

Your cover memorandum describes the type of testing that your facility is currently undergoing. If you are going through INITIAL accreditation, accreditation RENEWAL or REINSTATEMENT, you must submit both clinical and phantom images. If you are REPEATING a test on which you received a deficiency, you must only submit images from the deficient test.

The enclosed labels show when your testing materials are due to the ACR. Failure to meet this due date will jeopardize completion of your accreditation. If your facility is renewing its accreditation, we cannot guarantee completion before your ACR certificate expires.

PHANTOM IMAGE AND DOSE

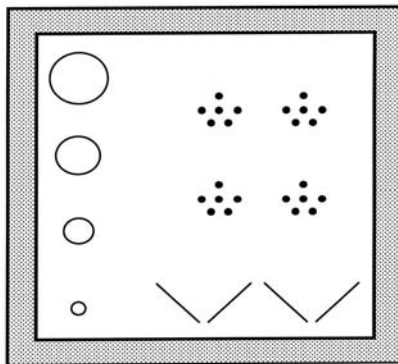
A. Required Items for testing

1. One approved accreditation phantom (RMI Model 156, CIRS Model 015, Nuclear Associates Model 18-220, or Nuclear Associates Model 18-250).
2. One Landauer thermoluminescent dosimeter (TLD) bar for each stereotactic breast biopsy unit to be tested. The serial number on the dosimeter must match the TLD number on the labels assigned to the stereotactic breast biopsy unit.
3. Control TLDs packed in a 1.5" x 2" envelope marked, "DO NOT OPEN-CONTROL TLD" for each stereotactic breast biopsy unit to be tested. Keep the control TLDs away from radiation and be sure to return these envelopes with your exposed dosimeter(s) to Landauer.
4. One 7" x 9" padded envelope addressed to Landauer and marked "FILM-DO NOT X-RAY". (Within each envelope you will find a clear plastic ziploc bag containing both the test dosimeter and the envelope with the control TLDs).
5. Bar-coded identification labels to be affixed to the phantom image and the Test Image Data sheet. **IMPORTANT:** These labels are for a *specific unit* and are marked "Phantom Image", Test Image Data", etc. Make sure that you put the appropriate label on the appropriate item.
6. Mailing labels for sending your films to the ACR in Reston, VA.
7. One Test Image Data sheet for each stereotactic breast biopsy unit you are testing.

B. Procedure

1. Phantom Images
 - a. Prepare your system for a stereotactic procedure by mounting the stereotactic localization device, its collimator and removing the grid (if necessary). Select the exposure mode that you typically use for obtaining scout images (either automatic exposure control [AEC] or manual). Also 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 50% adipose and 50% glandular tissue. If AEC is used, be sure the AEC detector is under the center of the phantom. Record all technique factors on the Test Image Data sheet. Follow the specific instructions for each phantom described below.
 - b. **Mini Digital Stereotactic Phantom (Nuclear Associates #18-250):** Orient the phantom as shown in Figure 1. Take one image without the TLD strip.

Chest Wall Side of Unit



**Figure 1
 Exposing the Mini Digital Stereotactic Phantom**

- c. **ACR Mammography Accreditation Phantom:** For screen-film systems, if you can remove the biopsy collimator and compression plate on your unit and still make an image, do so. Image the whole phantom centered on the film. The entire pink insert should be visible on the film. 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 four images as shown in Figure 2. Take four overlapping sections of the standard ACR Mammography Accreditation Phantom without the TLD strip. Use the AEC or manual mode – whichever is your typical technique for a scout image.

Chest Wall of Unit

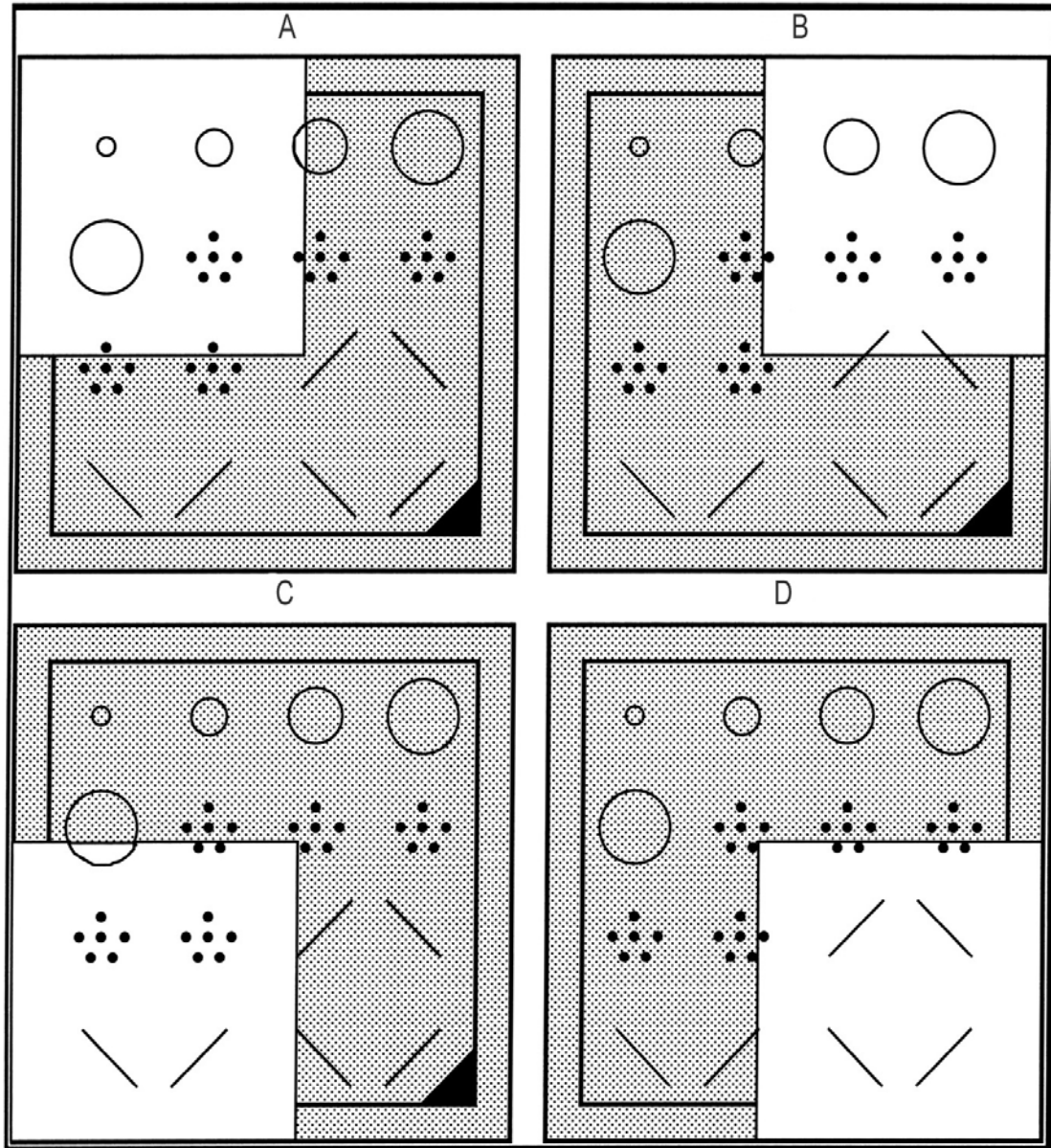


Figure 2
Exposing the ACR Mammography Accreditation Phantom

- d. For digital, print the image(s) *as close to "true size"* as possible (i.e., without magnification or minification). For screen-film, process the image(s) using the processor normally used for your stereotactic clinical images. Label the images with the enclosed bar-coded labels. **Do not put the phantom images on the same sheet of film that contains the clinical images you are submitting.** Phantom images may be submitted on film or high quality photographic paper as long as they are of equal quality to a transparency. If you wish to submit images on a CD, call the ACR for special instructions.

2. Dose
 - a. Place the phantom as indicated in Figure 3a for the ACR Mammography Accreditation Phantom (RMI 156, CIRS 015, or Nuclear Associates 18-220) or Figure 3b for the Mini Digital Stereotactic Phantom (Nuclear Associates 18-250).

Chest Wall Side of Unit

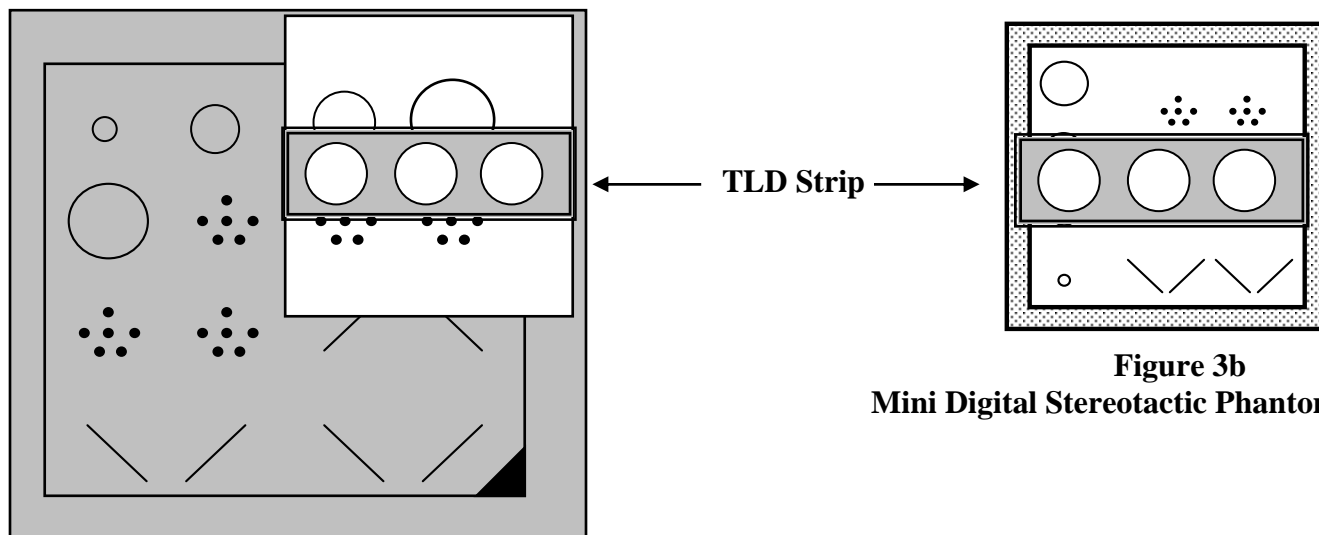


Figure 3a
ACR Accreditation Phantom

Figure 3b
Mini Digital Stereotactic Phantom

IMPORTANT: The ACR logo and Landauer name on the dosimeter must face the x-ray tube.

- b. Expose the phantom and dosimeter.
 - *For units with AEC, use a manual technique* as close as possible to the resultant AEC technique obtained in step B.1.a. for the phantom. (Do **not** use an AEC technique; the additional attenuation of the beam by the dosimeter will result in an excessive dose measurement.)
 - *For manual systems,* use the same technique used in step B.1.a. for the phantom. You may wish to make preliminary exposures of the phantom without the dosimeter to determine correct positioning of the phantom. For film systems, produce a test image with an average density in the center of the phantom image similar to that of clinical images.
- c. The phantom image **must show the entire dosimeter**. Place the TLD strip as shown on the appropriate diagram for your phantom.

WARNING: Each dosimeter may be exposed on the phantom once and once only; repeat exposures will yield excessive dose values. The single test image must include both the phantom and dosimeter properly positioned. If a mistake is made with the dosimeter, additional ones are available at a small fee. In this case, please call the ACR.

CLINICAL IMAGES

A. Required items for testing

1. Bar-coded identification labels to be affixed to the clinical images and the Test Image Data sheet. **IMPORTANT:** These labels are for a *specific unit* and are marked with the procedure image under evaluation. Make sure that you put the appropriate label on the appropriate item.
2. Mailing labels for sending your films to the ACR in Reston, VA.
3. One Test Image Data sheet (clinical image section) for each stereotactic unit you are testing.

B. Procedure

1. General

- a. Submit **one calcification biopsy** case that provides an example of your facility's **best work**.
 - Select the images based on the criteria described in the Clinical Image section of the Program Requirements.
 - The biopsy may have been performed with a gun-needle biopsy probe, a vacuum suction biopsy probe or another FDA-approved core biopsy device.
 - Lateral arm units are acceptable as long as the needle can be seen in relation to the calcifications in two views.
 - Although valuable for some calcifications, "target-on-scout" images are **not** acceptable for accreditation because reviewers cannot assess the needle position on 2 views.
 - The procedure must have been performed within **3 months of the date you obtained the accreditation phantom image**. (If you use a film processor, be sure the submitted processor QC data includes the dates that both the phantom and clinical images were obtained.)
- b. Clinical images may be submitted on film or high quality photographic paper as long as they are of equal quality to a transparency. If you wish to submit images on a CD, call the ACR for special instructions.
- c. You may submit copies of the mammograms (as long as they clearly demonstrate the target calcifications) or the originals. The calcifications to be biopsied **must be clearly marked** on each projection.

IMPORTANT: If the target calcifications are not marked on all mammogram projections, or more than one group are marked, the case **will not be evaluated** because the reviewers cannot be certain which calcifications are the targets for the biopsy.

- d. All images submitted must be from the **same patient**.
- e. Do **not** submit images that are obtained on models or volunteers.
- f. Do **not** include the radiology or pathology reports with the clinical cases. These will not be sent to the ACR reviewers.
- g. Each image must be clearly labeled with:
 - The patient's name and a unique identification number
 - Date of procedure
 - Designation of right or left breast
 - Facility name and zip code
 - Technologist identification
- h. Label each image with the enclosed bar-coded labels. (See the Labeling Guide on the last page.)
- i. 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 (gun-needle only)
 - Appropriateness of the post-fire, the post-fire pre-biopsy or the pre-biopsy stereo pairs (as applicable)
 - Appropriateness of the specimen radiograph
 - Exam identification (The ACR will keep all patient information confidential.)

REMEMBER: ACR reviewers assume that the case you submitted for accreditation is an example of your **best work**. Do **not** send images you believe are less than that. Consequently, your supervising physician must take an active role in selecting this case.

2. Required images for *gun-needle* biopsy probes:
 - a. A *2-view mammogram* (CC and Lateral or MLO projections) with the *calcifications to be biopsied clearly marked* on each image. Label the images "Calc Mammo 1" and "Calc Mammo 2" using the ACR labels.
 - b. A *Pre-Fire stereo pair* demonstrating needle positioning. Label the images "Calc Pre-Fire" using the ACR labels.
 - c. A *specimen radiograph* demonstrating calcium. Label the image "Specimen Radiograph" using the ACR labels.
3. Required images for *vacuum suction* biopsy probes:
 - a. A *2-view mammogram* (CC and Lateral or MLO projections) with the *calcifications to be biopsied clearly marked* on each image. Label the images "Calc Mammo 1" and "Calc Mammo 2" using the ACR labels.
 - b. A *Post-Fire, Pre-Biopsy stereo pair* demonstrating needle positioning for *tissue acquisition*. Label the images "Calc Pre-Biopsy" using the ACR labels. Do *not* submit images with the probe in the Pre-Fire position.
 - c. A *specimen radiograph* demonstrating calcium. Label the image "Specimen Radiograph" using the ACR labels.
4. Required images for *other FDA-approved core biopsy devices* (e.g., intact tissue device):
 - a. A *2-view mammogram* (CC and Lateral or MLO projections) with the *calcifications to be biopsied clearly marked* on each image. Label the images "Calc Mammo 1" and "Calc Mammo 2" using the ACR labels.
 - b. A *Pre-Biopsy stereo pair* demonstrating needle positioning for *tissue acquisition*. Label the images "Calc Pre-Biopsy" using the ACR labels.
 - c. A *specimen radiograph* demonstrating calcium. Label the image "Specimen Radiograph" using the ACR labels.

IMPORTANT: Labels help us keep track of your films. If you would like to submit additional mammography views that demonstrate the calcifications, use the additional image labels included in this package. Do not make copies of the existing barcode labels. Use one label per film and fill in all the blanks on each label. Retain a copy of the completed label sheet with the blanks filled in for your records. If you need additional labels, please contact the ACR.

MAILING INSTRUCTIONS

- A. Mail the exposed dosimeter and control TLDs in the pre-addressed, bubble envelope to:

Landauer, Inc.
2 Science Road
Glenwood, IL 60425-1586
ATTN: Mammography Analysis Laboratory

- B. Return the QA Questionnaire, Test Image Data sheet, phantom images, and clinical images to the following address by *a traceable method*.

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

The images submitted for review will be returned once the accreditation evaluation is complete. However, you should *maintain copies of all images* as well as a record of the patient names whose clinical images were sent for accreditation purposes until you receive official notification your accreditation is approved.

The enclosed labels show when your testing materials are due to the ACR. Failure to meet this due date will jeopardize completion of your accreditation. If your facility is renewing its accreditation, we cannot guarantee completion before your ACR certificate expires.

Submit **one calcification case** with any probe. Attach the bar-coded 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.

Stereotactic Breast Biopsy Accreditation Clinical Images

Gun-Needle Biopsy Probes

IMAGES	LABELS
2-view mammogram with the calcifications clearly marked	Calc Mammo 1 Calc Mammo 2
Pre-fire stereo pair demonstrating needle position	Calc Pre Fire Str Pair (Gun-needle)
Post-fire stereo pair demonstrating needle position	NA
Specimen radiograph	Calc Specimen

Vacuum-Suction Biopsy Probes and Other FDA-Approved Core Biopsy Devices

IMAGES	LABELS
2-view mammogram with the calcifications clearly marked	Calc Mammo 1 Calc Mammo 2
Post-fire, pre-biopsy stereo pair (for vacuum suction) OR Pre-biopsy stereo pair (for other core biopsy devices) demonstrating needle position	Calc Pre Biopsy Str Pair (Vacuum/Core Biopsy)
Specimen Radiograph	Calc Specimen