use the density control setting to compensate for inadequate performance of the
22 AEC. When performing this test, the medical physicist may use a technique chart to adjust other
23 factors such as kVp, filter, anode track or AEC mode to the extent such factors are used clinically.
24 If the AEC performance test fails, the medical physicist may create a temporary technique chart that
25 includes the appropriate density settings (in addition to the other technique factors). This temporary
26 technique chart may then be used by the facility for up to 30 days, or until the problem has been
27 corrected and the equipment passes the AEC performance test, whichever comes first.

28
29 When the AEC is functioning properly, the radiologic technologist shouldn't need to adjust the
30 density control setting while imaging patients who are in the 2 to 6 cm range. If the radiologic
31 technologist needs to continually adjust the density control to achieve films of adequate density, the
32 AEC may need adjustment and the medical physicist should be consulted.

33
34 The regulations do not restrict the use of technique charts by radiologic technologists. While a
35 properly functioning AEC should reduce the need to use the density setting component of a
36 technique chart, radiologic technologists may use these charts to change the density control settings
37 whenever they believe it appropriate during the performance of clinical mammographic
38 examinations. In addition, the regulations do not preclude the use of the manual mode and under
39 that scenario, the use of technique charts is essential.

Question 3: During the annual physics survey, how must the medical physicist test AEC performance and what action limits apply?

Due to the proliferation of mammography units with multiple AEC modes, testing of AEC performance has become more complex in recent years. When units had only one AEC detector, a single AEC mode, and a single target-filter combination, testing was relatively straightforward. That is no longer the case for most units. The following guidance is designed to help medical physicists adequately test a unit's AEC performance without over-testing the unit.

During the annual physics survey, the physicist can limit testing of AEC performance to the contact (grid) configuration. To fulfill MQSA requirements, all AEC detectors (that can be independently selected by the operator) and all AEC modes used clinically over the 2 to 6 cm range in the contact configuration must be tested. While there are several ways to do the test, medical physicists who use the following guidance will have fulfilled this requirement. Note: Facilities that do not clinically use their AEC in the 2 to 6 cm range (only use manual techniques) must still test the AEC to ensure that at least one AEC mode for each available AEC detector meets the regulatory requirements.

Step 1: Determine the Mean Optical Density

- A) For an AEC detector used in the contact configuration, perform exposures using a uniform attenuator of 2, 4, and 6 cm thickness. The exposures are to be performed using an AEC mode clinically used at each of the thicknesses. For example, if a facility typically uses fixed kVp mode at 2 cm, fixed mA mode at 4 cm and OPDOSE at 6 cm, then the medical physicist should use these same modes when performing the AEC performance test.
- B) Note: Even if a facility clinically uses more than one AEC mode at a particular thickness, no more than one of the AEC modes should be tested at each thickness to establish the Mean Optical Density (MOD). For example, if a facility clinically uses both the fixed kVp and the AOP CONTRAST modes at 2 cm, the medical physicist should use the more commonly used of these modes to determine the Mean Optical Density.
- C) Measure the optical density of the images obtained at 2, 4 and 6 cm (total of three images) and average them. This is your Mean Optical Density (MOD).

Step 2: Determine if the AEC detector used in Step 1 meets the regulatory action limit of +/- 0.15 OD of the MOD (+/- 0.30 OD if done before 10/28/2002)

- A) Check to see that all three of the optical densities obtained in Step 1C are within the action limit when compared to the MOD
- B) If ALL three ODs are within the action limit AND no other AEC modes are clinically used in the 2 to 6 cm range, then this AEC detector has passed. The medical physicist then needs to repeat Steps 1 and 2 for each additional AEC detector clinically used in the 2 to 6 cm range (See question #5 for additional guidance on testing multiple AEC detectors).
- C) If ALL 3 ODs are within the action limit AND the facility clinically uses an additional AEC mode(s) in the 2 to 6 cm range (other than the ones used to originally establish the MOD), the facility must test the additional AEC modes. The medical physicist needs to test EACH additional AEC mode(s) at any ONE clinically used thickness in the 2-6 cm range. If the

1 OD(s) is within the action limit when compared to the MOD, then this AEC detector has
2 passed. The medical physicist then needs to repeat Steps 1 and 2 for each additional AEC
3 detector clinically used in the 2 to 6 cm range (See question #5 for additional guidance on
4 testing multiple AEC detectors).

5 The medical physicist does not have to test the other clinically used equipment configurations during
6 the annual physics survey, but will have to test these configurations whenever a mammography
7 equipment evaluation involving the AEC is performed.

8

9 **Question 4: During the mammography equipment evaluation, must the medical**
10 **physicist test the AEC performance in all equipment configurations used**
11 **clinically by the facility or can it be limited to the contact configuration? What**
12 **action limits apply?**

13

14 During an equipment evaluation, the AEC must be operable in all equipment configurations (e.g.,
15 grid, nongrid; magnification, nonmagnification; and various target-filter combinations) used clinically
16 by the facility. The term "operable," means the AEC must meet the performance requirements of
17 900.12(e)(5)(i) within the 2 to 6 cm range. Compliance with this requirement may be demonstrated
18 by any of the following three methods:

19

20 1. Confirming AEC performance in the contact configuration. In the contact configuration, the
21 AEC must maintain the film optical density (OD) over the 2-6 cm thick range within the action limit
22 of +/- 0.15 OD (+/- 0.30 OD if done before October 28, 2002) of the mean (See question 3 for
23 additional guidance).

24 AND

25 Confirming AEC performance in all other clinically used configurations. This can be done by
26 demonstrating that the AEC meets the density and reproducibility limits established by the
27 manufacturer for those other configurations.

28 Note: Method #1 can be used only in those cases where the manufacturer has established AEC
29 performance standards for the non-contact configurations provided.

30

31 2. Confirming AEC performance in the contact configuration. In the contact configuration, the
32 AEC must maintain the film optical density over the 2-6 cm thick range within the action limit of +/-
33 0.15 OD (+/- 0.30 OD if done before October 28, 2002) of the mean.

34 AND

35 Confirming AEC performance in all other clinically used configurations. This can be done by
36 comparing the mean film optical density obtained from the data for the 2-6 cm thicknesses
37 measured in the contact configuration with measurements obtained using the 4 cm thick phantom in
38 the other configurations used clinically at the facility. When results across different configurations
39 are compared, the facility may use the action limit of +/- 0.30 OD even after October 28, 2002.

40

41 3. Confirming AEC performance by demonstrating that the AEC maintains the mean film
42 optical density within +/- 0.15 OD (+/- 0.30 OD if done before October 28, 2002) in all

1 configurations used clinically by the facility. The action limit applies only within each specific
2 configuration tested and does not apply to data collected across the different configurations.

3
4 Because of conflicting recommendations that existed in the professional community regarding
5 measurement of AEC performance during mammography equipment evaluations, facilities that
6 measured AEC performance only in the contact configuration before October 28, 2002 will not be
7 cited for failure to measure AEC performance for all clinically used configurations. However, those
8 that continue this practice after October 28, 2002 will be subject to citation.

9
10 ***Question 5: Must medical physicists test all AEC detectors for AEC***
11 ***performance in mammography units with multiple AEC detectors and can the***
12 ***testing procedures be modified if the detectors are in the same cassette holder***
13 ***(bucky)?***

14
15 The general principle is that all AEC detectors must be tested. What is considered adequate testing
16 will depend on the arrangement of the AEC detectors in the mammography unit.

- 17 1. Where a mammography unit has different AEC detectors in the different size
18 cassette holders (buckys), each detector must be tested separately as described
19 above in questions #3 or #4.
- 20 2. Where a mammography unit has more than one AEC detector in a single cassette
21 holder (bucky), the physicist must test all the independently selectable AEC
22 detectors and may test the detectors using either of the following methods:
 - 23 i. All detectors as described above in questions #3 or #4, OR;
 - 24 ii. One detector as described above in questions #3 or #4 AND comparing
25 the OD obtained at 4 cm from each of the other detectors to the MOD
26 obtained from the first detector. When results across different detectors are
27 compared, the medical physicist may use the action limit of +/- 0.30 OD
28 even after October 28, 2002.
- 29 3. Where a mammography unit has multiple AEC detectors that are not individually
30 selectable by the operator, the AEC can be tested as if it was a single detector. An
31 example of such a system is one with three fixed detectors in which the system
32 automatically chooses which detector will be active during the exposure. Similarly,
33 a large field detector that automatically selects its active area needs to be tested only
34 as a single detector. However, a system with three fixed detectors, each of which
35 can be selected individually by the operator, needs to have all three detectors tested
36 as described in section #2 above. Please note that a detector that can be moved to
37 different positions by the operator is still considered a single detector and needs to
38 be tested at only one of those positions.

1 **Question 6: If the AEC performance test fails, does that automatically mean that**
2 **the AEC is the cause of the failure?**

3
4 No. Because the AEC performance test involves many parts of the imaging chain, the medical
5 physicist needs to make sure that the AEC is the part responsible for the failure. For example,
6 problems with the processor, film emulsion or the use of different cassettes during the performance
7 of this test may lead to a failure that is not the fault of the AEC. Facilities are reminded, however,
8 that whatever the cause of the failure it needs to be corrected within the appropriate time frame.
9

10 **Question 7: For purposes of AEC testing, is the large image receptor considered**
11 **a different "configuration" from the small image receptor? Does the large image**
12 **receptor have to be tested separately from the small?**

13
14 If the large image receptor uses the same AEC detector as the small image receptor, it is not
15 considered a different configuration and would not have to be tested separately during the
16 mammography equipment evaluation. With respect to AEC testing during the annual physics
17 survey, the medical physicist can limit testing in the contact configuration to one size image receptor
18 (usually the small size). However, FDA does recommend that in addition to this required testing,
19 the medical physicist also measure the optical density obtained using the large image receptor and a
20 4 cm thick attenuator and compare it to the mean optical density obtained for the small image
21 receptor. When results across different size receptors are compared, the facility should use the
22 action limit of +/- 0.30 OD even after October 28, 2002.
23

24 **Question 8: The regulations in 900.12(e)(5)(i) require that an x-ray unit pass an**
25 **annual test for AEC performance over a range of 2 to 6 cm thick absorbers. If a**
26 **unit is used clinically at combinations of kVp and filtration that include tissue**
27 **thicknesses outside the 2 to 6 cm range, must it meet the AEC performance**
28 **requirements at the thicknesses where it operates and must it be tested at those**
29 **technique factors under the annual quality control requirements? What about**
30 **AEC performance testing during a mammography equipment evaluation?**

31
32 During the annual physics survey, the unit is not required to meet the AEC performance action limit
33 outside the 2 to 6 cm range and the medical physicist is not required to test the AEC using
34 thicknesses outside this range. However, we recommend that in addition to the required testing in
35 the 2 to 6 cm range, the unit also be tested at all clinically used thicknesses outside this range and
36 that the action limits specified in the regulations be applied to the extended test. If the unit cannot
37 meet these action limits outside the 2-6 cm range, FDA recommends that a technique chart be
38 developed showing appropriate techniques (kVp and density control settings) for the different
39 breast thicknesses and compositions so that optical densities (OD) within +/- 0.15 OD (+/- 0.30
40 OD if done before October 28, 2002) of the MOD under AEC testing conditions can be produced.
41

1 During the mammography equipment evaluation (as defined in 900.12(e)(10)), the medical physicist
2 must evaluate the AEC in all clinically used configurations (See Question 4). Section 900.12(e)(10)
3 requires that the AEC meet the requirements of 900.12(b) and (e). Under 900.12(b)(10), the AEC
4 is required to be "operable" under "configurations provided." The term "operable," means the AEC
5 must meet the performance requirements of 900.12(e)(5)(i) within the 2 to 6 cm range. If designed
6 to operate outside that range, the unit should meet the manufacturer's specifications over such
7 additional ranges.
8

9 ***Question 9: A facility only performs screening mammography and never***
10 ***performs any magnification (nongrid) studies. Must the medical physicist test***
11 ***the AEC in the magnification configuration, even though the unit won't be used***
12 ***in that configuration by that facility?***

13
14 No. The intent of the regulation is to ensure that the AEC mode is operable in all equipment
15 configurations used clinically by the facility. The term "operable," means the AEC must meet the
16 performance requirements of 900.12(e)(5)(i) within the 2 to 6 cm range. One way is to have the
17 AEC tested in all the configurations provided by the system. An alternative method is to ensure that
18 the facility does not clinically use the AEC in those configurations not previously tested by the
19 medical physicist. This can be accomplished by placing a label on the unit's control panel listing the
20 configurations that cannot be used because they were not tested. These non-operational
21 configurations must also be identified in the facility's quality assurance records.
22

23 ***Question 10: A facility's x-ray unit has a single AEC detector that may be***
24 ***moved to any of three positions along the chest wall to nipple midline of the***
25 ***breast. It cannot be placed under all areas of the breast. Would this meet the***
26 ***intent of the regulation?***

27 Yes. It is not necessary that the AEC detector be mobile over the entire area of the breast.
28

29 ***Question 11: On the facility's x-ray unit, the indication of the detector size and***
30 ***position options is projected onto the input surface of the compression paddle.***
31 ***However, when the paddle is moved up and down, the indicated detector size***
32 ***does not change with distance. Is this an acceptable indication under***
33 ***900.12(b)(10)(ii)(A)?***

34
35 Yes. The size and positions indicated at the input surface should be indicative of the size and
36 positions of the detector in the plane of the detector. Compliance could be achieved by
37 representations permanently marked on the paddles or by a projected image that approximates the
38 size and position of the detector.
39

1 **Question 12: A facility's unit indicates the selected position of the detector by**
2 **the relative position of the adjustment lever located on one side of the unit and**
3 **is only visible from that side of the unit. Does this meet the regulation?**

4
5 Yes. The relative position of the selector would be an adequate display of the detector position,
6 and this display need be visible from only one location.
7

8 **Question 13: The position of the AEC detector is indicated by a knob under the**
9 **bumper that can be felt but not seen. Does this satisfy the requirement of being**
10 **"clearly indicated"?**

11
12 Yes.
13

14 **Question 14: How much variability from the "normal" optical density setting**
15 **must the system provide?**

16
17 The regulations do not specify the range of variability that must be provided; only that some
18 variability is available.
19

20 **Question 15: Do all possible positions of the AEC detector have to be indicated**
21 **on the compression paddle?**

22
23 The intent of this regulation is to help the radiologic technologist optimally position the AEC
24 detector. Under some AEC detector designs it may be difficult to show all possible positions.
25 Some detectors cover the entire area of the image receptor and once the exposure begins, they
26 automatically select the region of maximum density as the active area. For these systems, indication
27 of the entire potential active area, along with appropriate instructions (usually found in the user
28 manual), would satisfy this requirement. Since the area is automatically selected, the display of the
29 size of the detector is not required. Other designs may have an essentially infinite number of
30 locations under all or part of the image receptor. An indication of the complete range and detector
31 size, coupled with adequate instructions, would be sufficient. Still others may indicate the range of
32 multiple positions on the paddle. Again, this would satisfy the requirement. There may be other
33 methods employed that also satisfy the requirement. The key is that the operators know what areas
34 they may select and the size of the detector.
35

36 **Question 16: The position of the AEC detector is infinitely variable over the**
37 **entire area of the image receptor. How can the position of such a detector be**
38 **identified on the compression paddle?**

1 An indication of the range of coverage and the detector size, along with appropriate instructions
2 (usually found in the user manual), would satisfy this requirement.
3

4 **Question 17: Do paddles designed to be smaller than the full size of the image**
5 **receptor have to display the AEC detector position and size?**

6
7 No. Paddles designed to be smaller than the full size of the image receptor do not have to display
8 AEC detector position and size. Paddles used only for invasive procedures do not have to display
9 AEC detector position and size because they are not covered by the regulations.
10

11 **Question 18: If the AEC performance is found to be outside the action limit**
12 **during physicist testing, can a facility adjust the density control settings or use**
13 **manual techniques until the unit is fixed? Would it require the physicist to come**
14 **and recheck it or if the repairman did so would that be satisfactory?**

15
16 The answer to the first question is yes. According to 900.12(e)(5)(i)(A), when the AEC
17 performance is found to be outside the action limit during physicist testing, the medical physicist may
18 create a temporary technique chart that includes the appropriate density settings (in addition to the
19 other technique factors) to be used with the malfunctioning AEC. The facility can use this temporary
20 chart for up to 30 days, or until the problem has been corrected and the equipment passes the AEC
21 performance test, whichever comes first. If the AEC is completely non-functioning, the medical
22 physicist may create a manual mode technique chart that includes all the appropriate manual
23 technique factors. Use of the manual mode would be acceptable under the complete failure
24 situation raised by the question. The facility can use manual techniques for up to 30 days while the
25 non-functioning AEC is being repaired and can continue to use the unit on patients during this
26 period.
27

28 The answer to the second question depends on the repair needed to fix the problem. If the repair is
29 classified as “major” (see **Table: Medical Physicist Involvement in Equipment Adjustments,**
30 **Changes, or Repairs**), then the medical physicist must be onsite to perform the post repair testing.
31 If the repair is not classified as “major” then the post repair testing may be done under the medical
32 physicist’s oversight. In either event, the appropriate testing must be performed and passed within
33 the specified time frames.
34

1 **Air Kerma and AEC Reproducibility Annual Quality Control Test**

2

3 *Citation:*

4 *900.12(e)(5)(v): Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air*
5 *kerma and mAs shall not exceed 0.05.*

6

7 ***Question 1: Must medical physicists test all AEC detectors for AEC***
8 ***reproducibility in mammography units with multiple AEC detectors in a single***
9 ***cassette holder (bucky)?***

10

11 No. Because the AEC detectors are also being evaluated as part of the AEC performance test,
12 only a single detector per bucky needs to be tested by the medical physicist. Units that have
13 different AEC detectors in different buckys (e.g., different AEC detectors for the different size
14 cassette holders) will need to have one detector in each bucky tested for reproducibility.

15 ***Question 2: Must medical physicists test AEC reproducibility in all clinically***
16 ***used AEC modes?***

17

18 No. The medical physicist can limit AEC reproducibility testing to the AEC mode used most
19 commonly for the standard breast.

20

1 **Phantom Images Exposed in a Fully Automatic AEC Mode, if that is the**
2 **Clinically-used Technique**

3
4 Many mammographic x-ray systems have more than one AEC mode of operation. A commonly
5 used AEC mode requires the radiologic technologist to set a specific kVp value with the AEC
6 automatically determining the mAs for the exposure (commonly called fixed kVp or Auto-mAs
7 modes). The radiologic technologist can vary the exposure in this AEC mode by setting the kVp,
8 adjusting the density control setting, or both. A more advanced AEC mode is where the system
9 automatically controls the kVp and the mAs (commonly called the Full-Auto mode). In this latter
10 mode, the radiologic technologist can only adjust the exposure by use of the density control. The
11 actual names for the different AEC modes of operation will vary with the different make and model
12 of mammographic unit.

13
14 For equipment testing involving the phantom, inspectors should use the same technique factors and
15 AEC mode of operation that the facility uses for its patients with the standard breast (compressed
16 breast thickness of 4.2 cm, with breast tissue consisting of approximately 50% adipose (fat) tissue
17 and 50% glandular tissue in composition). When a facility typically uses the Full-Auto AEC mode
18 for its clinical examinations, the inspector should make an exposure of the phantom using the Full-
19 Auto AEC mode and record the kVp selected by the x-ray system. This same kVp should be used
20 when the beam quality (HVL) testing is conducted in the manual mode of operation. In the event
21 that the displayed kVp after the exposure with the phantom has a three-digit display (e.g.,
22 25.7 kVp), but the manual mode only allows selection of two digits (e.g., 25 kVp), round up or
23 down based on the final digit (example: for 25.1 to 25.4, use 25 kVp; for 25.5 to 25.9, use
24 26.0 kVp).

25
26 Note about facility phantom QC: If the facility typically uses the Full-Auto AEC mode for its clinical
27 examinations, it must use this same AEC mode for its weekly phantom QC test.

28

1 **Quality Assurance Records**

2
3 *Citation:*

4 *900.12(d)(2): Quality assurance records. The lead interpreting physician, quality control technologist, and*
5 *medical physicist shall ensure that records concerning mammography technique and procedures, quality*
6 *control (including monitoring data, problems detected by analysis of that data, corrective actions, and the*
7 *effectiveness of the corrective actions), safety, and protection employee qualifications to meet assigned quality*
8 *assurance tasks, are properly maintained and updated. The quality control records shall be kept for each test*
9 *specified in paragraphs (e) and (f) of this section until the next annual inspection has been completed and*
10 *FDA has determined that the facility is in compliance with the quality assurance requirements or until the test*
11 *has been performed two additional times at the required frequency, whichever is longer.*

12
13 ***Question 4: Is it acceptable for a technique chart to simply state that the facility***
14 ***is using the unit in its fully automatic AEC mode (e.g., BACE, AOP, or similar***
15 ***modes) for all routine examinations?***

16
17 Yes. However, if such a technique chart is the only one available, the facility may not use the unit if
18 the automatic AEC mode listed on the technique chart fails during medical physicist testing. For this
19 reason, FDA strongly recommends that the facility develop, and have available, a technique chart
20 that includes other AEC modes (such as fixed kVp mode) and/or manual techniques. The technique
21 chart could then be used as a guide for the radiologic technologist in the event that the fully
22 automatic AEC mode failed or was not suitable for use with a specific patient.

1 **Weekly Equipment Quality Control Tests**

2
3 *Citation:*

4 *900.12(e)(2)(i),(ii),(iii),(iv): (2) Weekly quality control tests. Facilities with screen-film systems shall*
5 *perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.*

6 *(i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be*
7 *at least 1.20 when exposed under a typical clinical condition.*

8 *(ii) The optical density of the film at the center of the phantom image shall not change by more than*
9 *± 0.20 from the established operating level.*

10 *(iii) The phantom image shall achieve at least the minimum score established by the accreditation body*
11 *and accepted by FDA in accordance with 900.3(d) or 900.4(a)(8).*

12 *(iv) The density difference between the background of the phantom and an added test object, used to*
13 *assess image contrast, shall be measured and shall not vary by more than ± 0.05 from the established operating*
14 *level.*

15
16 ***Question 10: We perform our weekly phantom images using an AEC mode***
17 ***different from the Full-Auto AEC mode that we typically use for patients. Is this***
18 ***acceptable toward meeting the requirement?***

19
20 No. If the facility clinically uses the Full-Auto AEC mode for its standard breast patients, the
21 weekly phantom images must be obtained using that mode. FDA requires the weekly phantom
22 image be produced using the same clinical conditions that are used for its patients with the standard
23 breast (compressed breast thickness of 4.2 cm, with breast tissue consisting of approximately 50%
24 adipose (fat) tissue and 50% glandular tissue in composition). Prior to performing mammography
25 on patients, the phantom image must achieve at least the minimum phantom score established by the
26 accreditation body and must be within the action limits established for the three optical density
27 requirements.