This guide provides all of the instructions necessary for clinical tests and general submission for the ACR Breast Ultrasound Accreditation Program.

For assistance, contact the ACR Monday through Friday 8:30 am to 5:00 pm (ET).

Telephone: 800-227-6440

Email: BreastUltrasound-ACCRED@acr.org

Website: http://www.acraccrerditation.org/Modalities/Breast-Ultrasound
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# I. Revisions

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<tr>
<td>4/27/17</td>
<td>All</td>
<td>All</td>
<td>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>4/27/17</td>
<td>4-5</td>
<td>Testing Materials Memo</td>
<td>Added where to find frequently used items on ACR Website, and explained how to complete the testing package using new online accreditation database, ACRedit Plus</td>
</tr>
<tr>
<td>4/27/17</td>
<td>17</td>
<td>Testing Materials Checklist</td>
<td>Added list of items required for online submission of the breast ultrasound testing package.</td>
</tr>
<tr>
<td>7/5/17</td>
<td>8</td>
<td>Breast Ultrasound Clinical Images - Simple Cyst</td>
<td>Removed labeling instructions. All label instructions are included now included in Section V. Submitting and Labeling All material</td>
</tr>
<tr>
<td>7/31/17</td>
<td>5, 7, 11</td>
<td>Annual System Performance Evaluation; Clinical Testing Instructions; Mailing Instructions</td>
<td>Added recommendation to send all PHI by traceable methods that require signature upon delivery</td>
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</table>
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 breast ultrasound accreditation.

A. Introduction

Your Accreditation Team

Successful accreditation is a team effort involving the lead supervising physician and breast ultrasound technologist. 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 Breast Ultrasound Accreditation process:

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

Keep copies of all documents and images submitted to ACR for your records.

There are two portions to your ACR Breast Ultrasound submission:

1. Annual System Performance Evaluations
   - The ACR strongly recommends that Annual System Performance Evaluations are done under the supervision of a qualified medical physicist. If it is not possible for a qualified medical physicist to perform these tasks they may be performed by personnel approved by the physician(s) directing the clinical ultrasound practice.

2. Clinical Testing
   - The ACR Breast Ultrasound Accreditation Program is facility-based. Only one set of images per type (i.e., simple cyst, solid mass, CNB and/or FNAC) is required regardless of the number of breast ultrasound units or the number of physicians at the facility.

B. Online Application

The application for ACR Breast Ultrasound is found 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 (BUAP #) 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 ACRedit Plus 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 Breast Ultrasound 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 under modality details and on the dashboard). 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.

Only film submission is available at this time. Uploading of images will be available in the near future.

Your Testing Package

After your application is processed, an online testing package will be activated, which will contain all of the 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 bar coded identification labels for all images and forms.

The following items are generic forms available on the Breast Ultrasound 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 exam data form(s) from the database and include with your images.

1. Test Image Data Form
2. Quality Assurance Questionnaire (pdf)

C. Materials Due Date

The online testing package has the image submission due date. You must collect your test images and return 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 for Breast Ultrasound and Breast Ultrasound Guided Biopsy Images

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. Annual System Performance Evaluation

Effective, June 1, 2014, documentation of quality control (QC) is required as part of the application process. All facilities applying for accreditation must comply with the minimum frequencies listed below. As part of the accreditation application, facilities must demonstrate compliance with the ACR requirements for QC by providing:

- Report from the most recent annual survey performed by the medical physicist or designee
- Documentation of corrective action (if the annual survey and/or QC data identify performance problems)

The ACR strongly recommends that QC be done under the supervision of a qualified medical physicist. The qualified medical physicist may be assisted by properly trained individuals in obtaining data, as well as other aspects of the program. These individuals should be approved by the qualified medical physicist, if available, in the techniques of performing tests, the function and limitations of the imaging equipment and test instruments, the reasons for the tests, and the importance of the test results. The qualified medical physicist should review, interpret, and approve all data. If it is not possible for a qualified medical physicist to perform the tasks designated for a medical physicist, these tasks may be performed by other appropriately trained personnel with ultrasound imaging equipment experience. These individuals must be approved by the physician(s) directing the clinical ultrasound practice.

Submit the following:

1. Annual System Performance Evaluation or Equipment Evaluation Summary Form
   - The Equipment Evaluation Summary Form may be used to detail the results of the Annual Survey. Please submit one form per transducer.
   - Note: Facilities can submit either the summary form (one per transducer) or a complete evaluation report from the system engineer/physicist. Facilities do not need to submit both.

2. Documentation of any corrective action taken if recommended in the Annual System Performance Evaluation (i.e. test failures or data outside of action limits).

If submitting by mail, staple all forms together, and place the annual system performance evaluation barcode label on the first page of the report. Please note that your accreditation submission contains HIPAA data, so we strongly recommend that you send your submission via traceable method with a signature required for delivery.

IV. Clinical Testing Instructions

A. Important Considerations When Selecting Clinical Cases

1. Submit 1 simple cyst and 1 solid mass for breast ultrasound accreditation; submit a solid mass for the biopsy module. Sonograms and correlating mammograms that demonstrate multiple cysts or masses may be submitted. However, the cyst/mass being evaluated must be well visualized and clearly circled on both mammographic views. Spot views, XCL, magnification or tomosynthesis can only be submitted in addition to the CC/MLO views. C-View images are acceptable, as long as the meet all of the criteria. This allows the ACR reviewer to determine if the physician can appropriately triangulate the cyst/mass. If you do not circle the cyst/mass, you will fail accreditation.

2. Submit 2 orthogonal ultrasound projections (e.g., if 1 image is in the transverse plane, the other should be in the sagittal plane) without calipers and 1 projection with appropriate caliper measurements of the cyst/mass in its longest dimension. The cyst/mass must be visible on both projections. Only print the requested sonographic images; do not submit split-screen images; do not submit additional images/frames. ACR reviewers will only evaluate the requested images.

3. To make the caliper measurement, record the dimensions, to include the longest dimension. Submit 1 view in the scan plane demonstrating the longest dimension, which may not correspond to the two orthogonal views submitted in #2 above. This image must include the caliper measurement. See below:
Note that the scan plane of the lesion’s longest diameter may not correspond to the radial or anti-radial scan planes.

4. Clearly label each image with the information below. PLEASE NOTE THAT ANY IMAGE MISSING THE INFORMATION MARKED “REQUIRED” WILL FAIL.
   - Patient’s first and last names (required)
   - Identification number and/or date of birth (required)
   - Examination date (required)
   - Facility name
   - Facility location
   - Designation of right or left breast (required)
   - Anatomic location using clock face notation or labeled diagram of the breast (required)
   - Transducer orientation (required)
   - Distance from the nipple to the abnormality measured in millimeters or centimeters (required). Note: You may indicate “retroareolar” without a measurement if the abnormality is behind the nipple, no matter how deep.
   - Sonographer’s and/or physician’s identification number, initials or other symbol

5. Submit original sonograms electronically (uploading of images will be available in the near future) or on either film or high quality photographic paper. CDs are not accepted at this time. If submitting by film, print each case on separate film (or paper).

6. Submit 2 orthogonal views of correlating mammograms (either copies or originals) with each case.
   - Mammograms must have been taken within 60 days prior to the sonograms.
   - Mammogram copies must be good quality and clearly labeled with the patient ID and exam date.
   - The mammograms submitted may be copies of mammograms from another facility as long as they are of good quality. They do not have to be from the facility undergoing breast ultrasound accreditation.
   - Digital mammograms must be printed “true size” (i.e., without magnification or minification) or with a scale. 2D and synthetic 2D images from breast tomosynthesis are acceptable to submit, however, individual slices from tomosynthesis are acceptable in addition to the CC/MLO views.
   - The cyst/mass must be visible on both views.
   - The cyst/mass must be circled on both views (if submitting by film, do not use a radiopaque marker).

7. If submitting via film or high quality photo paper, label each image and form with the appropriate ACR bar-coded label (see Labeling Guide at end).

8. Do not submit images that are performed on models or volunteers.

9. All images for each exam must be from the same patient.

10. Do not send the mammography or pathology reports; they will not be sent to the 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.

11. Submit examples of your best work. The ACR reviewers will evaluate your images accordingly. The facility’s breast ultrasound supervising physician must review and approve images prior to labeling and sending them to the ACR for review. Please note that your accreditation submission contains HIPAA data, so we strongly recommend that you send your submission via traceable method with a signature required for delivery.
B. Breast Ultrasound Clinical Images-Simple Cyst

For the simple cyst, submit 1 case. Mammograms must have been taken within 60 days prior to the sonograms. The sonograms must not be older than 6 months from the date that the testing package was released to the facility.

IMPORTANT: The cyst must meet the BI-RADS® criteria for a simple cyst: a) anechoic, b) circumscribed margin, c) posterior enhancement, and d) round or oval. Complicated cysts or complex masses are not acceptable for accreditation. Color Doppler images are not acceptable for accreditation. Compound images and harmonic images are now acceptable.

1. Mammograms
   - Submit only 2 orthogonal projections (e.g., CC and MLO, CC and ML, CC and LM) of the breast being evaluated by ultrasound. The cyst must be visible on both mammographic views. Spot views or individual slices from tomosynthesis can only be submitted in addition to the CC/MLO views.
   - Circle only the cyst being evaluated on each mammogram (if submitting via film or high quality photo paper do not use a radiopaque marker).

2. Sonograms without calipers (submit only the requested sonographic images/frames)
   - Submit 2 orthogonal sonographic images of the cyst without calipers (e.g., if 1 image is in the transverse plane, the other should be in the sagittal plane).

3. Sonogram with calipers (submit only the requested sonographic images/frames)
   -Submit another sonographic image (of either plane) showing the appropriate caliper measurements.

4. Complete the corresponding section of the online cyst exam data form.

C. Breast Ultrasound Clinical Images-Solid Mass

For the solid mass, submit 1 case with a breast mass. Do not select an intramammary node or dermal lesion. Mammograms must have been taken within 60 days prior to the sonograms. The sonograms must not be older than 6 months from the date that the testing package was released to the facility.

1. Mammograms
   - Submit only 2 orthogonal projections (e.g., CC and MLO, CC and ML, CC and LM) of the breast being evaluated by ultrasound. The mass must be visible on both mammographic views. Spot views or individual slices from tomosynthesis can only be submitted in addition to the CC/MLO views.
   - Circle only the mass being evaluated on each mammogram (for film submission do not use a radiopaque marker).

2. Sonograms without calipers (submit only the requested sonographic images/frames)
   - Submit 2 orthogonal sonographic images of the mass without calipers (e.g., if 1 image is in the transverse plane, the other should be in the sagittal plane).

3. Sonogram with calipers (submit only the requested sonographic image/frame)
   - Submit an additional sonographic image (of either plane) showing the appropriate caliper measurements.

4. Complete the corresponding section of the online solid mass exam data form.

D. ULTRASOUND-GUIDED BREAST BIOPSY MODULE CLINICAL IMAGES

There are 3 options for the breast biopsy module:

1. Core needle biopsy (CNB) for facilities that perform only CNB
2. Fine needle aspiration cytology (FNAC) for facilities that perform only FNAC of breast masses (not cysts or axillary lymph nodes)
3. CNB and FNAC for facilities that perform both types of biopsy procedures

E. CNB-Core Needle Biopsy

Submit 1 BI-RADS® Category 4 or 5 case. Mammograms must have been taken within 60 days prior to the sonograms. The sonograms must not be older than 6 months from the date that the testing package was released to the facility.

1. Devices used in fire mode (i.e., FIRED into TISSUE SAMPLING POSITION)
   a. Mammograms
      - Submit only 2 orthogonal projections (e.g., CC and MLO, CC and ML, CC and LM) of the breast being evaluated by ultrasound. The mass must be visible on both mammographic views. Spot views or individual slices from tomosynthesis can only be submitted in addition to the CC/MLO views.
      - Circle only the mass being evaluated on each mammogram (for film submission do not use a radiopaque marker).
   b. Pre-biopsy sonograms in 2 views (submit only the requested sonographic images/frames)
      - Submit 2 orthogonal sonographic images of the mass to be biopsied (e.g., if 1 image is in the transverse plane, the other should be in the sagittal plane).
   c. Pre-fire sonogram with needle (submit only the requested sonographic image/frame)
      - Submit a pre-fire sonographic image demonstrating the needle aiming towards the mass just prior to insertion. The position of the needle should be in the long axis and approximately parallel to the chest wall.
   d. Post-biopsy (post-fire) sonogram (submit only the requested sonographic image/frame)
      - Submit a post-biopsy (post-fire) sonographic image (from the same mass) demonstrating the position of the needle in the long axis.
   e. Complete the corresponding section of the online CNB exam data form.

2. Devices used in non-fire mode (i.e., MANUALLY ADVANCED into BIOPSY POSITION)
   a. Mammograms
      - Submit only 2 orthogonal projections (e.g., CC and MLO, CC and ML, CC and LM) of the breast being evaluated by ultrasound. The mass must be visible on both mammographic views. Spot views or individual slices from tomosynthesis can only be submitted in addition to the CC/MLO views.
      - Circle only the mass being evaluated on each mammogram (for film submission do not use a radiopaque marker).
   b. Pre-biopsy sonograms in 2 views (submit only the requested sonographic images/frames)
      - Submit 2 orthogonal sonographic images of the mass to be biopsied (e.g., if 1 image is in the transverse plane, the other should be in the sagittal plane).
   c. Post-biopsy sonogram (submit only the requested sonographic image/frame)
      - Submit a post-biopsy sonographic image (from the same mass) demonstrating the long axis of the needle in tissue acquiring position, either under or through the mass.
   d. Complete the corresponding section of the online CNB exam data form.
F. FNAC- Fine Needle Aspiration Cytology

If your facility performs FNAC, submit 1 BI-RADS® Category 4 or 5 case. Mammograms must have been taken within 60 days prior to the sonograms. The sonograms must not be older than 6 months from the date that the testing package was released to the facility.

Only submit images from a solid mass for FNAC; do not submit images from cyst aspirations or axillary lymph nodes.

1. **Mammograms**
   - Submit only 2 orthogonal projections (e.g., CC and MLO, CC and ML, CC and LM) of the breast being evaluated by ultrasound. The mass must be visible on both mammographic views. Spot views or individual slices from tomosynthesis can only be submitted in addition to the CC/MLO views.
   - Circle only the mass being evaluated on each mammogram (for film submission, do not use a radiopaque marker).

2. **Pre-biopsy sonograms in 2 views** (submit only the requested sonographic images/frames)
   - Submit 2 orthogonal sonographic images of the mass to be biopsied (e.g., if 1 image is in the transverse plane, the other should be in the sagittal plane).

3. **Post-biopsy sonogram** (submit only the requested sonographic image/frame)
   - Submit a post-biopsy sonographic image (from the same mass) demonstrating the needle positioned clearly within the mass in the long axis.

4. Complete the corresponding section of the online FNAC exam data form

**WARNING:** Before submitting your images to the ACR, be sure that the cyst/mass is clearly circled on each submitted mammogram so the ACR reviewers will be able to determine if the intended cyst/mass was imaged with ultrasound or biopsied. **If the cyst/mass is not circled on each mammogram, your facility will fail accreditation.**

V. Submitting and Labeling All Material

A. Submitting

1. Log into the ACRedit database and fill out all required clinical data forms and submit the online testing package.

2. If submitting the clinical images by electronic upload, read and follow the **Instructions for Uploading Images**, (uploading of images will be available in the near future.)

3. If submitting materials by film, select and submit the documents that generate by accessing “print forms for submission,” under the testing package link of your online account.

4. For film submission, place the appropriate label **below** each required image (e.g., the “Cyst Sono 1” label below the transverse sonogram image; the “Cyst Sono 2” label below the sagittal sonogram image.) If this is impossible due to insufficient room on the film, draw an arrow from the label to the image it is referencing.

5. For film submissions, the breast images on the mammograms images must be as close to “true size” as possible (i.e., without magnification or minification) or they must be printed with a scale. If you minify the images to fit them all on 8x10 film and do not provide a scale, the ACR reviewers will not be able to correlate the size of the cyst or mass on the ultrasound with the one on the ultrasound image. You may fail accreditation as a result.

6. Only submit the requested sonographic images; do not submit additional images/frames.

7. Do not cover any pertinent clinical or identification information on either the mammogram nor the sonogram images. For example, you may cover the pectoralis muscle with the label as long as it does not cover any breast tissue.
8. IMPORTANT: Only print the requested images/frames. Be sure that the ACR bar-coded labels are placed below the requested image without covering any pertinent clinical or identification information on either the mammograms or the sonographic images.

B. Breast Ultrasound Clinical Image Labels

<table>
<thead>
<tr>
<th>SIMPLE CYST</th>
<th>SOLID MASS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IMAGES</strong></td>
<td><strong>IMAGES</strong></td>
</tr>
<tr>
<td>2-view mammogram with the cyst circled</td>
<td>2-view mammogram with the mass circled</td>
</tr>
<tr>
<td>2 orthogonal views (e.g. 1 transverse, 1 sagittal) with no calipers visible on the cyst</td>
<td>2 orthogonal views (e.g. 1 transverse, 1 sagittal) with no calipers visible on the mass</td>
</tr>
<tr>
<td>1 image with appropriate caliper measurements</td>
<td>1 image with appropriate caliper measurements</td>
</tr>
<tr>
<td><strong>LABELS</strong></td>
<td><strong>LABELS</strong></td>
</tr>
<tr>
<td>cyst 2-view correlating mammo image 1</td>
<td>solid 2-view correlating mammo image 1</td>
</tr>
<tr>
<td>cyst 2-view correlating mammo image 2</td>
<td>solid 2-view correlating mammo image 2</td>
</tr>
<tr>
<td>cyst sono image without calipers 1</td>
<td>solid sono image without calipers 1</td>
</tr>
<tr>
<td>cyst sono image without calipers 2</td>
<td>solid sono image without calipers 2</td>
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<td>cyst sono image with calipers</td>
<td>solid sono image with calipers</td>
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AND

C. Ultrasound-Guided Breast Biopsy Clinical Images

<table>
<thead>
<tr>
<th>CORE NEEDLE BIOPSY</th>
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<tbody>
<tr>
<td><strong>IMAGES</strong></td>
</tr>
<tr>
<td>2-view mammogram with mass circled</td>
</tr>
<tr>
<td>Pre-biopsy sonogram showing mass in 2 orthogonal views (e.g. 1 transverse, 1 sagittal)</td>
</tr>
<tr>
<td>Pre-fire sonogram showing needle in the long axis (label only for devices in fire mode)</td>
</tr>
<tr>
<td>Post-biopsy (post-fire) sonogram showing needle in the long axis</td>
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AND (if applicable)

<table>
<thead>
<tr>
<th>FINE NEEDLE ASPIRATION CYTOLOGY</th>
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<tbody>
<tr>
<td><strong>IMAGES</strong></td>
</tr>
<tr>
<td>2-view mammogram with the mass circled</td>
</tr>
<tr>
<td>Pre-biopsy sonogram showing mass in 2 orthogonal views (e.g. 1 transverse, 1 sagittal)</td>
</tr>
<tr>
<td>Post-biopsy sonogram showing the needle clearly within the mass in the long axis</td>
</tr>
</tbody>
</table>

VI. Mailing Instructions

For film submission, send the Annual System Performance Evaluation (one per unit), Exam Data form(s) (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 traceable method with a signature required for delivery.

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

Your printed clinical 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. Breast Ultrasound 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 packet is in a submitted status, (uploading of images will be available in the near future.)

B. Film Submissions

- **Annual System Performance Evaluation** (for each unit, containing the required QC testing information, manufacturer, model, and serial number of the unit tested and labeled with a Quality Control label for each unit)
- **Exam Data Form(s)** printed from the online testing package and appropriately labeled.
- **Clinical Images** (appropriately labeled). The supervising physician must review and approve the clinical image selection. All sonograms and mammograms must be from the same 60-day period; the sonograms may not be older than 6 months from the date the testing package was released to the facility.
  - **Important:** Remember to circle only one mass or cyst being evaluated on the mammograms. ACR reviewers will fail the case if the mass or cyst is not circled or if multiple ones are circled.