An Update on the ACR Stereotactic Breast Biopsy Accreditation Program

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ACR Breast Imaging Centers of Excellence (BICOE)

- Initiated in October 2006
- A center must be fully accredited in:
  - Mammography by ACR (or FDA-approved state accrediting body)
  - Stereotactic Breast Biopsy by the ACR
  - Breast Ultrasound by the ACR (including the Ultrasound-Guided Breast Biopsy module)
- For more information, go to www.acr.org/accreditation/bicoe.aspx

ACR Breast Imaging Accreditation Programs

- Mammography – MAP (1987)
- Stereotactic Breast Biopsy - SBBAP (1996)
- Ultrasound-Guided Breast Biopsy (1998)
- Breast Ultrasound, with USGBB Module – BUAP (2000)
- Breast MRI - BMRAP (to be launched early 2010)

Units and Facilities Accredited in SBBAP

- Assesses entire facility performance
  - Personnel qualifications (professional guidelines developed by ACR/ACS Joint Task Force in 1997)
  - Equipment
  - Quality control
  - Quality assurance and outcome data
  - Exam identification and labeling
  - Clinical performance
  - Phantom image quality
  - Radiation dose
- Report provides detailed recommendations for improvement
Physician • Medical Physicist • Technologist

SBBAP Personnel qualifications

In 1997 ACR and the American College of Surgeons agreed on and published guidelines for physician training, qualifications, and continuing experience*

- Collaborative setting: radiologists and surgeons work together
- Independent settings: radiologists or surgeons work independently


SBBAP Personnel Qualifications – Physician: Collaborative Setting

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Radiologist*</th>
<th>Other Physician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td></td>
<td>Qualified as an interpreting physician under MQSA</td>
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<td></td>
<td></td>
<td>Experienced in post-biopsy patient management</td>
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<tr>
<td></td>
<td></td>
<td>AND 3 hours of Category 1 CME in stereotactic breast biopsy (that includes image triangulation for lesion location)</td>
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<tr>
<td></td>
<td></td>
<td>AND Evaluated 480 mammograms every 2 years in consultation with MQSA-qualified physician</td>
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SBBAP Personnel Qualifications – Physician: Independent Setting

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Radiologist*</th>
<th>Other Physician</th>
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</thead>
<tbody>
<tr>
<td>Initial</td>
<td></td>
<td>24 stereotactic breast biopsies in prior 24 months (or requalify according to above requirements)</td>
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<tr>
<td></td>
<td></td>
<td>AND Evaluated 480 mammograms every 2 years in consultation with MQSA-qualified physician</td>
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<tr>
<td></td>
<td></td>
<td>AND 3 hours of Category 1 CME in stereotactic breast biopsy in prior 36 months that includes post-biopsy management of the patient</td>
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* Radiologists must be currently qualified as an interpreting physician under MQSA.
SBBAP Personnel Qualifications – Radiological Technologist

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Radiological Technologist</th>
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<tbody>
<tr>
<td>Initial</td>
<td>Qualified to perform mammography under MQSA AND 3 Category A CEUs in stereotactic breast biopsy AND Performed 5 stereotactic breast biopsy procedures under supervision of a qualified physician or technologist</td>
</tr>
<tr>
<td>Continuing Experience</td>
<td>24 stereotactic breast biopsy exams in prior 24 months</td>
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SBBAP Personnel Qualifications – Radiological Technologist

<table>
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<th>Radiological Technologist</th>
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<tr>
<td>Initial</td>
<td>Registered technologists - In compliance with CE requirements of certifying organization for the imaging modality in which they perform services - CE includes credits pertinent to tech’s accredited practice - State licensed technologists - 24 hours of CE every 2 years - CE relevant to imaging and radiologic sciences, patient care - CE includes credits pertinent to tech’s ACR accredited practice - All others - 24 hours of CE every 2 years - CE relevant to imaging and radiologic sciences, patient care - CE includes credits pertinent to tech’s accredited practice</td>
</tr>
<tr>
<td>Continuing Education (new)</td>
<td>State licensed technologists - 24 hours of CE every 2 years - CE relevant to imaging and radiologic sciences, patient care - CE includes credits pertinent to tech’s ACR accredited practice</td>
</tr>
<tr>
<td>Continuing Education (new)</td>
<td>All others - 24 hours of CE every 2 years - CE relevant to imaging and radiologic sciences, patient care - CE includes credits pertinent to tech’s accredited practice</td>
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SBBAP Personnel Qualifications – Medical Physicist

<table>
<thead>
<tr>
<th>Qualifications</th>
<th>Medical Physicist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>Qualified to perform mammography surveys under MQSA 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</td>
</tr>
<tr>
<td>Continuing Experience</td>
<td>2 stereotactic breast biopsy physics surveys over a 24-month period</td>
</tr>
<tr>
<td>Continuing Education</td>
<td>3 CEUs in stereotactic breast biopsy every 36 months</td>
</tr>
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SBBAP – Quality Assurance: Outcome Data

1. Total number of procedures
2. Total number of cancers found
3. Total number of benign lesions
4. Total number of stereotactic biopsies needing repeat biopsy (open excisional or stereotactic biopsy) - Insufficient sample - Non-concordance with imaging - Ductal atypia, radial scar - Other
5. Total number of complications - Hematomas requiring surgical attention - Infections requiring treatment - Other

SBBAP – Quality Control: Medical Physicist’s Annual Tests

1. Stereotactic Breast Biopsy Unit Assembly
2. Collimation Assessment
3. Focal Spot Performance and System Limiting Resolution
4. kVp Accuracy and Reproducibility
5. Beam Quality Assessment (Half-Value Layer Measurement)
6. Automatic Exposure Control (AEC) System or Manual Exposure Performance Assessment
7. Receptor Speed Uniformity
8. Breast Entrance Exposure, Average Glandular Dose and Exposure Reproducibility
9. Image Quality Evaluation
10. Artifact Evaluation
11. Localization Accuracy Test

• Published in 1999
• Addresses - Image quality - Patient radiation dose
• Provides guidance for - Technologist QC - Medical Physicist QC
• Waiting on FDA/MQSA decisions to update

Stereotactic Breast Biopsy QC Manual
**SBBAP – Quality Control: Radiologic Technologist’s Tests**

1. Localization accuracy test - Daily before patient exams
2. Phantom images - Weekly
3. Hardcopy output quality - Monthly
4. Visual checklist - Monthly
5. Compression - Semiannually
6. Repeat analysis - Semiannually
7. Zero alignment test (if required by manufacturer) - Before each patient
8. Any additional tests required by manufacturer

**Goal:** Determine ability to accurately perform the procedure

- Case material
- Devices
  - Gun-needle
  - Vacuum suction
  - Other FDA-approved core biopsy devices
- Submit examples of best work
- Criteria
  - Accurate needle positioning of biopsy probe in relation to the target at specified stage of procedure for the probe being used

**SBBAP - Equipment, Phantom Images and Dose Criteria**

Goal: Equipment functioning optimally; dose does not exceed level set for mammography

- QC evaluation
- Phantom image quality assessment
- Dose criteria - must be less than 300 mRads

<table>
<thead>
<tr>
<th>MAP Phantom</th>
<th>Mini Phantom</th>
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<tbody>
<tr>
<td>S/F Digital</td>
<td>S/F Digital</td>
</tr>
<tr>
<td>Fibers</td>
<td>4.0 5.0 2.0 3.0</td>
</tr>
<tr>
<td>Speck Groups</td>
<td>3.0 4.0 2.0 3.0</td>
</tr>
<tr>
<td>Masses</td>
<td>3.0 3.5 2.0 2.5</td>
</tr>
</tbody>
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**Two Types of Approved Phantoms**

- ACR Mammography Phantom
- "Mini" Phantom

**Mini Phantom Exposures**

Phantom Images Submitted for Accreditation – "Mini" Stereotactic Phantom

**Mammography Phantom Exposures**

Phantom Images Submitted for Accreditation – Mammography Accreditation Phantom

Fifth exposure with dosimeter in center of field.
ACR Accreditation Changes as Practice and Technology Evolves

- Program instructions revised to accommodate shift away from screen-film
- Requirement for clinical mass case eliminated as these biopsies are now primarily performed under ultrasound guidance

ACR Accreditation Changes as Practice and Technology Evolves

- All units at the site must pass evaluation for accreditation to be maintained
- A certificate and decal will be issued for each unit
- Accreditation is granted for 3 years

If the Site Does Not Pass the First Time

- Retest
  - A facility will have the option to retest
- Appeal
  - Sites have the option to appeal the final outcome
  - The films are reviewed by a senior reviewer, not involved with the first review

If the Site Does Not Pass the First Time

- All units at the site must pass evaluation for accreditation to be maintained
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SBBAP Pass Rate

19% of units do not pass on 1st attempt (2009)

Reasons for Failures

1st attempt 2007 - 2009

- Failures are primarily clinical, targeting issues
- Phantom failures also show image quality problems
- Dose failures (300mrad) much higher than in MAP
- After corrective action, less than 2% of total applicants fail again

Patients and Referring Physicians Can Find Accredited Facilities

ACR Accreditation Changes as Practice and Technology Evolves
www.acr.org/Breast-Imaging

Thank you.
Questions?