American College of Radiology
Stereotactic Breast Biopsy Accreditation Program
Testing Instructions
(Revised June 2019)

This guide provides all of the instructions necessary for clinical and phantom tests and general submission for the ACR Stereotactic Breast Biopsy Program.

For assistance, contact the ACR Monday through Friday 8:30 am to 5:00 pm (ET).
Telephone: 800-227-6440
Email: stereo-accred@acr.org
Website: http://www.acraccreditation.org/Modalities/Stereotactic-Breast-Biopsy
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I. Revisions

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<th>Page(s)</th>
<th>Section</th>
<th>Description of Revisions</th>
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<tr>
<td>4/24/17</td>
<td>All</td>
<td>All</td>
<td>Combined the clinical and phantom testing instructions into one document. Updated testing instructions to include information regarding online accreditation database, ACRedit Plus.</td>
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<tr>
<td>4/27/17</td>
<td>All</td>
<td>All</td>
<td>Combined the “Frequently Asked Questions”, pertaining to testing package submission, within the testing instructions document</td>
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<tr>
<td>7/31/2017</td>
<td>12</td>
<td>Mailing Instructions</td>
<td>Added recommendation to send any packages containing PHI via traceable method with required signature delivery.</td>
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<tr>
<td>6/5/2019</td>
<td>11</td>
<td>Submiting and Labeling All Material</td>
<td>Revised instructions to include the ability to upload images into the ACRedit Plus database for accreditation submissions.</td>
</tr>
<tr>
<td>7/15/2019</td>
<td>11</td>
<td>Submiting and Labeling All Material</td>
<td>Added acceptable file types for electronic submission.</td>
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II. General Instructions

In addition to the information included in this document, should you have additional questions you can contact ACR breast imaging staff at (800)-227-6440. Phone lines are open business days from 8:30 AM to 5:00PM eastern time.

The ACR website provides a listing of accredited facilities and facilities that are under review. If a third party payer requests verification of your participation in one of the accreditation programs, please refer them to the ACR website Accredited Facility Search. Additionally facilities should check with your state’s department of radiologic health to see if your state currently requires stereotactic breast biopsy accreditation.

A. Introduction

Your Accreditation Team

Successful accreditation is a team effort involving the supervising physician, stereotactic technologist, and qualified medical physicist. Other personnel (administrators, managers, etc.) may also be a part of your team, depending on your facility. This team should be agreed upon before beginning the accreditation process, and should keep in close contact during the process. This will help ensure success.

Before You Begin

It is important that each pertinent member of the team read and understand the documents listed below before beginning the Stereotactic Accreditation process:

1. ACR Diagnostic Modality Accreditation Program Overview
2. ACR Stereotactic Breast Biopsy Accreditation Program Requirements
3. ACR Stereotactic Breast Biopsy Accreditation Testing Instructions (this document)
4. Stereotactic Breast Biopsy Frequently Asked Questions
5. Instructions for Uploading Images

Follow all instructions for every unit being reviewed for accreditation. Every unit must apply to be accredited. Keep copies of all documents and images submitted to ACR for your records.

There are three portions to your ACR Stereotactic Breast Biopsy Accreditation submission:

1. Medical Physicist Report
2. Clinical Testing
3. Phantom Testing

You must utilize the services of a qualified medical physicist for the Medical Physicist Report and oversight of your facility’s technologist quality control (QC) program. The ACR strongly recommends using the services of a qualified medical physicist for the image quality control portion of your submission.

Keep copies of everything that you submit to ACR for your records.

B. Online Application

The application for ACR Stereotactic Breast Biopsy is online at https://acreditplus.acr.org.

New Facilities

If your facility has never applied for accreditation before, you will “register” as a new facility. New facilities will be assigned a unique identification number (SBBAP #) after the online application is submitted. This number appears on all correspondence from the ACR, your online records, and on all of the barcode labels (if submitting by film). Please use this number on all submitted materials and to identify your facility when contacting the ACR for assistance.
Existing Facilities

If your facility has applied for accreditation before, but you have not logged into the ACReditPlus database, you will need to activate your existing accreditation account. Use the ACRedit Plus Activation Instructions to access your account online.

Renewing Facilities

Approximately eight months prior to the expiration of the Stereotactic Breast Biopsy Accreditation, the ACR will email an Accreditation Renewal Notice to the facility. The facility user should log into the online database at https://acreditplus.acr.org and select the “start renewal” link (found on the dashboard or under modality details). This should be started no later than 6 months prior to expiration of your current accreditation, to ensure that there are no gaps in your accreditation.

Your Application

Your online application will inform you of the examinations to submit, and any forms and fees required for the application. There are instructions on the webpage every step of the way to assist you. There are also information buttons to give you more details. ACR staff will confirm and accept your application after we receive all required documents. If you need to fax your forms to the ACR, or keep copies for your records, access these forms using My Applications and click the Print Forms for Submission link.

Your Testing Package

After your application is processed, an online testing package will be activated which will contain all of the clinical and phantom data forms required for accreditation review. Your facility will receive an email with a link to the online testing package. The facility user must log into the account and fill out all required forms. The testing package must be submitted online.

If you are submitting your images on film, the ACR will mail barcoded identification labels for all images and forms.

The following items are generic forms available on the Stereotactic Breast Biopsy Accreditation page of the ACR website to assist you in gathering data. Do not submit these forms. You must log on to the ACR accreditation database, at https://acreditplus.acr.org to enter and submit data into your online testing package. If submitting by film, print the clinical and phantom exam data forms from the database and include with your images.

1. Test Image Data Form
2. Quality Assurance Questionnaire

C. Materials Due Date

The online testing package has the image submission due date. You must collect your images and submit them to the ACR by that date. Failure to meet this due date will jeopardize completion of your accreditation. Thus, if your facility is renewing its accreditation, we cannot guarantee completion in a timely fashion before your ACR certificate expires. If your site cannot submit the required materials by your due date, notify the ACR immediately.

D. Image Collection Time Period Stereotactic Breast Biopsy

All examinations submitted must have been performed within 6 months of the date that the testing package link was released to the facility. No images will be accepted for review that predates this date by more than six months.

III. Medical Physicist Equipment Survey

Medical physicists for all sites applying for accreditation or renewal must demonstrate compliance with the ACR requirements for quality control and Annual Medical Physicist Survey or Acceptance.
Testing Evaluation (for new units) as outlined in the Stereotactic Breast Biopsy Program Requirements. These must be performed by a qualified medical physicist.

Documentation of quality control is required as part of the application process. All facilities applying for accreditation must comply with the minimum frequencies listed in the Stereotactic Breast Biopsy Program Requirements. Detailed instructions for each of these tests are contained in the 1999 ACR Stereotactic Breast Biopsy Quality Control Manual. Upon acceptance of a facility's initial application, the ACR will send a QC manual to the modality's supervising physician at the practice site address.

Submit the following:

1. Annual Medical Physicist Survey (The entire report must be submitted).
2. Medical Physicist Stereotactic Unit QC Test Summary (found on the ACR website, to include evaluation of the technologist QC) signed by a qualified medical physicist. Your medical physicist must use the summary form provided by the ACR or one similar that itemizes the pass-fail results of all the same tests using the same names and order as is outlined on the ACR form.
3. Documentation of any corrective action taken if recommended in the Medical Physicist Report (i.e. test failures or data outside of action limits).

If submitting by mail, staple all forms together, and place the Medical Physicist Report barcode label on the first page.

IV. Clinical Testing Instructions

PLEASE NOTE THAT ANY IMAGE MISSING THE REQUIRED INFORMATION MARKED REQUIRED WILL FAIL

A. Important Considerations When Selecting Clinical Cases

1. Select an example of your facility’s best work.
2. Select a case no older than 6 months from the date the testing package link was released to the facility.
3. Select a single BI-RADS® Category 4 or 5 calcification biopsy case with correlating mammogram that demonstrates accurate needle placement.
4. Your supervising physician must review and approve the images that you select for submission. If submitting by film, they must also review and approve all images once they are printed, and the barcode labels have been affixed.
5. Select a case with a 2-view mammogram (CC and MLO/ML/LM) performed prior to the stereotactic procedure that includes the entire breast on each image. 2D and C-view images are acceptable to submit, however, tomosynthesis images are NOT acceptable.
6. Additional images (i.e. XCCL or magnification views) may be submitted in addition to, but not instead of, the 2-view mammogram.
7. Calcifications being biopsied must be visible and easily appreciated on all submitted images
   • Mammogram images (calcifications to be biopsied must be clearly circled)
   • Biopsy images
   • Specimen image
8. The following biopsy devices are acceptable
   • A vacuum suction biopsy probe
   • A gun-needle biopsy probe
   • Another FDA-approve core biopsy device. (Lateral arm units are acceptable only if the lateral arm device is the only option for biopsy and the needle can be seen in relation to the calcifications in 2 views.)
9. Although valuable for some calcifications, “target-on-scout” images are not acceptable for accreditation because reviewers cannot assess the needle position on 2 views.

10. Mammograms must have been taken sometime in the 60 days immediately prior to the date of the biopsy (the mammography images can be from an outside facility).

11. All images (stereotactic breast biopsy and mammogram) submitted, must be from the same patient.

12. Do not submit images that are obtained on models or volunteers.

13. Do not include any patient reports with your image submission. These reports will not be sent to ACR reviewers. Please note that the ACR will shred any submitted materials containing protected health information (PHI) that are not necessary for the accreditation review process.

14. During accreditation review, ACR radiologist reviewers will assess the following case attributes
   • Visualization of the calcifications in the pre-biopsy mammogram
   • Appropriateness of the pre-fire stereo pair (as applicable)
   • Appropriateness of the pre-biopsy (post-fire) stereo pair (as applicable)
   • Appropriateness of the specimen radiograph
   • Examination identification (The ACR will keep all patient information confidential)

B. Vacuum-Suction Biopsy Probe or Other FDA-Approved Core Biopsy Device Required Images

1. A 2-view mammogram (CC and MLO/ML/LM) performed prior to the stereotactic procedure that includes the entire breast with the calcifications to be biopsied circled on each image. Spot views from the mammogram are not accepted.

2. One of the following (as applicable to your practice):
   • Pre-Biopsy (post fire) stereo pair demonstrating needle positioning for tissue acquisition (preferred); the calcifications must be visible on both stereotactic views.
   OR
   • Pre-Fire stereo pair demonstrating needle positioning for tissue acquisition; the calcifications must be visible on both stereotactic views. Only submit Pre-Fire images if it is not possible to submit pre biopsy (post-fire) image or if the needle on the pre-biopsy (post-fire) obscures calcifications.

3. A specimen radiograph demonstrating calcium

C. Gun-Needle Biopsy Required Images

1. A 2-view mammogram (CC and MLO/ML/LM) performed prior to the stereotactic procedure that includes the entire breast with the calcifications to be biopsied circled on each image. Spot views from the mammogram are not accepted.

2. A Pre-Fire stereo pair demonstrating needle positioning; the calcifications must be visible on both stereotactic views.

3. A specimen radiograph demonstrating calcium.

D. Examination Identification

Each image should contain the following information on the image, or in the DICOM header; a permanent sticker is acceptable if submitting on film.

ANY IMAGE MISSING THE INFORMATION MARKED REQUIRED WILL FAIL
   • The patient’s first and last name (required)
   • Identification number and/or date of birth (required)
   • Examination date (required)
• Facility name
• Facility location (city, state, and zip code)
• Designation of left or right breast (required)
• Annotation of mammographic view (e.g., CC, MLO/ML/LM)
• Technologist’s identification number or initials

E. Prepare Your Case

1. Clearly circle the calcifications to be biopsied on each mammographic projection. The case will fail if more than one group of calcifications is circled, or if the calcifications are not circled on all mammogram projections.

2. If you are submitting on film
   a. Only print and submit images on 10 X 12 inch films (or smaller). If you can only print on larger film trim the film so that it is no larger than 10 x 12 inches. Films that are too large will be returned to the facility.
   b. You may submit original mammograms or copies (as long as the copies clearly demonstrate the target calcifications).
   c. Mammogram copies must be good quality and clearly labeled with the patient ID and procedure date.
   d. Digital mammograms must be printed “true size” (i.e., without magnification or minification) or with a scale.

V. Phantom Image Instructions

You must acquire a phantom image specifically for accreditation purposes. You must take the phantom image within the 45-day testing period.

NOTE: As of 7-1-16 a dosimeter is no longer required for accreditation. Your physicist must still check AGD during the medical physicist survey.

1. One approved accreditation phantom
   • Mini Digital Stereotactic Phantom (Gammex RMI) 156D or Nuclear Associates (Fluke) 18-250
   OR
   • ACR Mammography Accreditation Phantom (Gammex RMI) 156, Nuclear Associates (Fluke) 18-220, or CIRS 015

2. One Phantom Exam Data form for each stereotactic breast biopsy unit you are testing.

A. Prepare Your System for a Stereotactic Procedure

1. Mount the stereotactic localization device with its collimator and remove the grid (if necessary).

2. Select the exposure mode that you typically use for obtaining scout images (either automatic exposure control [AEC] or manual).
   • If AEC is used, be sure the AEC detector is under the center of the phantom
   • Select the kVp, mAs (for manual modes), focal spot, target, and filter used for stereotactic localization of a 4.2 cm thick compressed breast of a 50% adipose and 50% glandular tissue

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B. Mini Digital Stereotactic Phantom Instructions

1. Orient the phantom as shown in Figure 1.

2. Take 1 image using your typical technique for a scout image (AEC or manual mode).

3. Record all technique factors on the Phantom Exam Data form.

![Figure 1 Chest Wall Side Mini Digital Stereotactic Phantom](image)

C. ACR Stereotactic Accreditation Phantom Instructions

1. If you can remove the biopsy collimator and compression plate or have a large enough field-of-view to image the entire insert on 1 image, you may submit 1 image, as long as the entire insert is visible.

2. If you have a large enough field-of-view to image the entire insert on 1 image but the needle holder appears on the image, you may submit 2 images: one with the needle holder as far to the left as possible, the other with the needle holder in the far right position.

3. If you cannot remove the biopsy collimator, the system is restricted to the biopsy aperture, or the system is a dedicated stereotactic breast biopsy unit with small field-of-view digital detector, you must submit 4 images as shown in Figure 2 in order to image all of the test objects. Take 4 overlapping sections of the phantom.

4. Use your typical technique for a scout image (AEC or manual mode).

5. Record all technique factors on the Phantom Exam Data form.
Figure 2 Chest Wall Side ACR Mammography Accreditation Phantom
D. Prepare Your Case

1. Print the image(s) as close to “true size” as possible (i.e., without magnification or minification).
2. Do not print the phantom images on the same film that contains the clinical images.
3. For screen-film, process the image(s) using the processor normally used for your stereotactic clinical images.

VI. Submitting and Labeling All Material

A. Submitting

1. Log into your online account at https://acreditplus.acr.org and fill out all required clinical and phantom data forms and submit the online testing package.
2. If submitting the images by electronic upload read and follow the Instructions for Uploading Images.
   a. Correlating mammogram: Upload 2D (acquired or synthesized) mammogram (2 views: CC and MLO/ML) with a single ROI circled. Do not submit images with more than one circled ROI. OPTIONAL: If placing the ROI removes required labeling, or disables the measurement functions, you must also submit non-DICOM images that show the ROI. You may also upload mag views, spot compression images and/or tomosynthesis slices to show the area of interest more clearly, but only in addition to the two view mammogram.
   b. Stereotactic pair and specimen images: Upload your two stereo pair images demonstrating correct needle positioning with calcifications visible on both views, and your specimen radiography demonstrating calcium. All images must be in DICOM format.
3. If submitting materials by film
   a. Select and submit the documents that generate by accessing the “print forms for submission,” under the testing package link of your online account.
   b. Print the images on film or high quality photographic paper (as long as the paper image is of equal quality to a transparency). CDs are not accepted.

B. Stereotactic Breast Biopsy Clinical Image Labeling for Film Submission

For film submission, once you have printed your images, and checked them for complete examination identification, attach the barcoded labels to the designated images as described below. Be sure that the labels do not cover any pertinent clinical or identification information on either the mammogram or the stereo images.

Please note for your stereo pair images you are provided 2 Stereo Pair Image labels. Ensure you are labeling the images appropriately and use the label titled Stereo Pair Image 2 if you are printing the stereo pair on two separate films.

Vacuum-Suction Biopsy Probe or Other FDA-Approved Core Biopsy Device

<table>
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<tr>
<th>IMAGES</th>
<th>LABELS</th>
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<tbody>
<tr>
<td>Required for all submissions</td>
<td></td>
</tr>
<tr>
<td>2-view mammogram with the calcifications clearly circled</td>
<td>stereo correlating mammo image 1</td>
</tr>
<tr>
<td>Specimen radiograph</td>
<td>stereo correlating mammo image 2</td>
</tr>
<tr>
<td>Stereo Pair (only submit the)</td>
<td>specimen radiograph</td>
</tr>
<tr>
<td>Pre-biopsy (post-fire) stereo pair demonstrating needle position (preferred)</td>
<td>stereo pair image</td>
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Gun-Needle Biopsy Probe

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<tr>
<td>2-view mammogram with the calcifications clearly circled</td>
<td>stereo correlating mammo Image 1</td>
</tr>
<tr>
<td>Specimen radiograph</td>
<td>stereo correlating mammo Image 2</td>
</tr>
<tr>
<td>Pre-fire stereo pair demonstrating needle position</td>
<td>specimen radiograph</td>
</tr>
<tr>
<td>Pre-fire stereo pair image</td>
<td>stereo pair image</td>
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C. Stereotactic Phantom Image Labeling for Film Submission

3. Place 1 phantom barcode label on each phantom image (i.e., If submitting the large phantom, submit 4 phantom images with the ACR Accreditation Phantom. Use phantom labels 1-4. If submitting 1 phantom image with the Mini Digital Stereotactic Phantom, only use phantom label 1.) IMPORTANT: These labels are for a specific unit and are marked “Phantom Image” and “Phantom Exam Data.” Be sure to put the appropriate label on the appropriate item.

D. Mailing Instructions

For film submission, send the Medical Physicist Report (one per unit), Clinical and Phantom Exam Data forms (printed from your online testing package), and images to the following address.

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.

Stereotactic Breast Biopsy Accreditation Program
American College of Radiology
1891 Preston White Drive
Reston, VA 20191-4397

Your printed clinical and phantom images will be returned once the accreditation evaluation is complete. Submitted electronic images will be deleted from the ACR database after the accreditation process. Please maintain copies of all documents and images submitted to the ACR, and record the name of those patients whose clinical images were sent for accreditation until you receive official notification your accreditation was approved.

VII. Stereotactic Breast Biopsy Accreditation Checklist

Please ensure that all items below are complete before returning the submission to the ACR for accreditation review. The review process will not begin until your submission is complete. All items must be submitted for each unit being accredited.

A. Electronic Submissions

- If submitting electronically, ensure all appropriate items have been uploaded and the online testing package is in a submitted status.

B. Film Submission

- Medical Physicist Report for each unit
- Daily, weekly technologist QC tests (one month worth of data)
- Monthly, quarterly, semi-annual technologist QC tests (one year)
- Clinical Exam Data Form (one per unit) printed from the online testing package and appropriately labeled.
- Phantom Exam Data Form (one per unit) printed from the online testing package and appropriately labeled.
- Clinical images (appropriately labeled)
  - Mammogram images with the group of calcifications being evaluated circled
  - Specimen image
  - Pre-Biopsy (Post-Fire) OR Pre-Fire stereo pair
- Phantom images (appropriately labeled)
  - Phantom images must be on separate film from clinical images