

#### **Outline**

- Purpose of the SBB procedure
- Purpose of ACR SBB Accreditation Program
- · Historical context of ACR SBBAP
  - SFM Mammo era
  - MQSA
  - SBB procedures: Radiologists and Surgeons
- · Review of SBB QC activities
  - Modern interpretations on a "Classic" QC manual
- ACR SBBAP Scheduled On-Site Survey
- · Summary and Conclusion

#### **Disclosures**

- · Original co-author of ACAR SBB QC Manual
- Member of ACR Sub-Committee, Breast X-ray Imaging Physics
- ACR On-site Reviewer for SBBAP
- Thanks to
  - Maynard High, PhD
  - Ingrid Reiser, PhD

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# **Learning Objectives**

- Understand the purpose and historical context of ACR SBBAP
- Understand ACR SBBAP expected QC activities and accreditation submission requirements (and potential pitfalls) that pertain to the medical physicist
- Be aware of FAQ "updates" to the 1999 ACR SBB QC Manual
- Understand the process of a Scheduled On-Site Survey for SBBAP facilities

The American Critiqu of Edolology, with more than 30,000 members, is the principal organization of radiologion, reduction medical inedical physicians in the United States. The College is a suspend professional society whose primary purpose are to advance the science of calculage, susperve realistings cervices to the patients, study the societicements superior of the practice of radiology, and encourage continuing observation for radiologies, realisting controls, possible physicians, and personal practication as stilled performance facility.

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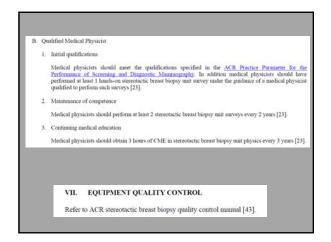
Each practice parameter and technical standard, representing a policy statement by the College, has undergoor a theorogic concessor poccess in which it has been subjected as extraouve review and approved. The practice parameters and reducing standards recognize that the softe and effective use of diagnostic and theresports endolling purpose specific remains a solic and the softe document. Reproduction or modification of the published parameter and technical standard by those entities not providing these services is not authorized.

Revised 2014 (Resolution 6)

ACR PRACTICE PARAMETER FOR THE PERFORMANCE OF STEREOTACTIC-GUIDED BREAST INTERVENTIONAL PROCEDURES

#### PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care<sup>3</sup>. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.





# **Requirements for SBB**



- Image Quality comparable to Mammography
- Acceptable dose
- · Localize with millimeter precision
- Withdraw biopsy sample

#### Who remembers life in 1999?

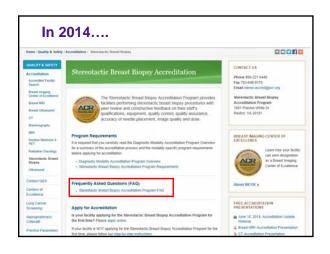


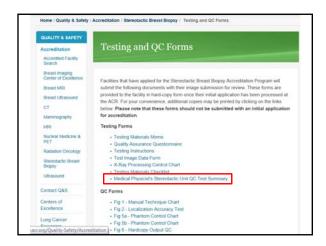
- Average ticket price, Boston Red Sox: \$28.33
- Movie ticket: \$5.06
- NBA All-Star game: cancelled (NBA lockout)
- The Soprano's First season (HBO)
- MQSA Final regs: Equipment requirements effective: min mR/sec, two size Bucky's, AEC position indicator and AEC performance, etc.
- FFDM: a research concept (resolution concerns)
- Bob still had dark hair... some in grade school?

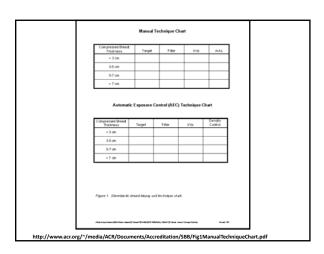
http://www.dailyfinance.com/2009/12/29/then-vs-now-how-prices-have-changed-since-1999/

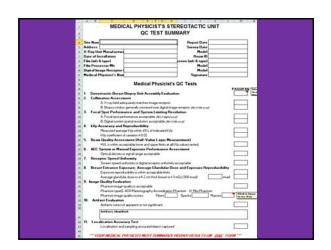
# It all started with digitizing film images...

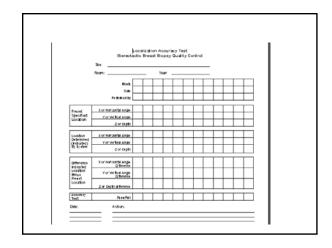






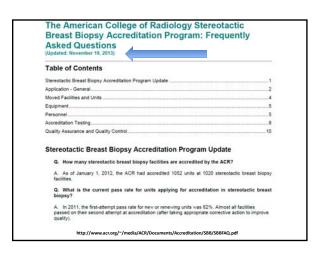






QC Forms

• Fig 1 - Manual Technique Chart
• Fig 2 - Localization Accuracy Test
• Fig 5a - Phantom Control Chart
• Fig 5b - Phantom Control Chart
• Fig 6 - Hardcopy Output QC
• Fig 7 - Visual Checklist
• Fig 8 - S-F Repeat Summary
• Fig 9 - Digital Repeat Worksheet
• Fig 10 - Digital Repeat Summary
• Fig 11 - Daily and Weekly Checklist
• Fig 12 - Monthly Checklist



#### **State Requirements for SBB**

- · MQSA does not apply to SBB units
- · Some states have implemented their own requirements



GUIDE FOR A QUALITY ASSURANCE PROGRAM FOR FACILITIES PERFORMING STEREOTACTIC BREAST BIOPSY

### Manufacturer **QC Testing Recommendations**

ACR SBBAP defers to OEMs -may recommend tests specific to the unit.





#### **FAQ**

- Q. We have a mammography unit that is used solely for stereotactic breast biopsy. The unit is not MQSA certified. During the course of these procedures, we take mammographic images. Because our unit is not MQSA certified, what restrictions exist on the mammographic images we may perform during such procedures?
- A. Because stereotactic breast biopsy is currently excluded from FDA regulation, units that are used solely for stereotactic breast biopsy do not have to be MQSA certified. However, these uncertified units must not be used to perform conventional mammographic examinations. Uncertified units may be used to produce mammographic images only if they meet all of the following conditions:
- 1. The mammographic images obtained are an integral part of the stereotactic breast biopsy
- procedure.

  2. Facilities must not bill separately for these mammographic images. They must bill only for the
- Facilities must not bill separately for these mammographic images. They must bill only for the stereotactic breast biopsy procedure. If the mammographic images obtained as part of the stereotactic breast biopsy procedure result in the cancellation of the procedure (e.g., lesion or calcifications no longer seen, calcifications are determined to be in the skin), the facility must not report nor bill the attempted procedure as a mammogram, but rather as a canceled procedure. If the procedure is canceled for reasons described in 3, FDA strongly recommends that the findings (or absence of findings) be confirmed by an immediate follow-up study performed on an MQSA-certified unit. See the FDA Policy Guidance Help System for more information.

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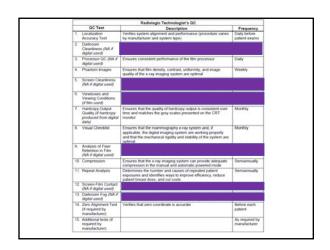
#### **FAQ**

- Q. May our Physician's Assistant independently perform stereotactic breast biopsy procedures at our accredited facility?
- A. No. Only qualified physicians may independently perform stereotactic breast biopsy procedures at facilities accredited by the ACR.
- Q. May our Radiologist's Assistant independently perform stereotactic breast biopsy procedures at our accredited facility?
- A. No. Only qualified physicians may independently perform stereotactic breast biopsy procedures at facilities accredited by the ACR.

# How to Order Manual

https://shop.acr.org/Default.aspx?TabID=55&ProductId=631





# **Localization Accuracy**



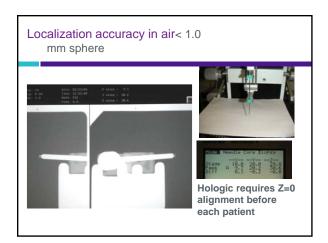
- Closed loop system test
- Position needle to a known coordinate
- Digitize position of needle tip
- Targeting software calculates position of needle tip
- Coordinates should be identical
- $\pm$  1.0 mm sphere
- Procedure varies by OEM

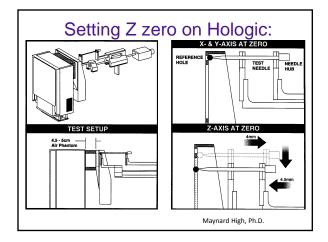
# Zero Alignment Test



- · Perform before each patient
- Verify that zero coordinate is accurate
- Assures that stereotactic unit is not improperly installed
- If required by manufacturer









#### **FAQ**

		-	
	Computerized Imaging Reference Systems, Inc.	Gammex, Inc.	Fluke Biomedical, RMS
Model #	CIRS Model 015	Gammex Model 156 Gammex Model 156D	Nuclear Associates Model 18-220 Nuclear Associates Model 18-250
Phone #	(800) 617-1177 or (757) 855-2765	(800) GAMMEX-1	(800) 850-4608
Website	www.cirsinc.com	www.gammex.com	www.flukebiomedical.com/rms

At least 2 ACR-trained medical physicist phantom image reviewers will score the image. The ACR evaluation criteria are outlined in the 1999 ACR Stereotactic Breast Biopsy Quality Control Manual<sup>3</sup>. The minimum scores required to pass accreditation will depend on the type of phantom and image recording system:

Recording	ACR Mammography Phantom			Mini Digital Stereotactic Phantom		
System	# Fibers	# Speck Groups	# Masses	# Fibers	# Speck Groups	# Masses
Digital	5.0	4.0	3.5	3.0	3.0	2.5
Screen-Film	4.0	3.0	3.0	2.0	2.0	2.0

Facility personnel must expose the ACR-supplied dosimeter at the same time the phantom image is produced. The average glandular dose may not exceed 300 mrad (3 mGy).

#### Hardcopy Output Quality



- Mammo QC sufficient, for printers also used for digital mammography
- Consider printing phantom image



#### **FAQ**

- Q. Our facility has a mammography unit with an add-on stereotactic biopsy device. Should we shoot the phantom the same way we usually do for the mammography unit?
- A. No. In order to expose the phantom, you must set up the equipment with the stereotactic biopsy device in place. Please refer to the <u>Testing Instructions</u>.
- Q. We have a prone stereotactic breast biopsy table. May we tape the phantom to the breast support when we produce the images for image quality evaluation?
- A. Yes. However, be careful not to cover the test objects with the tape.

#### **Visual Checklist**

- Use ACR checklist or equivalent
- Lights, switches, motion, accessories
- Customize for your machine/room
- Documentation (date, initials)



#### **Repeat Analysis**



- Count repeated and rejected film by category and tabulate
- · Evaluate semi-annually, not quarterly
- Use a log of images repeated
- Document *analysis* and *corrective action* even if your repeat rate is low
- Repeat rate will typically be higher than for mammography



# STEREOTATIC BREAST BIOPSY DIGITAL SBB

#### REPEAT ANALYSIS WORKSHEET

(For each case performed, document any repeated exposures that required the patient to have additional dose beyond that of a "perfect" exam)

Six month period

#### **FAQ**

Q. I have a Hologic MultiCare Platinum stereotactic breast biopsy unit. The manufacturer specifies a maximum compression force of only 12-15 lbs under power drive. Is this acceptable?

A. Yes, The 1999 ACR Stereotactic Breast Biopsy Manual recommends a maximum compression force of at least 25 lbs (and between 25 to 40 lbs under power drive). Although the Hologic MultiCare Platinum's automatic compression only reaches a maximum of 15 lbs, manual compression and provide nearly 30 lbs of compression force. Your facility should watch to see that these numbers do not change significantly over time (both during compression and over the years), and that the compression meets the manufacture's specifications.

-		dical Physicist's System Performance Evaluation		
QC Test		Description		
	Stereotactic Breast Biopsy Unit Assembly	Ensures that the mechanical components of the system are reliable and safe for patient use		
2.	Collimation Assessment	Ensures that the x-ray collimation does not allow significant radiation to extend beyond the edges of the image receptor and that the biopsy window aligns with the x-ray field		
3.	Focal Spot Performance and System Limiting Spatial Resolution	Ensures that the focal spot performance is adequate to minimize geometric blur in the image, and that the system-limiting resolution is adequate for the imaging requirements of the procedure		
4.	kVp Accuracy and Reproducibility	Ensures that the indicated peak x-ray energy is accurate and reproducible, so that consistent contrast may be maintained		
5.	Beam Quality Assessment (Half-Value Layer Measurement)	Ensures that the x-ray beam is sufficiently penetrating to minimize patient dose, but not so penetrating that contrast is reduced		
6.	Automatic Exposure Control (AEC) System or Manual Exposure Performance Assessment	Assesses the performance of the system's AEC or manual techniques regarding appropriate film optical density or detector signal levels over a range of breast thicknesses		
7.	Receptor Speed Uniformity	Ensures that intensifying screens are adequately uniform in speed or that the digital detector is adequately uniform across its entire useful area		
8.	Breast Entrance Exposure, Average Glandular Dose and Exposure Reproducibility	Ensures that breast radiation doses are adequately low to protect the patient and sufficient to maintain adequate image quality		
9.	Image Quality Evaluation	Ensures that image quality is consistently high enough to meet the demands of the procedure		
10	. Artifact Evaluation	Detects the presence of artifacts, isolates their sources and ensures that they are eliminated or minimized		
11	Localization Accuracy Test	Ensures the accuracy of the localization system, including needle position, stereo position calculations and the user interface		

## **Compression Force**



- Bathroom scale or compression gauge
- Measure maximum compression in manual and power modes
- The scale should read 25-40 pounds in automatic mode
- Documentation





Localization Accuracy (Gelatin Phantom)

- Performed annually by technologist under supervision of medical physicist
- Position gel-type phantom
- Image, target and sample
- Look for systematic "work-arounds"
- · Result: was the lesion collected?
- Asks the RT to go beyond her normal scope of work

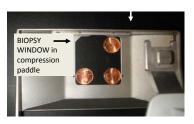


#### **Assembly Evaluation**

- · Free-standing unit is mechanically stable
- All moving parts move smoothly, without obstructions to
- Compressed breast thickness scale is accurate to  $\pm$  0.5 cm, reproducible to ± 2 mm
- Patient or operator is not exposed to sharp or rough edges or other hazards
- Operator technique charts are posted
- Operator protected by adequate radiation shielding



#### **Hologic Collimation** Assessment:



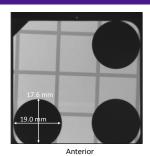
#### Collimation

- · X-Ray Field should extend beyond IR on all 4 sides
- X-ray Field should extend < 5 mm on any side (in plane of image receptor)
- · Note: X-rays beyond the digital image receptor will not be seen on the monitor
- · Does the biopsy window align with the image field of view?



### **Hologic Collimation Assessment: Digital Image**

- Measure visible diameter of coin with TOOLS/CALIPERS.
- Anterior missing image is 19.0 - 17.6 =1.4 mm
- Should be <5 mm</li>



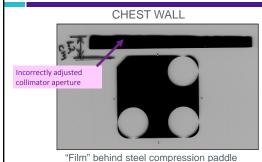
# **FAQ**

- Q. More and more often, facilities that have digital stereotactic breast biopsy equipment have gone totally filmless, removing all chemical processing. How can I best perform the collimation assessment when wet processing of film is unavailable?
- A. Several alternatives to standard screen-film and processing could be used for this test:
  - 1. CR cassettes may be substituted for screen-film cassettes
- ISP GAFCHROMIC XR-QA film is a self developing radiochromic film. This film may be cut to size and exposed directly without the need of a cassette.
   Polaroid Corporation provides sheet film that can be adapted for this use.

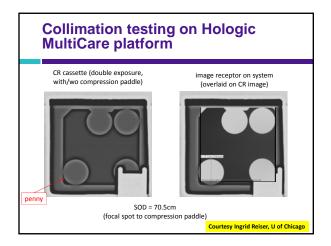
A revised test equipment list is given below:

Tape
One or two mammography screen-film cassettes and sheets of mammography film,
OR
ISP – GAFCHROMIC XR-QA cut to appropriate size,
OR

# **BUT...** how about the X-Ray Field?



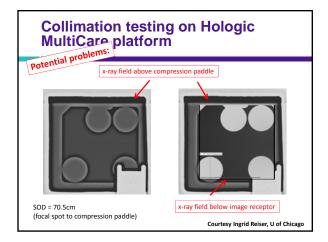
shows full extent of x-ray field.

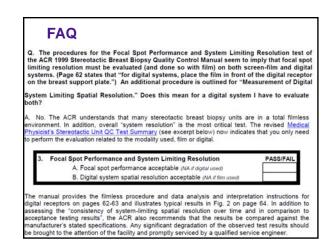


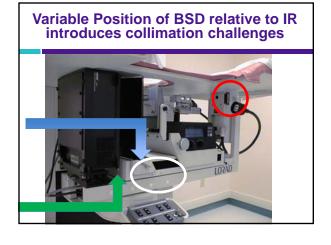
### Focal Spot Size Performance - System Limiting Resolution

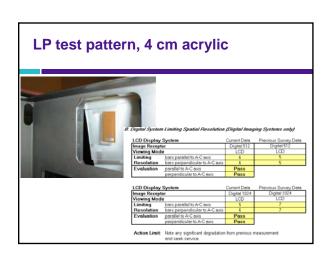
- Line Pair Test Pattern
- Use film (x-ray machine)
- Technique, clinical kVp
- Scoring the image
   Lines distinct, correct # over
  any part of pattern











# kVp Accuracy – Reproducibility HVL

- · Substantially same as Mammo (except gravity!)
- HVL minimum = kVp/100
  - No compression paddle in the beam
- · Calibration challenges
  - Diode systems typically calibrated with compression paddle (or Al "equivalent")
  - May alter energy spectrum and affect results of diode based systems
  - Know your detectors!



## **Uniformity**

- Image a uniform phantom
- Follow manufacturer's recommendations



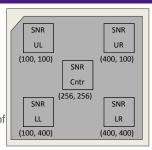
# **AEC System Performance**

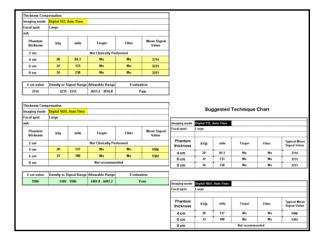
- · AEC available on all newer digital SBB units
- · Performance Capability
  - -Record signal level as function of thickness and technique
- · Monitor exposure time
- Performance Capability (4,6,8 cm)
- · Provide suggested technique chart



# Digital Receptor Uniformity: Hologic Protocol

- 28 kVp
- mAs for DSV# =4000
- Measure SNR's with <u>TOOLS/STATS</u> at specified locations.
- 32 x 32 pixel ROI –set with trackball.
- Hologic spec +/-20% of SNR(center).





#### **FAQ**

Q. The Stereotactic Breast Biopsy Quality Control Manual's Digital Receptor Uniformity Test calls for the SNR value at the corners of the image field of a uniform absorber to be within ± 15% of the center. Our Lorad/Hologic stereotactic breast biopsy table fails this test at 2 of the 4 corners. Our Lorad service engineer referred me to their 2/17/95 protocol for this test. It calls for obtaining the SNRs using 32x32 ROI boxes centered well away from the corners of the 512x512 image. (These coordinates are: 100,100; 100,400; 400,100; and 400,400.) Under these conditions, the unit passes. Is it acceptable to follow the manufacturer's protocol in this case?

A. Yes, It appears that many Lorad-based systems exhibit a signal intensity gradient at one or more edges of the field, which leads to a SNR gradient. Since the non-uniformity occurs only at the edge of the field, it should not compromise patient imaging. Also, it is a gradient, not isolated inhomogeneities that might be mistaken for abnormalities. Throughout the Stereotactic Breast Biopsy Quality Control Manual, we have consistently deferred to manufacturer's specifications in the absence of hard data on how performance variations might affect image quality in many areas. Therefore, one can accept the manufacturer's test conditions and action limits.

#### **FAQ**

That being said, it may be possible to improve the uniformity on your Lorad system. Some medical physicists have found, and Lorad engineers have confirmed, that the gradient problem may arise because of the way flatfielding (a service engineer's task) is done. The digital image receptor is "flatfielded" without the steel compression paddle (which is also an X-ray beam-limiting aperture) in place to allow calibration of the image receptor to its edges. However, in phantom testing and in clinical use, the compression paddle/beam aperture is always in place, and the resultant reduced-size X-ray beam may have a different symmetry with respect to the edges of the receptor than when it was flatfielded. This effect can be minimized if the collimation at the X-ray tube is adjusted so the X-ray beam is larger than the compression paddle aperture by precisely the same amount on each of the 4 edges. Lorad recommends between 5-10 mm for this margin.

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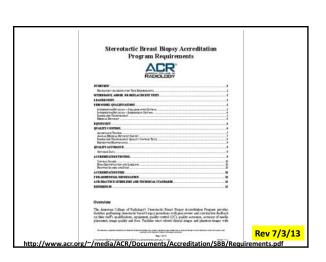
#### **Artifact Evaluation**

Unwanted irregularity not caused by structures of interest

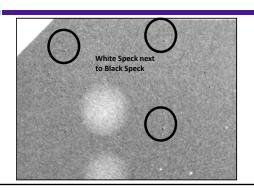
#### Causes (Digital)

- -Digital Image Receptor
- · Dust (camera, screen, lens, mirror)
- Pixel defects (dropouts)
- Non-uniformities (light pipe stucture, vignetting, linear shading)
  - corrected by white-fielding
- Clipping (dose too high)





#### "Moved" Dust Artifacts



#### **FAQ**

Q. We did not pass accreditation because our technologists selected and submitted the wrong images. May we appeal the decision and submit new cases?

A. Although you may appeal the decision, you may not submit new cases. During accreditation review, the ACR reviewers assume that the submitted cases were reviewed by the modality's supervising physician (as specified in the <u>Testing Instructions</u>) and are examples of your best work. Consequently, during an appeal, you may only submit the original images with the original ACR labels.

Q. We did not pass accreditation because our technologist did not submit all required images and provided insufficient information with the images that were submitted. May we appeal the decision and submit the rest of the required information?

A. Possibly, Please call the Breast Imaging Accreditation Programs at (800) 227-6440 for further guidance on your specific situation. However, any image/film that does not include the patient and facility ID will fail.

#### If site does not pass...

- First time
  - Option to Appeal, review by senior reviewer
  - Withdraw
  - Repeat
- · Second time Reinstate
  - Appeal
  - Submit CAP
  - Re-submit all testing materials

#### **SOSS** process

- Radiologist Radiologist: case review
- RT RT: Credentials, submission docs
- MP-MP:
  - 2 most recent Annual Survey reports
  - Review report, test results
  - Acquire new phantom, review scoring
- MP-RT: Review RT QC
- Initial verbal report
- · Final report and resubmission

#### If site does not pass Reinstate Cycle (third attempt)

- Scheduled On-site Survey (SOSS)
  - Radiologist
  - Medical Physicist
  - Technologist (ACR staff)
- Corrective Action Plan
- Pre-test images
- Reinstate

#### **Recommended steps for success**

- Timely annual MP surveys (<14 months)</li>
- · Include RT QC Program review
- · Up to date credentials
- Offer to review phantom images before ACR SBBAP submission
- · Expose dose strips, if site is unsure
- · Check technique factors
  - Submitted images match yours
  - Dose strip image same as others
- · Critically score phantom images

#### **FAQ**

#### Q. My facility did not pass accreditation. May we appeal the decision? If so, what's involved?

- A. Yes. Facilities that receive a deficiency or a failure may appeal the determination in writing within 15 days of the date of the final report. You must send the original images for all of the submitted cases in the category that did not pass along with a letter describing your reason for appealing. Only those images reviewed for the original determination (and having the original labels) will be considered during the appeal evaluation. These will be forwarded to an arbitrator (a reviewer who did not participate in the initial review) with a copy of the previous reviews and the appeal elater written by the facility. No other images will be sent to the reviewer for consideration in the evaluation. The arbitrator's determination will be final.
- Q. We did not pass accreditation because our technologists selected and submitted the wrong images. May we appeal the decision and submit new cases?
- A. Although you may appeal the decision, you may **not** submit new cases. During accreditation review, the ACR reviewers assume that the submitted cases were reviewed by the modality's supervising physician (as specified in the <u>Testing Instructions</u>) and are examples of your best work. Consequently, during an appeal, you may only **submit the original Images** with the original ACR labels.

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