



Docket No. 00D-1497
Dockets Management Branch (HFA 305)
Division of Management Systems and Policy
Food and Drug Administration
5630 Fishers Lane, room 1061
Rockville, MD 20852

2983 '00 DEC 18 P1:32

Enclosed are the comments of the American College of Radiology on The Mammography Quality Standards Act Final Regulations Document # 4. Please contact me if you wish to discuss any of the comments, or if we can assist in explaining our rationale more completely. I can be reached at (703) 716-7550.

Sincerely,

Lynne A. Fairobent
Director, Federal Programs

cc: Charles Finder, FDA
Penny Butler, ACR
Pam Wilcox-Buchalla, ACR
Carla Morrissey, ACR

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Comments
Compliance Guidance Document #4 for the
Mammography Quality Standards Act Final Regulations

Prepared by:
The American College of Radiology
December 12, 2000

The following comments are offered to enhance the transition to the final regulations.

PERSONNEL

Page 5, - Medical Physicist 21 CFR 900.12 (a)(3)(i), *Initial qualifications*

The ACR agrees with the FDA in this guidance. Not requiring an individual with a degree in physics (who typically has a sufficient number of hours in order to obtain the degree) to document his or her semester hours in physics is reasonable and eliminates unnecessary paperwork.

EQUIPMENT

Page 6, 21 CFR 900.12 (b)(8)(i) - *Application of compression*

The ACR does not believe that providing fine compression with a light tap on the foot pedal, such as provided by the GE 500T and the 600T machines, is adequate. The response time is too slow and the movements are too large (when the paddle movement starts to respond, the movement is gross, not fine).

Page 7, 21 CFR 900.12 (b)(10) - *Automatic exposure control (AEC)*

In order to prevent confusion in the answer to the 2nd question (page 8), ACR recommends removing the word "nongrid" and changing "magnification" to "magnification without a grid" in the parenthetical expression. Facilities rarely, if ever use a "nongrid" technique any more. However, magnification techniques are almost always performed without a grid.

For units that have separate AECs for different bucky assemblies, the guidance should point out that the test must include evaluation of the separate AECs (e.g., Siemens Mammomat 3).

MEDICAL RECORDS

Page 10, 21 CFR 900.12(c)(4) *Recordkeeping*

The ACR agrees with the FDA's guidance that, for purpose of transferring films, the facility must be able to provide hard copy films of primary interpretation quality. Considering the current costs of digital mammography equipment, it will be a number of years before most of the mammography facilities in the United States will have the capability of accepting and viewing a soft copy image at the appropriate image quality for primary interpretation. Furthermore, in our mobile society, it is essential that women have the capability to transfer their images to new mammography centers in order to provide their physicians with adequate medical history.

QUALITY CONTROL (QC) TESTS - GENERAL

Page 10, 21 CFR 900.12(d)

The ACR agrees with the FDA's guidance that allows medical physicists to use their experience and professional judgment to determine what constitutes "applicable tests" and "equipment requirements" for equipment evaluations after major repairs.

Some QC test failures do indeed require repair before being used on patients, but some require repair only within 30 days. The first sentence in the answer to the 2nd question ("After the adjustment or repair has been completed, the test(s) have to be repeated and must show that the unit is within the appropriate action limit before it can be used on patients.") is misleading, unless the question specifically refers to a QC test that requires that the unit not be used on patients or to an equipment evaluation performed after a major repair. This answer needs to be clarified.

Page 11, Table: Required QC Tests* for Facilities Using Multiple Units & Screen-Film Combinations

Uniformity of screen speed and screen-film contact:

It would seem more appropriate to test the film type with the screen type with which it is typically used, rather than one film type for all. For example, one combination might be used with one AEC setting, and another might be used with a different AEC setting. It is not necessary to require uniformity between types of receptors as long as they are sufficiently differentiated in use, appearance and by policy/procedure.

AEC performance-kVp & thickness tracking:

The table indicates to use "One screen-film combination (typically used with the unit)". This should read "*All screen-film combinations clinically used under the conditions they are used.*" For example, a faster screen-film combination may be routinely used only for magnification studies. It is important that the magnification AEC performance be tested as it is used clinically. Testing only one screen-film combination gives no assurance that the AEC is calibrated properly for the others.

Weekly Quality Control Tests

FDA should encourage the replacement of the phantom cover plate when they suspect that it is the cause of artifacts, so that the facility can be uniform in its testing process with other facilities. This could be essential when submitting the images to the accreditation body for evaluation. The AB's reviewers do not have the luxury of seeing the cover plate and knowing that the artifact seen on the image was caused by flow/damage on the cover plate. Such a replacement can hardly be considered a burdensome expenditure.

Page 14, 21 CFR 900.12(e)(4) - Compression Device Performance

The ACR recommends rewording the parenthetical statement in the answer to the 1st question as follows: (*such that the image quality is adversely affected*). The problem is that one doesn't always know what is missing.

QC TESTS - ANNUAL

Page 15 - 16, 21 CFR 900.12(e)(5)(i) - Automatic Exposure Control Performance

The answer to the 2nd question states that the medical physicist needs to test AEC performance only in the contact configuration during the annual physics survey. The ACR recommends that the AEC also be tested at least for a 4-cm phantom in magnification mode in the standard configuration of small focal spot and no grid. The magnification mode should be tested because the small focal spot results in much longer exposure times affecting dark noise and reciprocity failure, the different geometry and lack of grid result in different scatter conditions affecting the response of the AEC detector, and most units use a different calibration table for magnification mode. Recommended action limits can be addressed as was done in the first question for thicknesses outside of the 2 – 6 cm range by using a technique chart.

Page 16, 21 CFR 900.12(e)(5)(iv) *Beam Quality and Half-Value Layer (HVL)*

The ACR agrees with FDA's guidance to include the compression paddle in the x-ray beam during HVL measurements. The rationale is that the HVL is used in the determination of average glandular dose for the typical breast and the paddle is always in place during these clinical exposures. However, if the dose is to be determined for other procedures such as needle localizations where the paddle typically has a missing center, HVL measurements should be made without the paddle in place. It may also be useful to note that NEMA recommends that the tests be done without the compression paddle in place.

MEDICAL PHYSICIST'S ANNUAL SURVEY

Page 20, *Mammography Equipment Evaluations* – Table: Medical Physicist Involvement in Equipment Repairs

This is an excellent table, which is something both facilities and physicists have been needing. The ACR has only a few comments:

Film type change:

This should be changed from the "MP involvement optional" category to the "MP oversight" category because a film type change may involve a change in system speed (requiring AEC adjustment) which in turn will cause a change in the average glandular dose. It may also cause a change in contrast and phantom image score, and may be more susceptible to processor artifacts. All of the issues surrounding a film change make MP involvement mandatory, not optional.

Radiation output internal adjustment:

Several of our medical physicist committee members had no idea what this meant. Since it is marked as a major repair requiring "MP conducts evaluation in person", clarification is essential. Perhaps FDA could use a more recognizable term, or else explain it in a footnote.

High voltage generator adjustment:

ACR recommends that MP oversight, rather than an in-person evaluation, is all that is necessary.

MAMMOGRAPHY MEDICAL OUTCOMES AUDIT

Page 22, 21 CFR 900.12(f)(1) – *General requirements*

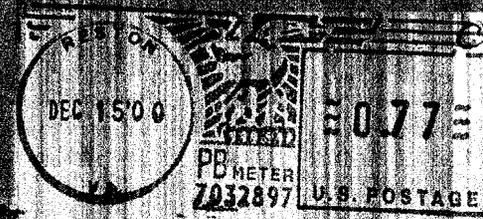
The guidance that FDA provides defining “positive” mammogram conflicts with that provided by the ACR. Previous FDA guidance has indicated that positive mammograms are those with final assessment categories of “Suspicious” or “Highly suggestive of malignancy.” The ACR specifies that for medical outcomes audit purposes any mammogram characterized as BI-RADS™ category 0, 4 or 5 is positive, and any characterized by BI-RADS™ category 1,2 or 3 is negative. Thus a mammogram coded as BI-RADS™ Category 0 for which cancer is discovered within 12 months would be a true positive. In the glossary of statistical terminology: “A *positive screening mammogram is one for which a recall is initiated (BI-RADS™ category 0) or one that requires tissue diagnosis without further assessment (BI-RADS™ category 4 or 5).*” Also within the glossary of terminology: “A *positive diagnostic mammogram is one that requires a tissue diagnosis (BI-RADS™ category 4 and 5).*”

Collection of these data (BI-RADS™ category 0, 4 and 5) allow measurement of practice outcomes by providing evidence pursuit of the three major goals of screening mammograms as stated in the BI-RADS:

1. Find a high percentage of cancers that exist in a screening population (measurement: cancer detection rate, sensitivity).
2. Find these cancers within an acceptable range of requests for recall (Category 0) and request for biopsy (Category 4 or 5), in an effort to minimize cost and morbidity (measurement: recall rate and positive predicative value).
3. Find a high percentage of small and node-negative cancers, which are likely to be more curable (measurement: rates of minimal cancers found, axillary lymph node positivity).

American College of Radiology (ACR). Illustrated breast imaging reporting and data system (BI-RADS™). Third Edition. Reston [VA]: American College of Radiology: 1998, page, 216

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