The American College of Radiology Stereotactic Breast Biopsy Accreditation Program: Frequently Asked Questions

(Revised: September 7, 2017; updated questions in red)

Table of Contents

Application - General .......................................................................................................................... 1
Moved Facilities and Units .................................................................................................................. 3
Equipment ......................................................................................................................................... 4
Personnel ............................................................................................................................................ 4
Accreditation Testing .......................................................................................................................... 7
Quality Assurance ............................................................................................................................... 8
Quality Control ..................................................................................................................................... 8
Breast Imaging Centers of Excellence ................................................................................................. 13

Application - General

Q. Where can I find out if my state currently requires stereotactic breast biopsy accreditation?

A. You can check with your state's department of radiologic health for this information.

Q. Must mammography units that are used exclusively for stereotactic breast biopsy be certified under MQSA?

A. Maybe. Although these procedures do involve radiography of the breast, stereotactic breast biopsy is currently exempt from MQSA regulations. However, any mammography unit or personnel involved, even occasionally, in routine screening or diagnostic mammograms must meet MQSA quality standards. These units must be included in the accreditation process and will be covered under the MQSA certificate. See the FDA Policy Guidance Help System for more information.

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 stereotactic breast biopsy procedure.

3. 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.

4. 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.
Q. How long does the accreditation process take?

A. If you submit all of the requested information within ACR deadlines, the process typically takes 4 to 6 months.

Q. Do facilities undergo a site survey as part of the accreditation process?

A. No. The ACR may perform random site visits with prior notification to validate maintenance of accreditation criteria.

Q. Will the ACR accept faxed, electronic or digital signatures for the application?

A. Yes, the ACR does accept faxed, electronic or digital signatures. These will be treated as legally binding.

Q. At our hospital, both radiologists and surgeons perform stereotactic breast biopsies using the same equipment. For reasons of their own, the 2 physician groups do not want to accredit as a “collaborative setting” practice. Can they practice independently but accredit as one facility?

A. No. In this case, the 2 practices would need to accredit as 2 separate facilities with 2 designated supervising physicians.

Q. We are close to the testing material deadline and have not been able to find appropriate images to submit. May we have an extension to this deadline?

A. Please call the Breast Imaging Accreditation Programs at (800) 227-6440 for guidance.

Q. We submitted our testing materials 3 weeks ago. When will we get our results?

A. The accreditation review process takes approximately 90 days from the time the ACR receives your testing materials. You should receive your results soon after that.

Q. Can the ACR provide my assistant with our accreditation results over the phone or by fax?

A. No. Because the ACR’s Accreditation Programs are peer-review processes, the information we receive or develop during accreditation is considered privileged and confidential. We will provide the results of your accreditation to your Modality-Specific Supervising Physician by mail as soon as the review is complete.

Q. What happens if we do not pass accreditation on our first attempt?

A. You will not have to repeat the entire process; you will have to repeat only the areas that are deficient.

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 letter 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.
Please note that your accreditation submission contains HIPAA data, so we strongly recommend that you send your submission via a traceable method with a signature required for delivery.

Q. We recently appealed an adverse accreditation decision. When should we receive the results of the appeal?

A. You should receive the appeal results within **30 to 45 days** of the date all required appeal materials were received by the ACR.

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 Testing Instructions) and are examples of your best work. Consequently, during an appeal, you may only **submit the original images** with the original ACR labels.

Please note that your accreditation submission contains HIPAA data, so we strongly recommend that you send your submission via a traceable method with a signature required for delivery.

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, please note that any image/film that does not include the patient's first and last name, patient’s identification number and/or date of birth, examination date, and designation of left or right breast will fail.

Please note that your accreditation submission contains HIPAA data, so we strongly recommend that you send your submission via a traceable method with a signature required for delivery.

Q. If we failed accreditation only because our images were not labeled with all of the required information, can we resubmit the same case when we repeat and add the information that was missing?

A. No. Once a case has been submitted for accreditation and deemed unacceptable, that same case cannot be resubmitted for accreditation for any reason.

Q. How does a facility add a new unit to their existing accreditation?

A. If you have more than 13 months left on your modality's accreditation certificate, you will need to complete an Add New Unit Addendum. If you have 13 months or less, you will need to start the renewal process early. In either case, you have the ability to apply for this new unit on-line.

**Moved Facilities and Units**

Q. We will be moving our stereotactic breast biopsy unit to a new room. Do I need to provide any information to the ACR?

A. No. If you are only moving the stereotactic breast biopsy unit to a different room within the same facility, you do not have to notify the ACR.
Q. **We will be moving our stereotactic breast biopsy facility to a new address. Do I need to provide any information to the ACR?**

A. Yes, any address changes can be submitted online. Please have the medical physicist evaluate the moved unit, and submit the new physicist report to the ACR.

**Equipment**

Q. **We recently replaced the detector on our stereo unit. The state requires us to notify them within 60 days of a replacement part on the stereo unit. Do we need to notify the ACR as well as the state?**

A. No. We do not require you to notify us when you replace a part on a stereo unit.

**Personnel**

Q. **If 2 physicians participate in a stereotactic breast biopsy procedure, may they both count towards their continuing experience requirements?**

A. Yes.

Q. **I have attended several breast conferences that included stereotactic breast biopsy lectures, but the CME certificate does not break out the specific number of hours pertaining to stereo. How do I document that I meet the initial requirements for CME?**

A. If you have the syllabus or the schedule of the lectures for the meeting, you can attach it to the CME certificate. If you do not have this information, document how much time was spent on the subject and attach it to the CME certificate.

Q. **In order to obtain continuing education credit for stereotactic breast biopsy; must the coursework be specifically designed for stereotactic breast biopsy?**

A. No. Many general or breast continuing education activities include topics relevant to stereotactic breast biopsy. The following are just a few examples:

- Breast imaging conferences that include discussion of stereotactic breast biopsy cases
- Breast tumor board meetings that include cases undergoing stereotactic breast biopsy
- Quality control seminars that include topics on film printer or processor quality control or mammography phantom image evaluation.
- Quality control seminars that include discussions on repeat analyses.
- Physics courses that cover generators or digital detectors.
- Courses on radiation dose that include discussions of dose from stereotactic breast biopsy.

You are responsible for documenting your own continuing education in stereotactic breast biopsy. This can be done by documenting how much time was spent on the stereotactic breast biopsy related subject and attaching a note to the syllabus or CME certificate.

Q. **Are there any MQSA requirements for personnel performing interventional mammographic procedures (e.g. needle localization, stereotactic breast biopsy, galactography)?**

A. No, currently there are no MQSA requirements for personnel performing interventional mammographic procedures. See the [FDA Policy Guidance Help System](https://www.fda.gov/medical-devices/mammography-quality-assurance-requirements) for more information.
Q. I have worked with stereotactic breast biopsy systems with digital image receptors prior to 4/28/99. Am I considered to have met the 8 hours of training specific to FFDM required for mammography under MQSA?

A. No. Because these stereotactic biopsy systems are currently excluded from MQSA regulation, experience with these systems cannot be used to meet the requirement of 8 hours of training specific to FFDM. See the FDA Policy Guidance Help System for more information.

Q. I have received training in digital image receptors used for stereotactic breast biopsy. Can that training count toward the 8 hours of training specific to FFDM required for mammography under MQSA?

A. Maybe. Training received in digital image receptors used for stereotactic biopsy can count toward the 8 hours of training specific to FFDM if the training is essentially the same as that being given for FFDM. For example, if the interpreting physician received training in the manipulation of stereotactic digital images, and the FFDM manipulation of images is essentially the same as with stereotactic, that training could count toward the 8 hours of training specific to FFDM. See the FDA Policy Guidance Help System for more information.

Q. May I count time spent presenting courses/lectures and/or reading/writing articles/papers towards the continuing education requirements?

A. Personnel may possibly receive continuing education credit for presenting courses/lectures and/or reading/writing articles/papers for journals. These credits must be from organizations who can assess and document the appropriate amount and type of continuing education awarded for the individual article/paper or course/lecture and are authorized to award such credit. Personnel should get a letter or other documentation from the authorized organization stating how many and what type of continuing education credits are awarded and the date the credit was given.

Faculty may claim credit for teaching in programs designated for AMA PRA Category 1 Credit by applying directly to the AMA. Two AMA PRA Category 1 Credits™ are awarded for every hour of interaction, up to 10 credits per year. The application is available at www.ama-assn.org/go/cme in the Physician Applications section. You will need to download, complete and submit the Direct Credit Application to the AMA for credit. No credits are given for repeat presentations of the same material, it is the responsibility of the applicant to only claim the credit once, and credit may not be simultaneously earned as both a presenter and learner.

Additional information on obtaining continuing education credit for these activities is also available for medical physicists from CAMPEP at http://www.campep.org/Criteria.asp and for technologists from ASRT at http://www.asrt.org/main/continuing-education.

Q. The application materials ask for the names of our “Practice Site Supervising Physician” and the “Modality-Specific Supervising Physician” in another section. Are they the same person?

A. Depending on your particular facility’s management structure, these may be the same person but do not have to be:

- The **Modality-Specific Supervising Physician** is responsible for the individual modality (e.g., stereotactic breast biopsy) at your practice site. This physician must oversee the clinical exam selection for accreditation and review all testing materials relating to that modality before they are sent to the ACR.

- The **Practice Site Supervising Physician** has overall responsibility for the entire practice site location (e.g., breast ultrasound, ultrasound, stereotactic breast biopsy, whatever your facility is accredited in with the ACR). This physician ensures that all terms stated in the Practice Site Accreditation Survey Agreement are met.
Q. Our Practice Site Supervising Physician just left. Do we need to designate a new one and report this to the ACR?

A. Yes. Your new Practice Site Supervising Physician and the Practice Site Officer or Owner must read and sign the conditions for accreditation in the Practice Site Accreditation Survey Agreement. You may download this from the ACR website.

Q. In a collaborative practice setting, does the radiologist need to be present during the procedure?

A. Yes. The radiologist is responsible for mammographic interpretation and therefore needs to be available at the time of the procedure.

Q. The ACR Stereotactic Breast Biopsy Accreditation Program’s initial requirements for the interpreting physician include the performance of “12 stereotactic breast biopsy procedures or 3 hands-on stereotactic breast biopsy procedures under a qualified physician.” May some of these procedures be conducted on a phantom?

A. No.

Q. May our Physician’s Assistant or 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. Physician Assistants or Radiologist’s Assistant cannot perform stereotactic breast biopsies without a qualified physician being in the room at the time of the biopsy procedure.

Q. Do technologists assisting with stereotactic biopsies have to be currently MQSA-qualified in mammography?

A. Yes. Under current requirements, all technologists must meet MQSA requirements. Under the FDA regulations, all technologists are required to perform at least 200 mammograms every 24 months.

Q. I am a medical physicist with a BS in a physical science. I meet all MQSA requirements and started performing mammography and stereotactic physics surveys before 1999. Would I be considered qualified to perform surveys on stereotactic units at accredited facilities even though I do not have a master's degree?

A. Yes, the ACR’s requirement for medical physicists performing surveys of stereotactic breast biopsy units is consistent with the MQSA requirements:

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Medical Physicist*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>Qualified to perform mammography surveys under MQSA</td>
</tr>
<tr>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td>Performed 1 hands-on stereotactic breast biopsy survey under a qualified medical</td>
</tr>
<tr>
<td></td>
<td>physiologist or at least 3 independent surveys prior to 6/1/97</td>
</tr>
<tr>
<td>Continuing Experience</td>
<td>Upon renewal, 2 stereotactic breast biopsy unit surveys in the prior 24 months</td>
</tr>
<tr>
<td>Continuing Education</td>
<td>Upon renewal, 3 CEUs in stereotactic breast biopsy in the prior 36 months</td>
</tr>
</tbody>
</table>

*medical physicists must be currently qualified under MQSA
Q. I am no longer qualified in stereotactic breast biopsy since I have not maintained my continuing experience. Is there a way I can requalify so that my facility can apply for accreditation with the ACR?

A. Yes, you may requalify as follows:

- Interpreting Physicians - perform 3 hands-on stereotactic breast biopsy procedures under a qualified physician.
- Medical Physicists - perform 1 hands-on stereotactic breast biopsy physics survey under a qualified medical physicist.
- Radiologic Technologists - perform 5 hands-on stereotactic breast biopsy procedures under a qualified physician or technologist.

Accreditation Testing

Q. Many of the physicians at my facility have begun using an intact tissue device larger than 11 gauge. Is this acceptable for stereotactic breast biopsy accreditation?

A. Yes. Stereotactic biopsies performed with any FDA-approved core biopsy device may be submitted for accreditation.

Q. We have selected a case to submit using a vacuum-suction probe but the needle obscures the calcifications on our pre-biopsy stereo pair image. What can we do?

A. While the ACR prefers a pre-biopsy (post-fire) stereo pair demonstrating needle placement if using a vacuum suction biopsy probe, the calcifications MUST be visible on BOTH stereotactic views. In this case, ONLY your pre-fire stereo pair images labeled with the ACR Stereo Pair label should be submitted. If printing the stereo pair on two separate films, the 2nd ACR Stereo Pair barcode label should be placed on the second image.

Q. I understand that you require an image with the biopsy needle aperture placed above or below the group of calcifications to be biopsied. We use an ATEC 9-gauge vacuum needle; when it is placed over the calcifications, it obscures them because they are usually in small groups. In order to get a picture of the calcifications above or below the needle, I would have to place the needle over tissue without the calcifications in it. It seems that this needle could be targeted anywhere in the patient’s breast since it is just targeting normal breast tissue, and I feel this is unethical. Can we submit pre- and post-biopsy films as proof that the procedure was successful in cases where the needle obscures the calcifications to be biopsied?

A. We require a pre-fire image with the needle in position and subsequently only a specimen radiograph for the manual throw needles when those are used for stereo biopsies. Currently, for calcifications, vacuum needles are used almost exclusively (as they should be). We need a pre-biopsy (or pre-acquisition) image with the calcifications adjacent to the aperture to ensure proper positioning. Targeting can and should be done just inferior or superior to the calcifications, especially for small clusters. This is true for accreditation and also for any clinical case because the calcifications should be identified on the image prior to obtaining specimens to ensure targeting has been accurate. If the needle obscures the calcifications, it is impossible to be certain they will be obtained during acquisition, since they may be off to one side and not close enough to the needle for acquisition. Since we have eliminated the need for a mass case, a facility should be able to find at least one case in which the proper needle placement is demonstrated on the images, even if their volume is low.

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 Testing Instructions.
Q. We have an add-on biopsy attachment that we use for our stereotactic biopsies. We currently use this add-on biopsy attachment on more than one unit at our facility. Do we need to accredit all units that this add-on system is used on?

A. Yes. The Stereotactic Breast Biopsy Accreditation Program is a unit based program, all units that the add-on biopsy attachment is used on for stereotactic biopsies must be accredited.

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.

Q. I heard that the ACR no longer requires that a dosimeter be exposed during the production of the phantom image as a part of the Stereotactic Breast Biopsy Accreditation process. Is this true?

A. Yes. In order to eliminate redundant testing (per the ACR Stereotactic Breast Biopsy Requirements, medical physicists are required to evaluate radiation dose of each unit used for stereotactic breast biopsies annually) we decided to eliminate the dosimeter component of phantom image quality evaluation for accreditation.

Quality Assurance

Q. Do we need to have a physician peer-review program in place (e.g., RADPEER™) for Stereotactic Breast Biopsy Accreditation?

A. No, it is not required for Stereotactic Breast Biopsy Accreditation, since applicants already have to submit biopsy outcome data (# procedures, # cancers, # complications, etc.).

Q. On the quality assurance questionnaire, we are asked to provide patient volume and outcome data. Should the data be from a specific time period?

A. Yes. If possible, submit your facility’s patient volume and outcome data from the past 12 months. If you are a new facility, submit all the patient volume and outcome data you have available.

Quality Control

Q. The ACR 1999 Stereotactic Breast Biopsy Quality Control Manual (both the Radiologic Technologist's and the Medical Physicist's sections) directs us to make 4 exposures of the ACR MAP phantom for QC testing. Since many stereotactic breast biopsy units have small field-of-views, this allows all test objects in the 4 quadrants of this larger phantom to be imaged. However, our stereotactic breast biopsy unit has a relatively large field-of-view that covers almost the entire wax insert. May we use fewer exposures for routine QC?

A. Yes. You may use the following test procedures if your stereotactic breast biopsy unit’s field-of-view is relatively large:

Page 8 of 13
## Test Procedure Steps

<table>
<thead>
<tr>
<th>Test Procedure Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>For Digital Image Receptors:</td>
</tr>
<tr>
<td>1. Position the phantom (without the acrylic disk) so that the wax insert is centered in the field of view. Use the light localizer to facilitate the positioning. If the lateral approach is most commonly used for biopsies, apply compression to the phantom using a paddle without an aperture. If the vertical approach is most commonly used, do not install a compression paddle.</td>
</tr>
<tr>
<td>2. Take a scout view (0°) exposure using the site’s standard technique for a 4–4.5 cm thick compressed breast. Inspect the image to ensure that the entire insert area has been included. Record the technique factors on the data form.</td>
</tr>
<tr>
<td>3. As shown in Fig. 1, position the needle holder as far as possible from the chest wall and toward the right side to enable visualization of the fifth and sixth fibers.</td>
</tr>
<tr>
<td>4. Acquire a scout view image.</td>
</tr>
<tr>
<td>5. As shown in Fig. 2, move the needle holder as far as possible from the chest wall and toward the left side to enable visualization of the third and fourth fibers.</td>
</tr>
<tr>
<td>6. Acquire a scout view image.</td>
</tr>
<tr>
<td>7. View the images from steps 4 and 5 to determine the number of fibers, speck groups, and masses visible. Adjust window level and width settings to maximize detection of each object type. Use the scoring method for fibers, specks, and masses described below.</td>
</tr>
<tr>
<td>8. Examine the phantom images for artifacts. It may help to use several different window level and width settings to be sensitive to all artifacts.</td>
</tr>
</tbody>
</table>

### Needle holder

**Figure 1. Position of the needle holder to enable imaging of the 5\(^{th}\) and 6\(^{th}\) fibers.**

**Figure 2. Position of the needle holder to enable imaging of the 3\(^{rd}\) and 4\(^{th}\) fibers.**

---

**Q.** If a facility is using the 2016 ACR Digital Mammography Quality Control Manual (and new digital phantom) for their digital mammography unit and is also doing 2D stereo with an upright add on stereo attachment, what phantom should they use for stereo?

**A.** The facility should continue using either the small ACR Mammography Phantom or the Mini Digital Stereotactic Phantom for routine quality control and submitting phantom images to the ACR for accreditation.
Q. The Radiologic Technologist’s Test #3 (Hardcopy Output Quality Test) in the ACR 1999 Stereotactic Breast Biopsy Quality Control Manual requires that a printed SMPTE pattern be reviewed monthly by measuring the optical density at “four consistent locations on the film.” We currently use a Hologic Affirm Breast Biopsy attachment on a Hologic Dimensions mammography unit. The Hologic Dimensions QC manual has a similar, weekly DICOM Printer Quality Control test with the SMPTE pattern, but only three locations are evaluated. Is it acceptable to follow the Hologic Dimensions QC test procedures to meet the requirements of the ACR’s Hardcopy Output Quality Test?

A. Yes, if the equipment manufacturer provides a different QC process and if it is reviewed and approved by the facility’s medical physicist, the facility may follow the manufacturer’s QC process for their hardcopy output device instead of the one provided in the Stereotactic Breast Biopsy QC Manual.

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 for the Compression test in the Radiologic Technologist’s section of the ACR 1999 Stereotactic Breast Biopsy Quality Control Manual?

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 can 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.

Q. Most facilities that have digital stereotactic breast biopsy equipment have gone totally filmless, removing all chemical processing. How can I best perform the Collimation Assessment test in the Medical Physicist’s section of the ACR 1999 Stereotactic Breast Biopsy Quality Control Manual 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
2. 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.
3. Polaroid Corporation provides sheet film that can be adapted for this use.

A revised test equipment list is given below:

<table>
<thead>
<tr>
<th>Required Test Equipment</th>
<th>Four coins</th>
<th>Tape</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>One or two mammography screen-film cassettes and sheets of mammography film, OR ISP – GAFCHROMIC XR-QA cut to appropriate size, OR Polaroid film Ruler with mm scale</td>
<td></td>
</tr>
</tbody>
</table>

Q. The upright digital stereotactic system I am testing fails the medical physicist’s Collimation Test criteria of “5 mm on any side” but passes the MQSA criteria of 2% of SID. Is this acceptable?

A. Yes. It is acceptable if the collimation results fall within ±2% of the SID.
Q. The procedures for the Focal Spot Performance and System Limiting Resolution test in the Medical Physicist’s section of the ACR 1999 Stereotactic Breast Biopsy Quality Control Manual seem to imply that focal spot limiting resolution must be evaluated (and done so with film) on both screen-film and digital systems. (Page 62 states that “for digital systems, place the film in front of the digital receptor on the breast support plate.”) An additional procedure is outlined for “Measurement of Digital System Limiting Spatial Resolution.” Does this mean for a digital system I must evaluate both?

A. No. The ACR understands that many stereotactic breast biopsy units are in a total filmless environment. In addition, overall “system resolution” is the most critical test. The revised Medical Physicist’s Stereotactic Unit QC Test Summary (see excerpt below) now indicates that you only need to perform the evaluation related to the modality used, film or digital.

<table>
<thead>
<tr>
<th>3. Focal Spot Performance and System Limiting Resolution</th>
<th>PASS/FAIL</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Focal spot performance acceptable (NA if digital used)</td>
<td></td>
</tr>
<tr>
<td>B. Digital system spatial resolution acceptable (NA if film used)</td>
<td></td>
</tr>
</tbody>
</table>

The manual provides the filmless procedure and data analysis and interpretation instructions for digital receptors on pages 62-63 and illustrates typical results in Fig. 2 on page 64. In addition to assessing the “consistency of system-limiting spatial resolution over time and in comparison to acceptance testing results”, the ACR also recommends that the results be compared against the manufacturer’s stated specifications. Any significant degradation of the observed test results should be brought to the attention of the facility and promptly serviced by a qualified service engineer.

Q. The Stereotactic Breast Biopsy Quality Control Manual’s Automatic Exposure Control (AEC) test calls for performance testing at phantom thicknesses of 2, 4, 6 and 8 cm. The performance criteria for digital systems specifies that “the signal value should remain within ±20% of the signal obtained for the 4 cm phantom...if it does not meet this criterion, the medical physicist should develop a technique chart which meets this criterion.” I have units which do not provide enough signal to pass this test for an 8 cm phantom. Manual techniques that meet this criteria result in excessively long exposure times. However, our radiologists have been using manual modes with lower signals on very thick breasts, and don’t find the lower signal a problem. How can these units become compliant with ACR’s requirements?

A. Although the 1999 manual recognizes that it may be difficult to maintain signal at 8 cm under AEC (and thus allows for a manual technique at 8 cm), more recent experience has shown that these techniques can be quite long, and in some cases, not permissible on the equipment. In addition, medical physicists are finding that radiologists are used to “reading through” noisier images of very thick breasts. Consequently, in order to pass this test, only 2, 4 and 6 cm must meet the ±20% criteria. However, if the 8 cm test does not meet the criterion, the medical physicist should develop a technique chart for 2, 4, 6 and 8 cm showing 2-6 cm within range and 8 cm being as close as possible using a manual technique (and clinically acceptable).

Q. Our unit has an add-on stereotactic breast biopsy device that is used with an upright digital mammography unit. The ACR 1999 Stereotactic Breast Biopsy Quality Control Manual requires that the medical physicist performs a test for Automatic Exposure Control (AEC) or Manual Exposure Performance Assessment. This is difficult to accomplish with the add-on device since the needle apparatus remains in the way. May the equivalent test that is annually performed for the digital mammography unit be used to satisfy this stereotactic breast biopsy requirement?

A. Yes, the test that is used to evaluate performance of automatic exposure control for the digital mammography unit may be used to satisfy the requirements for the stereotactic breast biopsy unit. It should be representative of stereotactic breast biopsy performance.
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 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.

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.

Q. The performance criteria of the Average Glandular Dose test in the Medical Physicist’s section of the ACR 1999 Stereotactic Breast Biopsy Quality Control Manual specifies that the “average glandular dose to an average (4.2 cm compressed) breast should not exceed 3 mGy (0.3 rads) per view for screen-film or digital image receptors.” For digital, does this only apply to a 512 matrix? Is a higher dose acceptable if a 1024 matrix is used?

A. For ACR accreditation, the intent is that the dose be assessed at the mode used clinically. The manual directs the medical physicist to use the technique that is clinically used to assess dose:

- Page 78 – “Measure the typical entrance exposure for standardized breast thickness and composition (approximately 4.2 cm compressed breast thickness – 50% adipose, 50% glandular composition), calculate the associated average glandular dose, and assess short-term exposure reproducibility.”
- Page 78 – “4. Select the exposure technique normally used for stereotactic localizations.”

If the facility typically uses the 1024 matrix for stereotactic breast biopsies, the dose requirement applies to that mode; if the facility typically uses the 512 matrix for stereotactic breast biopsies, the dose requirement applies to 512.

Q. Is the stereotactic breast biopsy facility required to provide a gelatin phantom on site for the physicist to use in performing the Localization Accuracy test that is outlined in the Medical Physicist’s section of the ACR 1999 Stereotactic Breast Biopsy Quality Control Manual?

A. No. Although most medical physicists provide their own test tools, it is also acceptable for the medical physicist to use test tools provided by the facility. As long as the medical physicist has access to a gelatin phantom to perform this test, it is a decision between the medical physicist and the facility who provides the phantom.
Breast Imaging Centers of Excellence

Q. Where can I get information on the ACR’s Breast Imaging Centers of Excellence (BICOE) designation?

A. Visit the ACR accreditation web site at http://www.acraccreditation.org/ and click on the BICOE gold seal. There you will find BICOE requirements and other information.