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1926 - 2001

May 15, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061,
Rockville, MD 20852

**Re.: Docket Number 03D-0025
Medical Devices: Draft Guidance for Industry and FDA; The Mammography Quality
Standards Act Final Regulations Modifications and Additions to Policy Guidance Help
System # 6; Availability**

To Whom It May Concern:

On behalf of the Diagnostic Imaging and Therapy Systems Division of the National Electrical Manufacturers Association, I am pleased to submit comments relative to the Proposed Rule: Automatic Exposure Control (AEC) Performance Testing.

NEMA, the National Electrical Manufacturers Association, is the nation's largest trade association representing the electro-industry. NEMA's Diagnostic Imaging and Therapy Systems Division represents the majority of the nation's manufacturers of X-ray imaging, computed tomography, diagnostic ultrasound, radiation therapy, magnetic resonance imaging, and nuclear imaging equipment. In addition, the division represents manufacturers of picture archiving and communications systems.

Note: Public comment regarding some of the topics discussed in this letter was presented to the National Mammography Quality Assurance Advisory Committee (NMQAAC) during its meeting, on April 28, 2003. A copy of that presentation is included as an appendix to this letter.

Automatic Exposure Control (AEC) Performance Testing

General Comment:

We agree with most of what is included in this draft guidance and we believe it will help reduce some of the confusion that currently exists regarding the evaluation of AEC performance. We believe that FDA could further reduce this confusion by reiterating and expanding on a statement that was included in the preamble to the publication of the Quality Mammography Standards. In

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03D-0025

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its response to Comment 498 regarding the original proposal in § 900.12(b)(15)(vii)(B), FDA stated (emphasis added):

“The agency also advises facilities to use film from the same batch so that film variability, if any, is not introduced while testing AEC performance. **Because film variability can be eliminated as a source of bias in the AEC performance test**, there is no justification for increasing the AEC actions limit to ± 0.30 OD because that would simply mean that the facility would have to contend with variability of ± 0.30 from the film and another ± 0.30 from the AEC.”

The highlighted statement leads us to believe that FDA’s intention in formulating the AEC performance test was to evaluate the performance of the exposure control system of the mammographic unit in the absence of variation caused by the film. We would like to infer that FDA also intended that variation due to the cassette and processor also be excluded when performing the AEC test.

We have encountered instances in which the test is performed in the “worst-case” scenario. Data have included a mix of configurations, cassette sizes, and film types as well as phantom thicknesses. Some physicists have argued that this is a valid approach since it represents the clinical reality. We do not disagree that this might represent the clinical reality, but we do not believe it represents FDA’s intention in developing the rule and, in particular, in setting the action limits.

It should also be recognized that interpretation of this rule can have a significant impact on the access and cost of mammography. Calibration of the AEC functions of a mammography unit can require about one-half of a day of a Field Service Engineer’s time. During this time, of course, the unit is unavailable for clinical mammography affecting accessibility for the patient and the revenue for the facility. If during or after re-calibration it becomes apparent that the source of the problem was due to factors external to the AEC system, e.g., processor instability or mis-match of cassette or film speeds, additional time and revenue may be lost as other solutions to the problem are sought. Ascertaining the root cause of a failure of the AEC performance test before calling for service has the potential for substantial cost savings to the facility.

An explicit statement of FDA’s intention regarding this rule and a discussion regarding control of all variables external to the AEC function of the mammography unit would be very helpful in reducing much of the confusion regarding this rule. The answer to Question 6 most closely addresses this issue, but it stops short of an explicit statement of FDA’s intent. In the specific comments below, we have provided a suggestion of wording that could be included in the answer to Question 6 to clarify the intent of the rule.

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Question 1:

While the answer provides definitions for both AEC and MOD, the material on “configuration” only quotes the regulation without providing a definition. But the regulation seems to lack consistency regarding just what constitutes a configuration. Installing the grid and setting up the mammography unit to acquire a mammogram in the contact geometry requires active involvement of the technologist. Likewise is the case for removing the grid and setting up the magnification geometry. After the geometry and accessory installation has been established, the choice of the target-filter combination might be manually selected by the technologist, but with far greater frequency it is selected automatically by the AEC. Hence, two of the examples of configuration cited in the rule require deliberate, active involvement of the user, but for the third example selection is most commonly automatic.

Another inconsistency arises from a consideration of the motivation associated with the examples. The technologist has in mind solving a particular clinical problem when setting up the mammography unit for either contact (grid) or magnification (nongrid) geometries. While specific problem solving may be in the operator’s mind in a few cases when selecting target-filter combinations manually, when exposure control is performed by the AEC, the choice of target-filter combination is driven by concerns that, in general, may not be associated with the specific clinical problem at hand.

We suggest that FDA consider the following as a definition of “configuration”:

A configuration is the collection of system elements and their geometric arrangement selected by the operator to achieve a specific, clinical imaging purpose.”

Based on this definition, contact and magnification would be configurations. Likewise, the field of view, e.g., 18 x 24 cm² or 24 x 30 cm², would be a configuration since the operator needs to make explicit selections of image receptor holder, cassette, and film size to accomplish a specific clinical task. However, target-filter combination would not be a configuration since in the majority of cases it is a selection made automatically by AEC system for the general purpose of achieving a balance among such competing factors as patient dose, exposure time, and image contrast.

In the context of Question 4, comparisons of optical density variation between image receptor sizes would be made at the ± 0.30 optical density level applied to configurations rather than at the ± 0.15 level applied within a configuration.

Question 2:

We agree with FDA’s answer to this question and appreciate its effort to clarify the intention of this rule, which has been somewhat muddled since the publication of the *Small Entity*

Compliance Guide in October 1997. To add a bit more to the clarification and emphasize the unique role played here by the film density control, we suggest a rewording of the third sentence after “Yes” to read (insertions underlined, deletions ~~struck through~~)

“This regulation places a restriction on the use of a specific element portion of the technique chart, ~~the~~ (density control setting), when the medical physicist is performing the AEC test after October 28, 2002.”

Question 6:

We recommend that FDA use the answer of this question to provide an explicit statement of the intent of the AEC Performance Test. NEMA has developed the following statement, which we recommend for inclusion in the answer:

The intent of the AEC performance test is to determine that the AEC system of the mammography equipment is capable of maintaining the film optical density within specified limits when tested in a manner representative of clinical use. This capability is to be evaluated under conditions where variations of optical density attributable to influences external to the AEC system, such as the cassette, screen, film, and processing, are either controlled or corrected.

Additionally, we recommend that FDA include some guides to good practice regarding the acquisition of data for the AEC test. These include

- using only one cassette (or at least cassettes of known and matched sensitivity). This includes using a small format cassette in a large format image receptor holder if physically possible and consistent with the types of cassette and film used clinically.
- using one type of film from a single box. This includes testing of the AEC for the large field of view using small format film if the same film type is clinically used for both fields of view.
- frequently (if not always) recording sensitometric strips on films to monitor the consistency of film and processor sensitivity.

Regarding the existing text, we recommend the following modification (insertion underlined) in the second sentence after “No.”

“For example, problems with the processor, film emulsion or the use of different cassettes and different types or batches of film during the performance of this test may lead to a failure that is not the fault of the AEC.”

We agree with FDA’s identification of the many causes for failure of this test. But we note that there remains some ambiguity in the answer to the question related to the intent of the test. If the

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test is intended to evaluate the AEC performance of the mammography unit apart from variations due to the screen, film, or processor, has the test actually failed if the reason for exceeding the action limits is due to one of these external influences. It may be that there is no “cause of failure” that needs to be corrected. Rather it may be that the influence of external variables needs to be taken into account. We believe that an explicit statement of the intent of the test along with recommendations on methods of controlling for or correcting the influences of external variables will reduce the number of apparent failures and better direct resources toward the solution of an identified root cause of the problem.

Question 7:

We recommend that a means of obtaining greater consistency would be to identify the large image receptor as a separate configuration as discussed in the comments regarding Question 1. In its answer to Question 7, FDA states that the large image receptor is not another configuration, but comparison of results across image receptor sizes is at the ± 0.30 optical density level. This is not consistent with the discussion in Question 4, which implies that performance within a configuration is evaluated at the ± 0.15 level.

By identifying the large image receptor as a configuration, by virtue of the fact that the operator must deliberately make specific choices for the image receptor holder, the cassette size, and the film size to address a specific clinical problem, the comparison level stated in the last sentence of the answer to Question 7 becomes consistent with the guidance developed in the answer to Question 4.

We would also again recommend that the reader be reminded to consider the guides to good practice discussed above in the event the system is considered not to have met the performance requirement.

Question 8:

An element of the answer to the question might be interpreted as limiting with respect to what parameters can appear as variables in a technique chart. We recommend that FDA also include the parameters mentioned in the answer to Question 2. In particular, we recommend the following change to the third sentence of the first paragraph (insertions underlined, deletions ~~struck through~~):

“If the unit cannot meet these action limits outside the 2-6 cm range, FDA recommends that a technique chart be developed showing appropriate parameters, e.g., kVp, filter, anode track, AEC mode, and density control setting, ~~techniques (kVp and density control settings)~~ for the different breast thicknesses and compositions so that optical densities (OD) within ± 0.15 OD (± 0.30 OD if done before October 28, 2002) of the MOD under AEC testing conditions can be produced.”

Quality Assurance Records

There appears to be a typographical error in the fourth line.

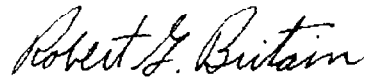
“effectiveness of the corrective actions), safety, and protection employee qualifications to meet assigned quality assurance”

should probably be

“effectiveness of the corrective actions), safety, ~~and~~ protection, and employee qualifications to meet assigned quality assurance”

NEMA is pleased to submit these comments and looks forward to working with the agency.

Sincerely,

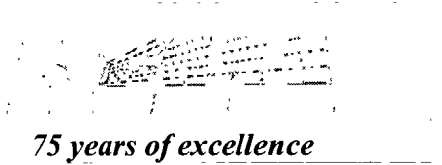


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AEC Performance Testing

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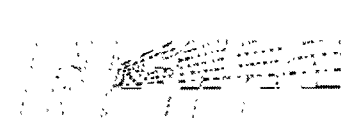
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Topics

- 💡 Definition of “Configuration”
- 💡 Intent of AEC Performance Test



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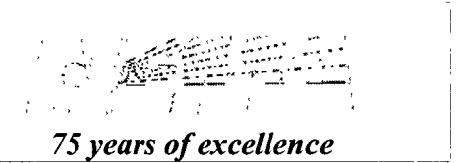
What is a Configuration?

“...all combinations of equipment configuration provided, e.g., grid, nongrid; magnification, nonmagnification; and various target-filter combinations.” 900.12(b)(10)(i)

🔔 “Configuration” is not defined.

🔔 Examples are not consistent.

- Most are clinical choices to achieve specific goals.
- Others are elements of AEC system spanning clinical applications.



What are Configurations?

“The collection of system elements and their geometric arrangement selected by the operator to achieve a specific, clinical imaging purpose.” A proposed definition

💡 Include

- Contact (grid)
- Magnification (non-grid)
- Image receptor size (18 x 24, 24 x 30)

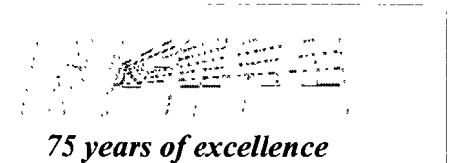
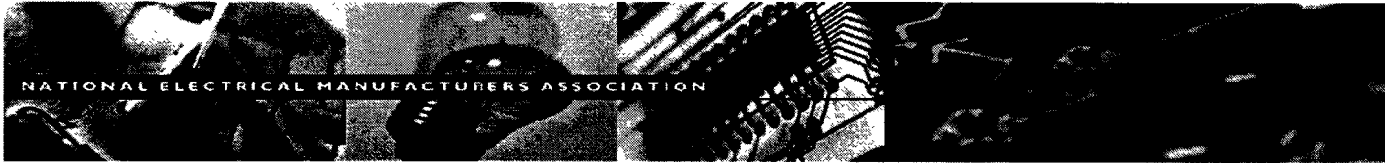
💡 Exclude

- Target-filter combinations



Configuration Consequences

- OD range within configuration = ± 0.15
 - Track-filter switching is element of AEC.
 - System can be calibrated for switching.
- OD range between configurations = ± 0.30
 - Differences of cassette and film speed vs. image receptor size are external to most AEC systems
- Consistent with FDA answers to Questions 4 and 7 of Draft Guidance #6



AEC Performance Test

Is the MQSA AEC performance test an evaluation of the x-ray unit or the total facility capability, i.e., x-ray unit, screens, film, and processor?



AEC - FDA's Intent?

“Because film variability can be eliminated as a source of bias in the AEC performance test, there is no justification for increasing the AEC actions limit ... ”

- Preamble to *Quality Mammography Standards; Final Rule*, Fed. Reg., October 28, 1997.

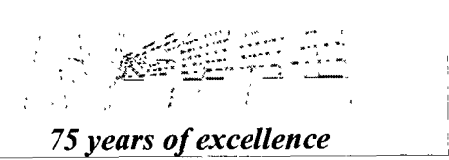
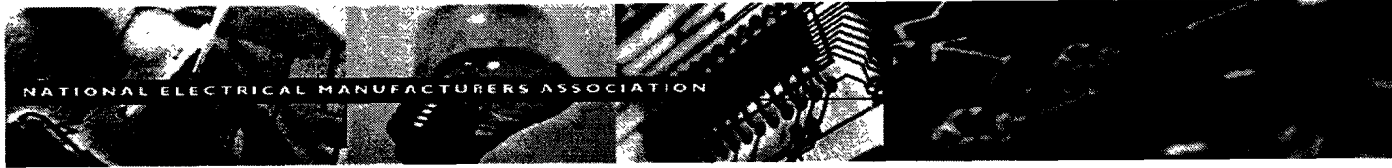
Suggests that FDA intended AEC Performance as a mammography unit test, not a facility test.



AEC - FDA's Intent?

“Because the AEC performance test involves many parts of the imaging chain, the medical physicist needs to make sure that the AEC is the part responsible for the failure. ... problems with the processor, film emulsion or the use of different cassettes ... may lead to a failure that is not the fault of the AEC.” Q. 6, PGHS Draft Guidance #6

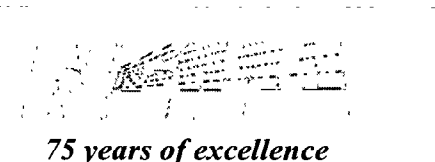
Further suggestion that AEC Performance is a mammography unit test, but short of an explicit statement .



AEC - Film variability

“A density difference of 0.30 [at a density of ~ 1.25] between any two films of the same type from the same manufacturer, exposed and processed together, is a reasonable maximum to be expected from manufacturing variability for films of roughly the same age and storage conditions.”

- in *Recommended Specifications for New Mammography Equipment*, CDC/ACR, June 1995.



AEC - Film variability

“Note that a difference of 0.30 at a density of ~ 1.25 may translate into a bigger difference for clinical films exposed at a greater OD. For example, high contrast mammography films, such as KODAK MIN-R 2000 Film, are frequently exposed at an OD between 1.50 to 1.70 in order to maximize contrast. The density difference at this OD level may be greater due to the increased contrast.”

- Mammography Optimization Guide, Kodak Pub. M3-108, 1999.

AEC - Screen variability

“Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and the minimum optical densities shall not exceed 0.30.”

- 900.12(e)(5)(viii)

AEC - Screen variability

Case Study

Screen Speed Test Results

Cass. ID	Size	OD
5	18 x 24	1.69
2	24 x 30	1.81
7	18 x 24	1.74
9	24 x 30	1.74

Cassettes chosen by physicist to test AEC with 18 x 24 and 24 x 30 image receptors.

Cassettes chosen by field service engineer.

Should the bias in OD introduced by the difference in screen speed be eliminated when testing the AEC?

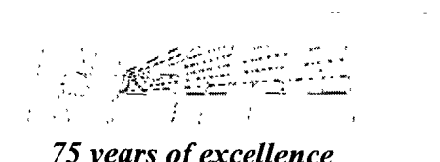


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AEC - FDA's Intent?

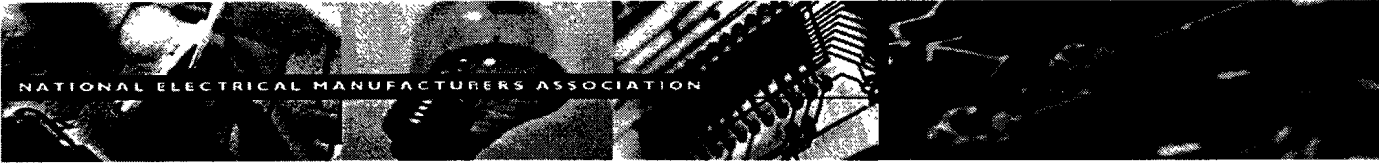
- 💡 Screen variability: 0.3 OD
 - regulated, tested
- 💡 Film variability: 0.3 OD or more
 - not regulated, not monitored
- 💡 Processor variability: mid-density, ± 0.15 OD
 - once-a-day monitoring required
- 💡 AEC Performance: ± 0.15 OD

Is the mammography unit expected to hold ± 0.15 OD limits without control of other variables?



Requests to FDA

- 💡 Develop definition of “configuration.”
 - Include image receptor size
 - Exclude target-filter combinations
 - Apply ± 0.30 OD limit between configurations
- 💡 Clarify intent of AEC Performance Test
 - Apply to mammography unit alone
 - Control of or correction for other variables expected
 - Develop guides to good practice in performing the test



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Thank you