

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

(Updated: November 3, 2010)

Stereotactic Breast Biopsy Accreditation Program Update

Q. How many stereotactic breast biopsy facilities are accredited by the ACR?

A. As of October 1, 2010, the ACR had accredited 810 units at 789 stereotactic breast biopsy facilities.

Q. What is the current pass rate for units applying for accreditation in stereotactic breast biopsy?

A. In 2009, the first-attempt pass rate for new or renewing units was 81%. Almost all facilities passed on their second attempt at accreditation (after taking appropriate corrective action to improve quality).

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. No, not at this time. 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.

Q. We have a mammography unit that is used solely for stereotactic breast biopsy. The unit is not MQSA certified. During the course of these procedures, we take mammographic images. Because our unit is not MQSA certified, what restrictions exist on the mammographic images we may perform during such procedures?

A. Because stereotactic breast biopsy is currently excluded from FDA regulation, units that are used solely for stereotactic breast biopsy do not have to be MQSA certified. However, these uncertified units must not be used to perform conventional mammographic examinations. Uncertified units may be used to produce mammographic images only if they meet **all** of the following conditions:

1. The mammographic images obtained are an integral part of the stereotactic breast biopsy procedure.
2. Facilities must not bill separately for these mammographic images. They must bill only for the 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.

Application - General

Q. I have questions about my facility's accreditation. Where can I go for help?

A. With just a click of the mouse you have 24/7, user-friendly access to the complete array of the ACR's highly respected accreditation programs, from easy-to-use applications, testing and quality control forms for each modality, to a list of the most frequently asked questions. Visit www.acr.org/accreditation today! If our on-line information does not address your specific question, please call the Breast Imaging Accreditation Programs at (800) 227-6440. Our phone lines are open business days from 8:30 AM – 5PM eastern time.

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 accreditation process is conducted primarily by mail. The ACR may perform random site visits with prior notification to validate maintenance of accreditation criteria.

Q. Our facility is currently accredited by the ACR. When should we expect to be notified that it is time to renew?

A. The ACR will notify your Modality-Specific Supervising Physician about renewal approximately 8 months prior to your ACR accreditation certificate expiration. If you do not hear from us, please call our office so we may follow up on this for you.

Q. Will the ACR accept faxed signatures for the application?

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

Q. Will the ACR accept electronic or digital signatures for accreditation applications?

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

Q. How long do I have to submit Initial or Renewal testing materials to the ACR?

A. You have **45 calendar days** from the date the testing materials are sent to complete and return them to the ACR. (The due date is printed on the labels.) If you have problems meeting this deadline, call the Breast Imaging Accreditation Programs at (800) 227-6440 for help.

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.

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.

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. You may appeal the decision; however, you may only submit the original images with the original ACR labels. Please call the Breast Imaging Accreditation Programs at (800) 227-6440 for further guidance on your specific situation.

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 a [New Unit Addendum](#). If you have 13 months or less, you will need to start the renewal process early. Please contact the Breast Imaging Accreditation Programs at (800) 227-6440 for further information.

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. However, ***if your entire facility is moving to a new location, please provide the ACR your new address*** (as well as any other pertinent changes, such as the Practice Site and/or Modality-Specific Supervising Physician or contact) so that you will be appropriately notified when it is time to renew your accreditation.

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. If your entire facility is moving to a new location, please provide the ACR the date of your move and your new address (as well as any other pertinent changes, such as the Practice Site and/or Modality-Specific Supervising Physician or contact) so that you will be appropriately notified when it is time to renew your accreditation. Also, 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. 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 processor or laser printer quality control or mammography phantom image evaluation.
- Physics courses that cover generators or digital detectors.

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](#) 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 https://www.asrt.org/content/CEsponsors/ASRTInFocus/Fall_05.aspx#6.

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 image 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 independently perform stereotactic breast biopsy procedures at our accredited facility?

A. No. Only qualified physicians may independently perform stereotactic breast biopsy procedures at facilities accredited by the ACR.

Q. May our Radiologist’s Assistant independently perform stereotactic breast biopsy procedures at our accredited facility?

A. No. Only qualified physicians may independently perform stereotactic breast biopsy procedures at facilities accredited by the ACR.

Q. Do technologists performing 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 are consistent with the MQSA requirements:

Qualifications	Medical Physicist*
Initial	Qualified to perform mammography surveys under MQSA AND Performed 1 hands-on stereotactic breast biopsy survey under a qualified medical physicist or at least 3 independent surveys prior to 6/1/97
Continuing Experience	2 stereotactic breast biopsy physics surveys over a 24-month period
Continuing Education	3 CEUs in stereotactic breast biopsy every 3 years

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. May we submit clinical images on paper?

A. Images should be submitted on standard transparency film. However, the ACR will accept images on high quality photographic paper.

Q. May I submit my images on CD instead of printing them?

A. No, not at this time.

Q. How far back may I go to select cases to submit for accreditation?

A. Cases should not be older than 2 months from the date on the Testing Memorandum. Call the ACR if you have difficulty finding appropriate cases with this time period.

Q. Are we required to submit original mammograms with the stereotactic breast biopsy images for accreditation?

A. No. Copies of mammograms will be accepted as long as they are of good quality and clearly labeled with the patient identification and the date of the procedure.

Q. May the mammograms come from an outside facility?

A. Yes. The mammograms submitted can 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 stereotactic breast biopsy accreditation.

Q. The calcifications are not visible on the mammogram. Do I still need to submit the mammogram?

A. The calcifications **must** be visible on both mammographic views. Please submit another case.

Q. I would like to submit a case where the calcifications are only visible on the 2-view spot compression mammograms. It is not visible on the routine CC and MLO views. May I submit only the spot compression mammograms?

A. Yes. Projections such as compression spots or magnification views are acceptable as long as they demonstrate the calcifications in **2 planes**, and the calcifications have been **clearly marked**.

Q. Does the patient ID have to be on each image on each sheet of film?

A. Yes.

Q. The testing package contains sticky labels for the images. What am I supposed to do with them? (We are applying for stereotactic breast biopsy accreditation with a vacuum-suction biopsy probe.)

A. ACR clinical image reviewers must evaluate the quality and appropriateness of a large number of images from a large number of stereotactic breast biopsy facilities. The reviewers want to know that facility personnel understand the type of each image requested. The sticky labels allow you to clearly indicate to the reviewers the types of images you have submitted for review.

If possible, print your images 6-on-1. Be sure to print **only** the requested images (CDs are not allowed at this time), and place the appropriate sticky label below its corresponding image. If the images are not labeled correctly, the reviewers will **fail** your case because the image will not meet the ACR criteria for the type of image requested. Please refer to the “Labeling Guide” in the [Testing Instructions](#).

In your specific case, you will need the following labels:

VACUUM-SUCTION BIOPSY PROBES	
IMAGES	LABELS
2-view mammogram with the mass marked	Calc Mammo 1 Calc Mammo 2
<i>Post-fire</i> , pre-biopsy stereo pair (for vacuum suction) OR <i>Pre-biopsy</i> stereo pair (for other core biopsy devices) demonstrating needle position.	Calc Pre Biopsy Str Pair (Vacuum/Core Biopsy)
Specimen Radiograph	Calc Specimen

Q. The testing package contains a large number of sticky labels. Must I use all of them?

A. No. Please refer to the “Labeling Guide” in the [Testing Instructions](#).

Q. My site uses a vacuum-suction probe. We had to print our pre-biopsy stereo pair images on two separate films but only one label is provided. Should I use the Calc Pre Fire Str Pair 3 (Gun-needle) label on the second image?

A. No. Please label this image with one of the Additional Image Labels provided. Do not use both the Vacuum-suction and Gun-needle labels.

Q. May I place the sticky labels anywhere on the film?

A. No. Place the sticky label ***below the image it identifies***. Do not cover any pertinent clinical or identification information. If the label will not fit, place it as close as possible to the image it identifies and use a wax pencil to draw an arrow to the correct 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 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. We have a prone stereotactic breast biopsy table. May we tape the dosimeter to the phantom so it does not fall off during exposure?

A. Yes. However, do not cover the center portion of the dosimeter with tape. Using 2 small pieces of tape, only tape the ends of the dosimeter to the phantom.

Q. I shot the phantom image with the dosimeter as described in the Testing Instructions. Should I submit this image to ACR even though the test objects are obscured by the dosimeter?

A. Yes. One phantom image with the dosimeter and one (or more) phantom images without the dosimeter are required for accreditation. It is normal for the test objects to be covered by the dosimeter.

Quality Assurance and Quality Control

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.

Q. What quality control data do we need to submit for accreditation?

A. As part of accreditation, you must submit a copy of your **most recent medical physicist's equipment survey for each unit used for stereotactic breast biopsy**. The ACR also recommends that routine quality control (QC) be performed by the technologist on all stereotactic breast biopsy units used for breast imaging. See the [Stereotactic Breast Biopsy Program Requirements](#) for details.

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 $\pm 15\%$ of the center. Our Lorad/Hologic stereotactic breast biopsy table fails this test at 2 of the 4 corners. Our Lorad service engineer referred me to their 2/17/95 protocol for this test. It calls for obtaining the SNRs using 32x32 ROI boxes centered well away from the corners of the 512x512 image. (These coordinates are: 100,100; 100,400; 400,100; and 400,400.) Under these conditions, the unit passes. Is it acceptable to follow the manufacturer's protocol in this case?

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

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. More and more often, facilities that have digital stereotactic breast biopsy equipment have gone totally filmless, removing all chemical processing. How can I best perform the collimation assessment when wet processing of film is unavailable?

A. Several alternatives to standard screen-film and processing could be used for this test:

1. CR cassettes may be substituted for screen-film cassettes

and toward the left side to enable visualization of the third and fourth fibers.

6. Acquire a scout view image.

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.

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.

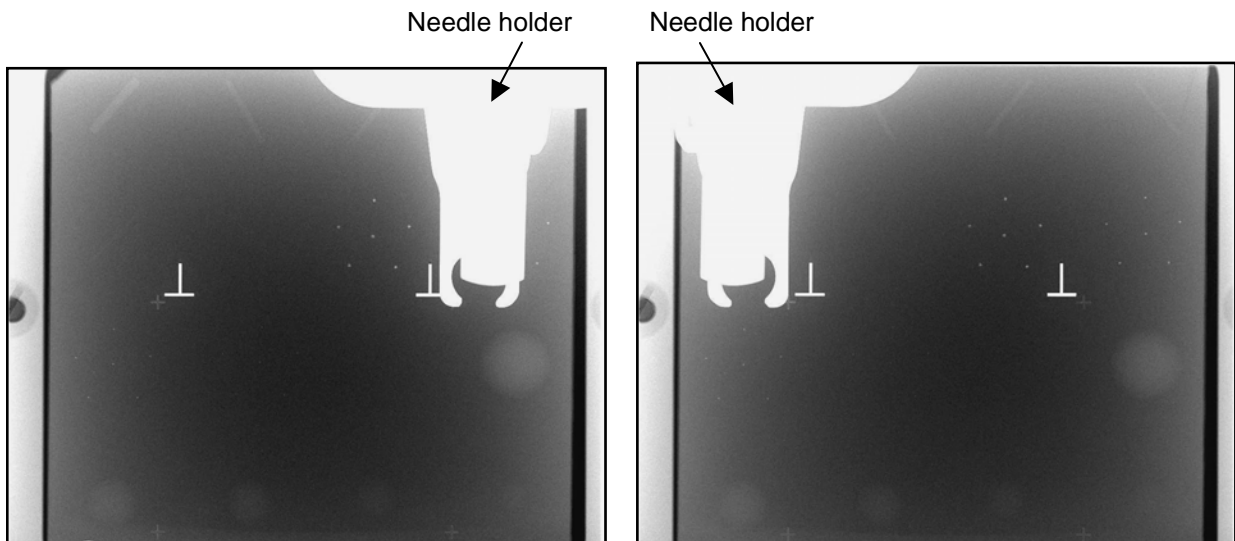


Figure 1. Position of the needle holder to enable imaging of the 5th and 6th fibers.

Figure 2. Position of the needle holder to enable imaging of the 3rd and 4th fibers.