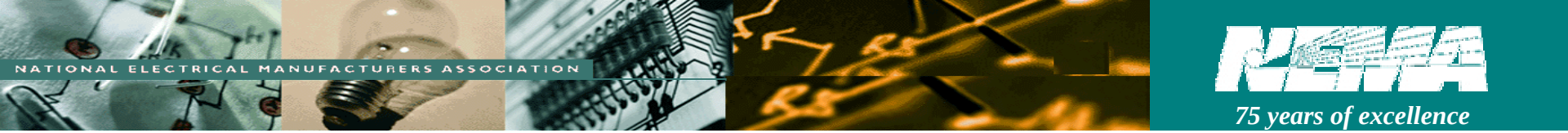


# AEC Performance Testing

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# Topics

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

# 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- Consistent with FDA answers to Questions 4 and 7 of Draft Guidance #6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 Q. 6, PGHS Draft Guidance #6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?**

# 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

# Thank you