AEC Testing Issues

The MQSA regulations are clear that x-ray equipment is not to be used clinically unless it has passed testing for compliance with the published requirements. The regulations establish, under the requirement for mammography equipment evaluations (MEE), conditions for pre-testing of equipment before clinical use and, under the annual survey requirement, conditions for the periodic retesting to assure that the equipment continues to operate as intended.

The automatic exposure control (AEC) is one of the components of the unit that must be tested both before initial clinical use, after a major repair, and at least annually during use. The intent of the requirement for the AEC performance test is to establish that the AEC is operating as intended under all conditions of use in the facility and is capable of providing images of consistent density across a normal range of breast thicknesses encountered in clinical practice.

When the regulations were written, most units had a single AEC detector and used the traditional mode of AEC operation where the operator selects a kV and the system automatically varies the x-ray on-time to control the exposure. Since then, the number and complexity of AEC systems has multiplied. In addition to the traditional mode, some systems control additional exposure parameters including the selection of kV, target, filter, and or mA (so called Full Auto mode). Some units go further with the Full Auto mode and add the capability to select programmable submodes, which allow operator selection of different exposure characteristics to enhance detail and contrast, dose, or other exposure aspects to customize the image to the patient’s need. In addition, the number of individual AEC detectors in a unit may vary. One type of unit has a many as eight separate independent AEC detectors. Because of the complexity and variation between manufacturers, models, and even installations of the same model, the AEC testing requirements need additional clarification in order to minimize chance of over or under testing of the equipment. The regulations and our current guidance referable to AEC systems are included in this document as attachment #1.

The regulations have different testing requirements depending on whether the unit is new or has undergone a major repair (requires an MEE) or is undergoing its periodic annual physics survey. The difference being that in an MEE, the unit has to have all configurations (e.g., grid, nongrid, magnification and various target-filter combinations) tested while during the annual physics survey the testing can be limited to the contact configuration (non-magnification grid). In both the MEE and annual survey, the testing criteria are the same, namely:

(A) The AEC shall be capable of maintaining film optical density within ±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 ±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 ±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.

Practically speaking, units are being tested at three thicknesses (2, 4, and 6 cm.)

I need to stress that the requirements stated in the regulations in attachment #1 have the force of law while the associated guidance represents one, but not necessarily the only way to comply with the regulations. In the event the committee believes that underlying regulation or associated guidance needs to be modified, the committee can recommend such changes. It should be kept in mind that while both the regulations and the guidance can be modified, the process for modifying guidance is generally quicker than that for regulations.

I think the use of a hypothetical unit may help you as you consider what testing of the AEC must facilities perform when doing an MEE on a new unit or during the periodic annual survey in this process. Let’s assume this unit has the following AEC modes and submodes: 1) time, 2) mAs, 3) mAs + kVp, 4) Full Auto with this mode having 3 submodes. In addition let’s assume that the unit has 3 targets (Mo, Rh, and W), three filters (Mo, Rh, and Al), 2 configurations (contact and magnification) and 2 independent AEC detectors. This generates a theoretical MEE testing matrix of 252 possibilities, each being tested at 2, 4, and 6 cm. This would bring the total number of exposures to 756. Assuming 4 minutes per exposure, testing time could take as much as 50 hours. Obviously, not all possible combinations would or even could be used clinically, so the actual testing time would be much less but still could be quite long. For the annual survey, things improve to a theoretical testing matrix of 14 possibilities, each being tested at 2, 4, and 6 cm for a total of about 2 ½ hours. The above discussion doesn’t take into account the possibility that some of the AEC modes software algorithms are different for the different image receptor sizes which could increase the testing time. Suffice it to say that there is a real need to ensure that the units are tested adequately but that over testing of the AEC could negatively impact mammography operations.

With that as background, I’m asking the committee to discuss the following situations:

1. The current requirement is that a mode or configuration needs to be tested prior to clinical use. That leaves the facility with 2 options; have all modes (annual survey) or modes and configurations (MEE) that could reasonably be used at the facility, tested (even if they weren’t actually being used) or have the medical physicist return onsite and perform the test in the event that sometime during the following year the facility needs or wants to use that new mode or configuration. If the facility chooses to pre-test the AEC, such testing must have been completed at the last applicable time. This means that it must have been tested during the mammography equipment evaluation or the last annual survey (within 14 months), whichever was the most recent. It’s important to remember that at a minimum, each system must have an operable AEC configuration even if the facility never plans to use it clinically. This means that at least 1 mode or configuration of AEC operation must have been pre-tested at the last appropriate time.

2. Since some or all of the AEC configurations may share key components or algorithms, is it reasonable to assume that the failure of one configuration immediately makes the
others suspect unless the cause of failure in one configuration can be isolated as unique to that mode. In that case only the manual mode could be used as back-up until repairs had been made. An example of an isolated configuration failure would be a system that incorporates separate AEC detectors for different image receptor sizes. If one detector fails and can be identified as the cause of failure, then the continued use of the AEC with other image receptor would be appropriate.

3. In the event of AEC failure the manual mode may be used for up to 30 days while the AEC is being repaired. Before the manual mode may be used clinically must it be tested for the dose requirement at the techniques used for the standard breast? If yes, how should the manual mode be tested and what action limits should be recommended?

4. Some facilities are tailoring their use of Full Auto submodes to specific breast thicknesses. For example, they may use submode 1 at 2 cm., submode 2 at 4 cm., and submode 3 at 6 cm. How should the AEC be tested under this scenario? Should it be tested as it is used clinically or should all 3 submodes be tested at 2, 4, and 6 cm.
Automatic Exposure Control (AEC)

Citation:

(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.

(ii) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target tissue.
   (A) The size and available positions of the detector shall be clearly indicated at the X-ray input surface of the breast compression paddle.
   (B) The selected position of the detector shall be clearly indicated.

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

Discussion:

Question 1: 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?

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.

Question 2: 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?

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

Question 3: 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)?

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.

Question 4: 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?

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 5: 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”?

Yes.
**Question 6:** How much variability from the “normal” optical density setting must the system provide?

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

**Question 7:** Do all possible positions of the AEC detector have to be indicated on the compression paddle?

The intent of this regulation is that the operator be aware of the characteristics of the AEC detector in order to aid in improving image quality. Under some AEC detector designs it may be difficult to meet the requirement. Some detectors cover the entire area of the image receptor and once the exposure begins, they automatically select the region of maximum density as the active area. For such systems, indication of the entire potential active area, along with appropriate instructions in the users manual, would satisfy the requirement. Since the area is automatically selected, the display of the size of the detector is not required. Other designs may have an essentially infinite number of locations under all or part of the image receptor. An indication of the complete range and detector size, coupled with adequate instructions, would be sufficient. Still others may indicate the range of multiple positions on the paddle. Again, this would satisfy the requirement. There may be other methods employed that also satisfy the requirement. The key is that the operators know what areas they may select and the size of the detector.

**Question 8:** The position of the AEC detector is infinitely variable over the entire area of the image receptor. How can the position of such a detector be identified on the compression paddle?

An indication of the range of coverage and the detector size, coupled with instructions on the correct use in the users manual, would satisfy the regulations.

**Question 9:** Do paddles designed to be smaller than the full size of the image receptor have to have the AEC detector position identified?

No. It was not the intent that paddles designed to be smaller than the full size of the image receptor bear the indication. Fenestrated paddles such as those used for invasive procedures are not covered by the regulations.

**Question 10:** The regulations in 900.12(e)(5)(i) require that an x-ray unit pass an annual test for AEC performance over a range of 2 to 6 cm thick absorbers. If a unit is used clinically at combinations of kVp and filtration that include tissue thicknesses outside the 2 to 6 cm range, must it meet the AEC performance requirements at the thicknesses where it operates and must it be tested at those technique factors under the annual quality control requirements?

No. The unit is not required to meet the AEC performance specification outside the 2 to 6 cm range and the physicist is not required to test the AEC performance requirements for thicknesses outside this range during the annual survey. However, we recommend that in addition to the required testing in the 2 to 6 cm range, the unit also be tested at all clinically used thicknesses outside this range and that the action limits specified in the regulations be applied to the extended test. If the unit cannot meet these action limits outside the 2-6 cm range, FDA recommends that a technique chart be developed showing appropriate techniques (kVp and density control settings) for the different breast thicknesses and compositions so that optical densities (OD) within +/- 0.30 OD (+/- 0.15 OD after October 28, 2002) of the average under phototimed conditions can be produced.

**NOTE:** After October 28, 2002, the technique charts referred to in the preceding paragraph may be used only for thicknesses outside the 2-6 cm range. For use of technique charts within the 2-6 cm range, see use of manual techniques when the AEC fails.

You should note that under the Equipment Evaluation outlined in 900.12(e)(10), an evaluation of the AEC under all clinically used configurations is required, not merely recommended (see Question 11). This is because 900.12(e)(10) mandates conformance with all pertinent aspects of 900.12(b) and (e). Under 900.12(b)(10), the AEC is required to be “operable” under “configurations provided.” In this context, “operable,” as applied to the AEC means that it must meet the density and reproducibility requirements of (e)(5)(i) within the range of 2 to 6 cm. If designed to operate outside that range, the unit must meet the manufacturer’s specifications over such additional ranges.
**Question 11:** During an equipment evaluation, must AEC performance be tested for all equipment configurations used clinically by the facility or can it be limited to the contact configuration? What action limits apply?

During an equipment evaluation, the AEC must be operable in all equipment configurations (e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations) used clinically by the facility. Compliance with this requirement may be demonstrated by any of the following three methods:

1. Confirming AEC performance in the contact configuration. In the contact configuration, the AEC must maintain the film optical density (OD) over the 2-6 cm thick range within the action limit of +/- 0.30 OD (+/- 0.15 OD after October 28, 2002) of the mean.
   AND
   Confirming AEC performance in all other clinically used configurations. This can be done by demonstrating that the AEC meets the density and reproducibility limits established by the manufacturer for those other configurations.
   Note: Method #1 can be used only in those cases where the manufacturer has established AEC performance standards for the non-contact configurations provided.

2. Confirming AEC performance in the contact configuration. In the contact configuration, the AEC must maintain the film optical density over the 2-6 cm thick range within the action limit of +/- 0.30 OD (+/- 0.15 OD after October 28, 2002) of the mean.
   AND
   Confirming AEC performance in all other clinically used configurations. This can be done by comparing the mean film optical density obtained from the data for the 2-6 cm thicknesses measured in the contact configuration with measurements obtained using the 4 cm thick phantom in the other configurations used clinically at the facility. When results across different configurations are compared, the facility may use the action limit of +/- 0.30 OD even after October 28, 2002.

3. Confirming AEC performance by demonstrating that the AEC maintains the mean film optical density within +/- 0.30 OD (+/- 0.15 OD after October 28, 2002) in all configurations used clinically by the facility. The action limit applies only within each specific configuration tested and does not apply to data collected across the different configurations.

Because of conflicting recommendations that currently exist in the professional community regarding measurement of AEC performance, facilities that currently are measuring AEC performance only in the contact configuration will not be cited for failure to measure AEC performance for all clinically used configurations until after October 28, 2002. (see evaluating AEC performance during the annual physics survey).
AEC Performance Quality Control Test

Citation:
900.12(e)(5)(i)(A)(B)(C): 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 ±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 ±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 ±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.

Discussion:

Question 1: 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?

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 2: Do units with multiple AEC detectors have to have each detector tested individually?

Where a mammography unit has multiple AEC detectors designed to function independently, each detector must be tested separately (e.g., different AEC detectors for the different size cassette holders or more than one independently selectable AEC detector in a single cassette holder). Where a mammography unit has multiple AEC detectors designed to function as a single unit, the AEC detector unit must be tested. For example, a single detector that can be moved to different positions needs to have the detector tested at only one of those positions. A system with three fixed detectors, each of which can be selected individually, needs to have all three detectors tested. A large field detector that automatically selects its active area needs to be tested only as a single detector.

Question 3: The regulations in 900.12(e)(5)(i) require that an x-ray unit pass an annual test for AEC performance over a range of 2 to 6 cm thick absorbers. If a unit is used clinically at combinations of kVp and filtration that include tissue thicknesses outside the 2 to 6 cm range, must it meet the AEC performance requirements at the thicknesses where it operates and must it be tested at those technique factors under the annual quality control requirements?

No, the unit is not required to meet the AEC performance specification outside the 2 to 6 cm range and the physicist is not required to test the AEC performance requirements for thicknesses outside this range during the annual survey. However, we strongly recommend that in addition to the required testing in the 2 to 6 cm range, the unit also be tested at all clinically used thicknesses outside this range and that the action
limits specified in the regulations be applied to the extended test. If the unit cannot meet these action limits outside the 2-6 cm range, FDA recommends that a technique chart be developed showing appropriate techniques (kVp and density control settings) for the different breast thicknesses and compositions so that optical densities within +/- 0.30 ( +/- 0.15 after October 28, 2002) of the average under phototimed conditions can be produced.

**NOTE:** After October 28, 2002, the technique charts referred to in the preceding paragraph may be used only for thicknesses outside the 2-6 cm range. For use of technique charts within the 2-6 cm range, see **use of manual techniques when the AEC fails**.

You should note that under the Equipment Evaluation outlined in 900.12(e)(10), an evaluation of the AEC under all conditions of use is required, not merely recommended. This is because 900.12(e)(10) mandates conformance with all pertinent aspects of 900.12(b) and (e). Under 900.12(b)(10), the AEC is required to be “operable” under “configurations provided.” In this context, “operable,” as applied to the AEC means that it must meet the density and reproducibility requirements of (e)(5)(i) within the range of 2 to 6 cm. If designed to operate outside that range, the unit must meet the manufacturer’s specifications over such additional ranges.

**Question 4:** During the annual physics survey, must AEC performance be tested for all equipment configurations used clinically by the facility or can it be limited to the contact configuration? What action limits apply?

During the annual physics survey, AEC performance in the contact configuration must be tested. The medical physicist does not have to test the other clinically used equipment configurations during the annual physics survey, see guidance on determining AEC performance during equipment evaluations. In the contact configuration, the action limit requires maintenance of the film optical density (OD) over the 2-6 cm thickness range within +/- 0.30 OD (+/- 0.15 OD after October 28, 2002) of the mean.
Air Kerma and AEC Reproducibility Annual Quality Control Test

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

Discussion

Question: Do units with multiple AEC detectors have to have each detector tested individually for AEC reproducibility?

Where a mammography unit has multiple AEC detectors designed to function independently, each detector must be tested separately (e.g., different AEC detectors for the different size cassette holders or more than one independently selectable AEC detector in a single cassette holder). Where a mammography unit has multiple AEC detectors designed to function as a single unit, the AEC detector unit must be tested. For example, a single detector that can be moved to different positions needs to have the detector tested at only one of those positions. A system with three fixed detectors, each of which can be selected individually, needs to have all three detectors tested. A large field detector that automatically selects its active area needs to be tested only as a single detector.