It has recently come to our attention that not all medical physicists have been conducting the system artifact test in accordance with the final regulations, e.g., some medical physicists have not conducted the test for all clinically-used target filter combinations. The purpose of this article is to reiterate the test requirements and lay out a course of action regarding FDA's future enforcement of these requirements.

The final regulations (which have been in effect since April 28, 1999) regarding this test are cited below:

**CFR 900.12(e)(5)(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.

To stress this point in the regulations, we repeated it in our Policy Guidance Help System and in the guidance document entitled "Mammography Facility Survey, Mammography Equipment Evaluation, and Medical Physicist Qualification Requirements under MQSA" that has been on our website since Nov. 6, 2000.
Some medical physicists erroneously believe that the final regulations can be met by conducting the test for all targets and filters and not for all target filter combinations. An example frequently cited is a unit that has two Molybdenum (Mo) targets (large and small focal spots) and one Mo filter, and two Rhodium (Rh) targets (large and small focal spots) and one Rh filter. The argument presented by some physicists is that even if the Mo/Rh combination is used clinically, the artifact test needs to be conducted only on the MoMo and Rh/Rh combinations and not on the Mo/Rh combination. They claim that this is justified because repeating the test for the Mo/Rh target filter combination does not reveal any new artifacts that were not revealed by testing the MoMo and Rh/Rh combinations alone.

FDA believes that, based on factual information regarding this unit, some artifacts may be missed if all combinations of targets and filters are not tested.

Because a significant number of medical physicists continue to be under the impression that merely testing all targets and filters satisfies the regulations, we are bringing this issue to the attention of the medical physicists and MQSA inspectors at this time as a reminder that all clinically-used target filter combinations must be tested for artifacts. FDA will provide a grace period through February 2005 to allow medical physicists to modify their testing procedures, as needed.

Any annual physics survey or mammography equipment evaluation conducted on or after March 1, 2005 that does not test all clinically-used target filter combinations will be subject to citation.

Enter - AAPM and ACR
A Teamwork Success Story

AAPM
Don Frey, Pres
Melissa Martin
Jerry White
Lynne Fairbent

ACR
Mike Yester,
Committee Chair
Penny Butler
Pam Platt

And the many medical physicists who rose to the call!
Who may apply

Applicants for Alternatives

- Citation: 900.18(b)(1)(2)(3): Applicants for alternatives.
- (1) Mammography facilities and accreditation bodies may apply for alternatives to the quality standards of section 900.12.
- (2) Federal agencies and State governments that are not accreditation bodies may apply for alternatives to the standards of section 900.12(a).
- (3) Manufacturers and assemblers of equipment used for mammography may apply for alternatives to the standards of sections 900.12(b) and (e).

Discussion:

- Question 1: What process is FDA currently following to arrive at a decision on a request for approval of an alternative requirement?
  - When a request is received, a staff member or members are assigned to review it to determine if it meets the criteria for approval established in 900.18(c). This individual or group may also consult with experts in other parts of FDA, with members of the National Mammography Quality Assurance Advisory Committee, and with FDA’s Office of the Chief Counsel. The end result of this review is a recommendation to the Chief of the Accreditation and Certification Branch that the request be accepted, rejected, or that more information be requested before a decision is made. If the Chief of the Accreditation and Certification Branch agrees, the recommendation is sent to the Director of the Division of Mammography Quality and Radiation Programs for the final decision. The Branch Chief and/or the Division Director may also seek information from additional scientific or legal experts to aid in making their decisions.

- Question 2: How long does this process take?
  - The amount of time required depends upon the complexity of the request. An even more important factor is how completely the applicant addresses the criteria for approval in 900.18(d) and/or how quickly he or she responds to requests for additional information. It has usually been possible to complete the process in 30 days or less but in cases where the original application was incomplete or there were delays in answering requests for additional information, a considerably longer period of time has been required.

Approved Requests for an Alternative Standard

Citation: 900.18(d)(2)(3)(4); (d) Ruling on applications.
- (2) Notice of an approved request for an alternative standard or any amendment or extension thereof shall be placed in the public docket file in the Dockets Management Branch and may also be in the form of a notice published in the Federal Register. The notice shall state the name of the applicant, a description of the published agency standard, and a description of the approved alternative standard, including limitations and conditions attached to the approval of the alternative standard.
- (3) Summaries of the approval of alternative standards, including information on their nature and number, shall be provided to the National Mammography Quality Assurance Advisory Committee.
- (4) All applications for approval of alternative standards and for amendments and extensions thereof and all correspondence (including written notices of approval) on these applications shall be available for public disclosure in the Dockets Management Branch, excluding patient identifiers and confidential commercial information.

Criteria

Citation: 900.18(a)(1)(2)(3): Upon application by a qualified party as defined in paragraph (b) of this section, FDA may approve an alternative to a quality standard under section 900.12, when the agency determines that:
- (1) The proposed alternative standard will be at least as effective in assuring quality mammography as the standard it proposes to replace; and
- (2) The proposed alternative:
  - (i) Is too limited in its applicability to justify an amendment to the standard; or
  - (ii) Offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to the human health; and
- (3) The granting of the alternative is in keeping with the purpose of 42 U.S.C. 263b.
Ruling on Applications for Alternative Standards

Citation:
• 900.18(d)(1): Ruling on applications.
• (1) FDA may approve or deny, in whole or in part, a request for approval of an alternative standard or any amendment or extension thereof, and shall inform the applicant in writing of this action. The written notice shall state the manner in which the requested alternative standard differs from the agency standard and a summary of the reasons for approval or denial of the request. If the request is approved, the written notice shall also include the effective date and the termination date of the approval and a summary of the limitations and conditions attached to the approval and any other information that may be relevant to the approved request. Each approved alternative standard shall be assigned an identifying number.

List of Approved Alternative Standards
1. Conducting the daily processor QC tests when the sensitometer is not available
2. Continuous display of the override status for machines with decompression devices
3. Conducting the weekly phantom image test at facilities with intermittent mammography operation
4. Post exposure indication of the machine pre-selected focal spot and or target material
5. Verification Testing After Certain Modifications of the AEC of Senographe™ 700T, 800T, DMR Mammography Systems
6. Conducting the Mammography Equipment Evaluation After a Software Upgrade Under Medical Physicist Oversight
7. Correction Period When Components of the Senographe™ 2000D FFDM System Fail QC Tests
8. Combined Mammography Medical Outcomes Audit for Multiple Mobile Mammography Units  
9. Separate Assessment of Findings For Each Breast  
10. Correction Period When Components of the Selenia FFDM System Fail QC Tests  
11. Amendment to the Alternative Requirement for the Correction Period When Components of the Senographe™ 2000D FFDM System Fails QC Tests  
12. Modifications in the Assessment Categories Used in Medical Reports  
13. Assessment category for “Post Procedure Mammograms for Marker Placement”  
15. System Artifact Testing of Target Filter Combinations

The approved alternative and the conditions for its use are:  
Software changes or upgrades are considered by FDA to be major repairs, thus the facility must have a mammography equipment evaluation performed after installation of such a change or upgrade.  
The mammography equipment evaluation must be performed and all failures to meet the applicable standards must be corrected before the affected equipment is used for patient examinations. The tests to be included in the mammography equipment evaluation must be specified by the manufacturer. The specified tests must be adequate for determining whether all of the standards of 21 CFR 900.12(b) and (e) that are applicable to the upgrade are met.  
If the tests included in the mammography equipment evaluation are all tests that are performed by the quality control technologist as part of the quality assurance program required by the manufacturer, then the mammography equipment evaluation may be conducted either during an onsite visit by a medical physicist or under Medical Physicist Oversight.  
If any of the necessary tests after the software upgrade are required to be performed by the medical physicist, the mammography equipment evaluation must be performed in its entirety by the medical physicist on site.

Conducting the Mammography Equipment Evaluation After a Software Upgrade Under Medical Physicists’ Oversight  
This alternative standard was approved on May 31, 2002. It defines the conditions under which the mammography equipment evaluations performed after some computer software upgrades may be performed either by a medical physicist on site or under the conditions of Medical Physicist Oversight. If these conditions are not met the mammography equipment evaluation after the upgrade must be performed by a medical physicist on site.  
The original standard is contained within 21 CFR 900.13(e)(10).  
10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a 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 paragraph (b) and (d) 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.

Correction Period When Components of the Senographe™ 2000D Full Field Digital Mammography (FFDM) System Fail QC Tests  
This alternative standard was approved on June 27, 2002. It allows a 30 day period for corrective actions following the failure of specified quality control tests for screen-film systems for which a 30 day correction period is already allowed.  
The alternative standard also divides into two groups the quality control tests whose failure requires corrective action before the failing component is used again during patient examinations. This division makes it clear that when the test failure is related to the acquisition of images only, the review of already acquired images can continue and when the test failure is related to the image review components only, images can continue to be acquired. The alternative was approved for an indefinite period.
Part 2

The importance of careful technique.

A few case studies from which to learn ....

Case 1 - The Hefty HVL

- Equipment Evaluation after tube replacement on Bennett Contour 2000
- 32 kVp Mo/Mo HVL exceeded the permissible kVp/100 + C
- Repeated measurements and found the same problem.
- What could be the problem?

- Possible sources of problem
  - kVp too high
  - Incorrect filter installed
  - Meter malfunction
  - Something else hardening the beam
- Process to solve problem
  - Find an error in my technique
  - Have facility call QSE to correct
  - I always try to eliminate myself as a source of error first

- Look at other HVL data
  - All values for this machine survey are somewhat higher than usual
  - 32 kVp Mo/Mo beyond permissible range
  - 28 kVp Mo/Mo also higher than usual
  - All values higher than last year
- Is Radcal malfunctioning?
  - Re-checked data from previous 3 surveys
  - ESE and AGD look fine at 25.5 kVp, Mo/Mo
- Any indication of incorrect filter?
  - Image contrast looks fine
• Critically examine the experimental set-up
• Compression paddle is only about 20 cm above ion chamber – the upper limit of travel before the machine automatically senses “magnification” mode
• Repeated measurements with Aluminum near x-ray tube port
• HVL is fine, and all other HVL’s lower than

Lessons Learned

1. Maximize distance between Al sheets and the ion chamber
2. Tape Al to tube port
3. …or use magnification paddle
4. Similar problem with
   1. Instrumentarium Alpha IQ
   2. Siemens 3000 Nova
5. Remember to check “Human Factors” first!

Case 2 – Annoying AEC

• During follow-up testing after AEC recalibration
• AEC failure on Lorad M-IV
• AEC selects 27 kVp Mo/Rh in Auto filter mode
• During AEC testing, kVp’s are very high and exposure times are long
**Possible sources of problem**
- kVp too low
- AEC cal file corrupted
- Thickness inaccurate, below "threshold"
- Something else...

**"Threshold" for Lorad M-IV**
- Typically set to ~3.5 cm
- Switches from 100 mA to 30 mA for contact imaging of thin breasts
- An engineering "fix" to problems with early Lorad M-IV's "exposure time too short" for HTC grid motion

**Thicknesses were accurate**
- But somehow, exposure times were long - consistent with lowered mA

**Solution**
- In-house biomed engineers obtained replacement compression paddle from 3rd party source
- Reflective metal strips on back were incorrect, selecting Magnification mode and 20 mA
- AEC Auto filter mode selected kVp for magnification imaging
- Verified by replacing old "cracked" paddle - AEC and kVp OK

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**Lessons Learned**

1. Ask if anything has changed, since last survey, or recent history of problems
   A. Site didn’t mention - assumed we would check out the new paddle as part of our testing
2. Post “Threshold” thickness on operator’s console
3. Review this with RT’s (rarely well understood)
4. Use all our senses (long exposure time could have been a clue)
5. Remember Human Factors - keep in mind the expertise of "QSE"

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**Case 3 - Languishing Line-Pairs**

- **Friday - Routine Annual Survey**
- Near the end of annual survey, asked RT “which hole do you use for magnification”
- RT is confident that “top holes” are used - 1.9x is displayed
- “My recollection is top holes are used only for SBB add-on device”
- Line pair resolution fails for both focal spot sizes, Mo and Rh targets
- Dinner plans in jeopardy, but hopeful for a reasonable solution
Repeat test at 1.8x (mid holes) and 1.5x (bottom holes)
Rh target, small FS LP FAILURE
Consult with department manager
Recommended (though not required) to reschedule tomorrow’s Dx cases
Order 2nd x-ray tube
Got home late, missed dinner with guests, ate at McDonald’s
....paid for it all night

Tuesday AM – Tube arrives, “come at 2 PM”
Bob calls at noon – Trusted service engineer says “come at 4 PM”
--------not a good sign
Dinner again in jeopardy
Engineer assures everything OK
Start at 5 PM – full MEE
At 7 PM, test small FS LP resolution
Rh filter fails
Repeat test 3 times at various magnifications - FAILURE
Consult with department manager
Order 2nd new x-ray tube, move tomorrow’s Dx cases
Engineer orders LP pattern, to test before I arrive next time
Home 10 PM, no dinner (better than McD)

Next tube arrives Thursday
Trusted engineer installs and checks LP resolution, calls Bob and says “OK”
Bob arrives and immediately tests Rh SF LP resolution
FAILS (3 attempts)! But how???
Compares with engineer’s test film
Engineer placed LP resolution pattern in center of FOV, not within 1 cm of CW
Verified difference in technique
GE Engineer says “Mag LP resolution only spec at 1.5x”
Review with manager - lots of good tubes at 1.8x - when NEW
Ordered another tube for “customer relations”
• After 5 x-ray tubes, LP performance is OK at 1.8x
• The cost:
  - Patient and facility inconvenience
  - Time and $$ for GE
  - 4 trips @ 200 miles RT each
  - 4 trips, but only charged for 2
  - 3 days of destroyed schedule
  - Bad food, stiff back - Priceless!
• Casual discussion at AAPM - another colleague with similar problem with Rh/Rh LP resolution

**Lessons Learned**

1. When re-testing, evaluate failed component FIRST
2. Remember that a trusted service engineer may not be experienced with LP resolution (or other MP tests)
3. ALWAYS include Human Factors as cause of discrepancies
4. Position of LP test pattern affects results - line-focus principle
5. Possible problems with Rh targets
6. "Never exceed 1.8x (clinically) on DMR" - GE
7. GE only specs LP resolution at 1.5 x (MQSA OK)
8. Communicate with manager, use "customer satisfaction" justification when necessary
9. Plan better, or bring a sandwich
Prep for a new GE 2000D or DS

- **ACR Phantom Imaging**
- GE requires NO CONTRAST DISC
- If disc was glued to the cover plate, site will need a new cover plate

GE 2000D

- **CNR Test**
  - ROI inside and adjacent to the largest mass

Fischer Senoscan

- **CNR**
  - ROI inside and adjacent to Contrast Disc

Lorad Selenia

- **CNR**
  - Use contrast disc
Siemens Novation DR

- CNR
  - Use contrast disc

Review Workstations

- Alert service engineer to your plan to test calibration of monitors
- Monitors are not factory calibrated
- Be sure they have the tools and procedure to calibrate, if needed

Got Questions?

- FDA’s Policy Guidance Help System (PGHS)
- The downloadable PGHS (with "old search engine" option) is best

Late Breaking News from FDA
Changes to the Toll-free MQSA Hot Line

- E-mail from Kathy Franke, Chief, Accreditation and Certification Branch DMQRP
- “… although we are (via the pilot) eliminating a real-time response to incoming calls, we are nevertheless retaining the voice response for the hotline with a timely turnaround time for follow up.

In undertaking this pilot, we are attempting to direct the community to the sophisticated website and policy guidance help system (PGHS), which contains the majority of answers to the questions that we receive through the hotline.

Also, as indicated in our email to everyone, we have made provisions for those callers who are unable to locate their answers via the PGHS.”
“Since the early days of MQSA, our program has been unique and offered many services unknown in other FDA program areas. Essentially, a one-of-a-kind arrangement. However, we are now at a point in our history where we need to assess our practices (as you do) and how we spend our resources in this arena.

I am sure ACR can appreciate the importance of self-assessment and our goal of being good stewards of our resources, particularly in light of the significant, long-term investment (time and money) dedicated to creating the PGHS and educating facility personnel over the last 12+ years.”

“We are naturally sensitive to the inconvenience this pilot may cause to some facility personnel. Yet, we believe that this pilot is worthwhile because it allows us to assess the appropriateness of maintaining our current approach -- or modifying it as described in our email. We, of course, will be judicious in our ultimate decision making based on the outcome of the pilot and the factors you addressed in your remarks.”

How many site QC RT’s have internet access?

So, don’t recommend calling FDA’s Help line if you need immediate help. Contact FDA if you think this is a problem.

ACR News...

ACR has recently applied to FDA to accredit Siemens Novation FFDM

Inner city and rural access through Mobile mammography...

Medical Physicists can do valuable volunteer work
Summary

1. FDA Approved Alternate Standard for Artifact Testing
2. 3 case studies illustrate problems encountered
   - Annual surveys
   - Equipment Evaluations
3. FFDM preparation and CNR test comparison
4. News from FDA and ACR
5. You too can help people in need...