

Recommendations on the Surgical, Radiologic and Pathologic Approaches to

Breast Disease: Using best practices based on multidisciplinary methodologies developed through the Allina Breast Committee.

Image guided core biopsies:

1. **Image guided core biopsies for the diagnosis of breast abnormalities:** Image guided core biopsy performed by a radiologist is the expected methodology to diagnose breast abnormalities for the vast majority of cases. Exceptions do exist based on clinical and anatomical reasons. If a core biopsy is not performed, it is expected that the surgeon state reasons explaining why the surgical approach was utilized in the patient's medical chart.
2. **Management of various core biopsy diagnoses:** The following represents a list of some of the core biopsy diagnoses, definitions, and suggestions for management.
 - Indeterminate epithelial proliferation (formally referred to as atypical ductal proliferation /ADP): term used to indicate the presence of microscopic features in the limited sampling of a core biopsy specimen that cannot be further clarified. Indeterminate epithelial proliferation is purely a pathologic term; it does NOT place a patient at an increased risk of developing breast cancer (unless more significant atypia such as ADH is present on the excision specimen). Excision should be performed around the targeted lesion to determine if this represents atypical ductal hyperplasia (ADH), ductal carcinoma in situ (DCIS), lobular neoplasia (LN), or cytologic changes of no clinical significance.
 - Atypical ductal hyperplasia (ADH): ADH is associated with an increased risk of developing breast cancer. When identified on core biopsy, an excision around the targeted lesion should be performed to determine if a more worrisome lesion (such as DCIS) is present.
 - Lobular neoplasia (LN) including atypical lobular hyperplasia (ALH) and lobular carcinoma in situ (LCIS): When ALH or LCIS are seen on core biopsy, radiologic and pathologic correlation is performed to determine if further excision around the targeted lesion is indicated. The pathology and radiology reports will provide further information to the surgeon for a particular case, based on rad-path correlation, NCCN guidelines, etc.

Based on a prospective study performed in our institution, protocols have been made for follow-up of LN on core biopsy (Susnik, Day, Abeln, Bowman, Krueger, Swenson, Tsai, Bretzke, Lillemoe: Surgical outcomes of lobular neoplasia diagnosed in core biopsy; prospective study of 316 cases. *Clin Breast Cancer* 2016, <http://dx.doi.org/10.1016/j.clbc.2016.06.003>).

- ✓ If there is discordance with the imaging findings, excision is recommended.
- ✓ If the core biopsy was performed for calcifications and LN is an incidental finding, the radiologist must correlate with imaging findings to determine if the targeted calcifications were adequately sampled and determine if excision is necessary.
- ✓ If LN is identified on core biopsy performed for a mass, density, asymmetry or area of MRI detected enhancement, excision may be recommended (based on the rad-path correlation).

- ✓ If there is florid LCIS (marked expansion of terminal duct-lobular units by LN) or extensive LN (greater than 4 foci of ALH or LCIS on core biopsy), excision is recommended (based on NCCN guidelines).
- Variant lobular neoplasia (pleomorphic LCIS and LCIS with necrosis). Variant type lobular neoplasias diagnosed on core biopsy require complete excision of the targeted lesion. These types of atypia behave more like a DCIS than a classic type LCIS, and up to 40% may be associated with invasive lobular carcinomas.
- Flat epithelial atypia (FEA): FEA has been infrequently seen in association with more significant lesions (ADH, DCIS, and invasive tumors) on excisional specimens, however the upgrade rate is very low. For FEA identified on stereotactic biopsies, excision will be recommended if the calcifications have not been adequately sampled, there is a co-existing atypia, or if the patient has a known gene mutation. Existing literature has not shown any significant risk of progression of FEA to a more significant lesion over time and does not place patients at increased risk of developing breast cancer.
- Mucocoele-like lesions (without associated atypia): Mucocoele-like lesions are characterized by mucin dissecting the stroma; this finding can be associated with benign, atypical or malignant processes. Generally, when mucocoele-like lesions are found in association with a mass or calcifications measuring greater than 1 cm, complete removal of that abnormality is recommended to exclude a heterogeneous process, since these lesions have been found in association with ADH, DCIS, or invasive mucinous carcinoma (this practice may evolve; it is known that the risk of finding more significant pathology in the excision specimen at Allina is very low). If the targeted lesion is less than 1 cm, radiographic follow-up may be sufficient.
- Papillary lesions without associated atypia: Intraductal papillary processes may be heterogeneous (may contain areas of atypia or in-situ carcinoma). However, when the lesion measures less than 1 cm, it may have been adequately sampled by the core biopsy procedure. If the lesion measures greater than 1 cm, excision is generally recommended. In cases of larger lesions (>1.0 cm) with imaging features of intraductal papillary process surgical excision (rather than image guided core biopsy) should be considered as the first choice of sampling.
- Papillary lesions with associated atypia: these patients should undergo excision of the targeted lesion.
- Radial scars: Radial scars are proliferative lesions that can rarely contain atypia or cancer. If the targeted lesion associated with the radial scar measures less than 1 cm, radiographic follow-up is generally sufficient. If the radial scar measures greater than 1 cm, adequate sampling by core biopsy may be unlikely and excision should be considered.

Breast-conserving surgery:

1. **Intraoperative orientation of lumpectomy specimens by surgeons using a standardized inking scheme:** It is expected that surgeons ink breast lumpectomy specimens intraoperatively to label margins for accurate margin identification. This applies to lumpectomy cases for suspected

cancer or atypia cases, including invasive cancer, ductal carcinoma in situ (DCIS), atypical ductal hyperplasia (ADH), and variant types of LCIS (pleomorphic lobular carcinoma in situ (PLCIS) and LCIS with necrosis). Most surgeons have now adopted this inking scheme for all lumpectomy specimens (including those for suspected benign disease). New surgeons are encouraged to view an inking video created by Allina, for procedural information:

<https://www.dropbox.com/s/dvj4hu3w02qe3lp/Spec%20Handling.wmv?dl=0>

The Allina standard inking scheme is as follows:

- Anterior: orange
- Posterior: black
- Superior: blue
- Inferior: red
- Medial: green
- Lateral: yellow

- 2. Intraoperative review of lumpectomy cases by pathology:** Lumpectomy cases performed for invasive cancer, DCIS, ADH, and variant lobular carcinoma in situ (PLCIS and LCIS with necrosis) should be sent to pathology for an immediate intraoperative evaluation and margin assessment by a pathologist, and to ensure proper handling of the specimen according to ASCP/CAP guidelines. If a margin is deemed involved or potentially involved by a neoplastic process on pathologic evaluation, immediate margin re-excision should be considered.

Lumpectomy specimens for presumed benign lesions may also be inked (many surgeons currently ink all lumpectomy specimens). This facilitates patient management in the presence of an unsuspected malignancy that is identified in a presumed benign specimen. No intraoperative assessment by a pathologist is needed for these cases, unless requested specifically by a surgeon.

- 3. Lumpectomy specimen imaging:** Most lumpectomy specimens localized by wires or radioactive seeds should be imaged for radiologic assessment to determine if the targeted lesion, core biopsy clip (if on target and expected to be removed) and biopsy localization wire or radioactive seed were removed with the specimen. In some hospitals, this imaging is performed in the pathology suite, with transmission of the images to the radiologist for interpretation. When imaging is performed in the pathology suite, two specimen images will be immediately transmitted to the radiologist, one of which has the specimen rotated at 90 degrees with respect to the first image. Some lumpectomy specimens may not require imaging review by a radiologist (if mass/lesion was not seen by initial imaging). For these cases, the specimen may be imaged in the pathology suite (currently available at ANW, Mercy, and United hospitals) for the surgeon's review, but image will not be transmitted to radiologist (and patient will not be charged for radiology review).
- 4. Lumpectomies with radioactive seed localization:** Lumpectomies that contain a radioactive seed will be sent to pathology in a sealed bag or cup, and in a lead container. The first image of the lumpectomy will be performed with the specimen within the plastic bag or cup, so the seed can be identified. Once the first image is obtained and the seed location is identified, a second image with the specimen rotated 90 degrees will also be obtained and sent to the radiologist.

5. **Lumpectomy imaging of specimen slices for DCIS cases with associated calcifications:** Imaging of the lumpectomy slices to assess targeted calcifications near the margins of the lumpectomy specimen may be a useful adjunct to margin assessment at the time of surgery. This procedure may be used when calcifications on the original stereotactic core biopsy were associated with DCIS (with or without an invasive component). For these types of cases, the radiologist will determine at the time of localization if the size/location of targeted calcifications remaining in the patient warrant additional imaging of the specimen slices once the lumpectomy specimen has arrived in pathology. And, the radiologist will inform the surgeon prior to surgery that additional imaging will be performed to assess specimen margins during the lumpectomy procedure.

The lumpectomy slices from these specimens will be imaged in pathology and sent to the radiologist for review. The pathologist will determine if there are any gross findings to indicate margin re-excision (biopsy cavity site relationship to the margin or mass lesion). The radiologist will determine if there are any radiographic findings that would indicate need for margin re-excision based on the relationship of the targeted calcifications to the perimeter of the lumpectomy slices (the perimeters of each slice represent margins). One exception: the 2 end slices may represent “margins” based on the thickness of these two slices, but further imaging of the end slices rotated with the margin to the periphery can also be performed). The radiologist will communicate to the pathologist regarding suspicious margins via designated lumpectomy slice number and clock face. The pathologist will determine the ink color(s) of the suspicious margins. Then, a conference call should be convened to include the pathologist, radiologist and surgeon regarding potential margins that should be immediately re-excised.

An overview of this process can be viewed in this video:

<https://www.dropbox.com/s/xn2evh0erijvpb2/Faxitron%202017%20Pathvision%20Abbott%20Process%20Rough-%20FINAL.mp4?dl=0>

6. **Management of DCIS with regards to surgical margins and recommendations for margins re-excisions in patients undergoing breast-conserving therapy:** Allina Breast Committee Consensus Guidelines follow the consensus statement for DCIS margins published by the Society of Surgical Oncology, American Society for Radiation Oncology, and the American Society of Clinical Oncology (jco.ascopubs.org/cgi/doi/10.1200/JCO.2016.68.3573). All margins involved with DCIS at ink, and all DCIS margins less than 0.2 cm should be considered for re-excision when possible (DCIS less than 0.2 cm from a posterior margin are considered adequate, if the lumpectomy specimen was excised to fascia). A multidisciplinary team should discuss exceptions. If re-excision is not performed for a margin less than 0.2 cm, it is recommended that the reason be documented in the medical record. If invasive tumor is associated with DCIS margins are assessed according to #7 or #9 (see below).
7. **Management of invasive tumor surgical margins and recommendations for margins re-excisions in patients undergoing breast-conserving therapy:** Allina Breast Committee Consensus Guidelines follow the consensus statement for invasive margins published by the Society of Surgical Oncology and American Society for Radiation Oncology (dx.doi.org/10.1016/j.ijrobp.2013.11.012). All margins involved with invasive tumor at ink should be considered for re-excision. Exceptions may occur when a margin less than 0.1 cm should be considered for re-excision. An example would be a tumor that is much larger in size

than appreciated by imaging or clinical exam (such as invasive lobular carcinoma), with a large volume of cancer within 1 mm of the margin (even though the tumor is not on ink); a “negative” pathologic margin in this situation may not be sufficient. Additional examples could include fragmented lumpectomy specimens, or those that have not been appropriately inked, causing uncertainty of margin status. A multidisciplinary team should discuss exceptions. If re-excision is not performed for a positive margin, it is recommended that the reason be documented in the medical record. For lumpectomy specimens with both invasive carcinoma and DCIS, no tumor on ink (for both invasive carcinoma and DCIS) is generally considered adequate unless there is extensive intraductal component (EIC) (see #8) or microinvasive tumor with DCIS (see #9).

- 8. Management of invasive tumor and DCIS surgical margins, and recommendations for margins re-excisions in patients undergoing breast-conserving therapy:** For lumpectomy specimens with both invasive carcinoma and DCIS, no tumor on ink (invasive carcinoma or DCIS) is generally considered adequate assuming patient will be treated with adjuvant therapy and whole breast radiation. These guidelines may not be adequate for invasive carcinomas with extensive intraductal component (EIC), due to the chance of remaining DCIS in these patients. Thus, the margin assessment for DCIS in a patient with EIC with DCIS margins less than 0.2 cm should be discussed at a multidisciplinary conference to determine if the margins are “adequate” prior to foregoing margin re-excision.
- 9. Management of microinvasive carcinomas with DCIS, and recommendations for margins re-excisions in patients undergoing breast-conserving therapy:** For microinvasive carcinomas with DCIS, no tumor on ink is generally sufficient for the microinvasive component, but 0.2 cm or greater is the expected margin width for the DCIS component (the guidelines for microinvasive carcinoma with DCIS follow the expected guidelines for DCIS-only lumpectomies).
- 10. Management of surgical margins in patients who have undergone neoadjuvant chemotherapy:** Lumpectomy and mastectomy specimens should be immediately sent to pathology for gross evaluation by a pathologist. The pathologist will evaluate for residual gross tumor, tumor bed changes, and prior evidence of biopsy (biopsy site changes or core biopsy clips). The pathologist will report to the surgeon regarding margin status to any identifiable tumor, and if tumor bed appears transected at a margin. Surgeon may request frozen section for immediate assessment of margins if indicated. For both invasive carcinoma and DCIS, no tumor on ink (invasive carcinoma or DCIS) is generally considered adequate:
- 11. Re-excision of lumpectomy margins:** When a second surgery is required for re-excision of lumpectomy margins, the surgeon should send re-excised margins immediately to pathology for an intraoperative evaluation. If invasive tumor was present at the original lumpectomy margin, the pathologist will render a gross evaluation of the new margin, and may do a frozen section of that margin if necessary. If DCIS was present at or close to the original lumpectomy margin, a frozen section in this setting has been shown to improve the accuracy of margin assessment. Thus, the pathologist/PA will freeze representative sections from the re-excised margins if DCIS was at or near the original lumpectomy margin.
- 12. Management of non-ADH atypias (flat epithelial atypia (FEA), indeterminate epithelial atypia, atypical lobular hyperplasia (ALH), lobular carcinoma in situ, classic type (LCIS)) in patients undergoing breast-conserving therapy:** Generally when a lumpectomy is being performed for certain types of non-ADH epithelial atypia, the margins of the specimen should be inked

intraoperatively by the surgeon and the specimen should be imaged for radiology review to assess the prior core biopsy site, radiographic clip, and targeted mass/lesion. After imaging is reviewed by a radiologist, these specimens should be placed immediately in formalin to ensure handling of the specimen according to ASCO/CAP guidelines. No immediate intraoperative assessment by a pathologist is necessary (unless specifically requested by a surgeon).

- 13. Evaluation of various atypias on microscopic review (permanent sections):** If only a focal area of ADH is present in a specimen (measuring less than 0.3 cm) and it is transected at a surgical margin, generally re-excision of that margin should be considered. When variant types of lobular neoplasia (pleomorphic LCIS and LCIS with necrosis) are surgically excised, margin assessments generally follow the DCIS recommendations. No margin assessments are given for classic type of lobular neoplasia (classic LCIS and ALH).

Mastectomy surgery:

- 1. Intraoperative orientation of mastectomy specimens by surgeons:** Surgeons should orient all mastectomy specimens with a stitch at 12 o'clock.
- 2. Intraoperative review of mastectomy cases by pathology:** All mastectomies performed for cancer (invasive carcinoma and DCIS) should be sent to pathology for an immediate intraoperative evaluation and margin assessment by a pathologist, and to ensure proper handling of the specimen according to ASCP/CAP guidelines. On a mastectomy specimen, if a suspicious margin is seen, a frozen section should be immediately performed to determine if tumor vs. biopsy site changes are present at a margin. If a margin is deemed involved, immediate margin re-excision should be performed when possible.

Nipple sparing mastectomies:

Nipple sparing mastectomies: Nipple sparing mastectomies (NSM) remove maximal breast tissue including clearing of ductal structures beneath the nipple, while preserving the nipple, areola, and breast skin. NSM can be performed if the patient's cancer meets the following criteria: no skin involvement and no significant segmental calcifications extending toward the nipple.

One immediate intraoperative assessment (frozen section) of the nipple ducts should be performed at the time of surgery; this specimen is obtained from the nipple ducts on the mastectomy specimen. The surgeon must place a stitch on the mastectomy specimen at the site of the nipple as well as at 12 o'clock, and send the mastectomy specimen immediately to pathology for frozen section. If the nipple ducts on the mastectomy specimen are involved by invasive carcinoma, DCIS, or variant LCIS on frozen section, the nipple (with or without the areola) should be removed. Ductal or lobular atypia or indeterminate pathology seen on frozen section should be deferred to the final permanent sections for definitive assessment and classification, rather than sacrificing the nipple at the time of the original mastectomy.












A separate specimen is submitted from the everted nipple ducts at the time of mastectomy and sent to pathology for routine pathology (permanent sections); no frozen section is necessary on the everted nipple ducts.






The nipple ducts from the NSM specimen (originally evaluated on frozen section) as well as the separately submitted nipple duct specimen from the everted nipple will be further evaluated on permanent sections. If either specimen contains invasive carcinoma, DCIS, or variant LCIS, the nipple (with or without the areola) should be ultimately removed.

Prophylactic mastectomies without history of gene mutations (such as BRCA) or suspicious imaging findings in the breast may be sent routinely to pathology (without frozen sections); defer to surgeon's preference. The surgeon must place a stitch on the mastectomy specimen at the site of the nipple as well as at 12 o'clock. A separate specimen should be submitted from the everted nipple ducts.

Sentinel lymph node evaluation:

- 1. Sentinel lymph node evaluation in patients undergoing lumpectomy:** Frozen sections of sentinel lymph nodes (SLNs) will not be routinely performed on lumpectomy cases (following the Z11 criteria). However, it is understood that certain exceptions may occur based on intraoperative or clinical findings, and thus frozen section evaluation of sentinel lymph nodes may be requested by the surgeon in these situations.
- 2. Sentinel lymph node evaluation undergoing mastectomy:** Frozen sections will be performed on SLNs from mastectomy cases with known cancers, as requested by the surgeon.
- 3. Sentinel lymph node evaluation (in patients undergoing lumpectomy or mastectomy) following neoadjuvant chemotherapy:** Frozen sections will be performed on SLNs from lumpectomy or mastectomy cases status post neoadjuvant chemotherapy, as requested by the surgeon.
- 4. Sentinel lymph nodes vs. axillary lymph nodes:** If 6 or more "sentinel" lymph nodes are obtained, they will be classified as an axillary dissection as per AJCC staging, 6 or more "sentinel" nodes constitute an axillary dissection for staging purposes.

| Diagnosis on core biopsy: | Steps for surgeon/OR: | Steps for radiology: | Pathologist needed for intraoperative assessment? | Steps for pathology/pathologist: | QA by pathologist on breast specimen: |
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| Fibroadenoma, complex fibroadenoma, granular cell tumor, fibroepithelial lesion | 1. Document time specimen removed from patient. 2. Order as *** in EPIC. 3. Send for imaging if needed. 4. If no imaging needed, document time specimen placed in formalin and send to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | No (unless specifically requested by surgeon)  | If specimen was imaged in radiology or if specimen imaged in lab (at ANW, Mercy, Unity, United), lab will place specimen into formalin and document time specimen placed into formalin. | None, assuming no intraoperative assessment. |
| Papilloma, radial scar, or mucocoele-like lesion without atypia (includes papilloma, radial scar or mucocoele-like lesion with indeterminate epithelial proliferation) | 1. Document time specimen removed from patient. 2. Order as *** in EPIC. 3. Send for imaging if needed. 4. If no imaging needed, document time specimen placed in formalin and send to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | No (unless specifically requested by surgeon)  | If specimen was imaged in radiology or if specimen imaged in lab (at ANW, Mercy, Unity, United), lab will place specimen into formalin and document time specimen placed into formalin. | None, assuming no intraoperative assessment. |
| Papilloma, radial scar, or mucocoele-like lesion with associated ADH or DCIS | 1. Document time specimen removed from patient. 2. Surgeon intraoperatively inks specimen 3. Order as *** in EPIC. 4. Send for imaging if needed. 5. If no imaging needed, send immediately to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | Yes  | 1. Identify lesion and core biopsy site; 2. Report to surgeon distances of gross lesion to margins, and if biopsy site present. 3. Place into formalin and document times* IO.BREASTG (or IO.BREASTFS) | QA as intraoperative error if: 1. ADH is transected at margin. 2. DCIS is present within 0.2 cm of margin (exception: if DCIS is less than 0.2 cm from deep margin and deep margin is at fascia per surgeon's op note, no QA error). |
| FEA | 1. Document time specimen removed from patient. 2. Order as *** in EPIC. 3. Send for imaging if needed. 4. If no imaging needed, document time specimen placed in formalin and send to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | No (unless specifically requested by surgeon)  | If specimen was imaged in radiology or if specimen imaged in lab (at ANW, Mercy, Unity, United), lab will place specimen into formalin and document time specimen placed into formalin. | None, assuming no intraoperative assessment. |
| Indeterminate epithelial proliferation (formally known as ADP) | 1. Document time specimen removed from patient. 2. Order as *** in EPIC. 3. Send for imaging if needed. 4. If no imaging needed, document time specimen placed in formalin and send to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | No (unless specifically requested by surgeon)  | If specimen was imaged in radiology or if specimen imaged in lab (at ANW, Mercy, Unity, United), lab will place specimen into formalin and document time specimen placed into formalin. | None, assuming no intraoperative assessment. |
| ADH (atypical ductal hyperplasia) | 1. Document time specimen removed from patient. 2. Surgeon intraoperatively inks specimen 3. Order as *** in EPIC. 4. Send for imaging if needed. 5. If no imaging needed, send immediately to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | Yes  | 1. Identify core biopsy site; 2. Report to surgeon distances of any gross lesion to margin, and if biopsy site present. 3. Place into formalin and document times* IO.BREASTG (or IO.BREASTFS) | If final diagnosis remains ADH, QA as intraoperative error if ADH is transected at margin. If final diagnosis is DCIS, follow QA guidelines below. |
| LCIS, classic type (NOS) | 1. Document time specimen removed from patient. 2. Order as *** in EPIC. 3. Send to radiology if imaging needed. 4. If no imaging needed, document time specimen placed in formalin and send to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | No (unless specifically requested by surgeon)  | If specimen was imaged in radiology or if specimen imaged in lab (at ANW, Mercy, Unity, United), lab will place specimen into formalin and document time specimen placed into formalin. | If final diagnosis remains LCIS, classic type: None, assuming no intraoperative assessment. |
| LCIS, variant types (LCIS with necrosis or pleomorphic LCIS) | 1. Document time specimen removed from patient. 2. Surgeon intraoperatively inks specimen 3. Order as *** in EPIC. 4. Send to radiology if imaging needed. 5. If no imaging needed, send immediately to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | Yes  | 1. Identify core biopsy site; 2. Report to surgeon distances of any gross lesion to margins, and if biopsy site present. (up to 40% of these cases will have associated ILC) . 3. Place into formalin and document times* IO.BREASTG (or IO.BREASTFS) | If final diagnosis remains variant LCIS, QA as intraoperative error if variant type LCIS is located less than 0.2 cm from margin (exception: if variant type LCIS is less than 0.2 cm from deep margin and deep margin is at fascia per surgeon's op note, no QA error). If invasive tumor found on final path, follow invasive scheme below. |
| DCIS | 1. Document time specimen removed from patient. 2. Surgeon intraoperatively inks lumpectomy specimen or places stitch at 12 o'clock on mastectomy specimen. 3. Order as *** in EPIC. 4. Send to radiology if imaging needed. 5. If no imaging needed, send immediately to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | Yes  | 1. Identify core biopsy site 2. Report to surgeon distances of any gross lesion to margins, and if biopsy site present. 3. Place into formalin and document times* Note: If imaging of the lumpectomy slices is initiated by radiology, refer to separate protocol for imaging of lumpectomy slices. IO.BREASTG (or IO.BREASTFS) | If final diagnosis remains DCIS, QA as intraoperative error if DCIS is located less than 0.2 cm from margin. (Exception: if DCIS is less than 0.2 cm from deep margin and deep margin is at fascia per surgeon's op note, no QA error.) If invasive tumor found on final path, follow IDC with DCIS scheme below. |
| IDC with DCIS | 1. Document time specimen removed from patient. 2. Surgeon intraoperatively inks lumpectomy specimen or places stitch at 12 o'clock on mastectomy specimen. 3. Order as *** in EPIC. 4. Send to radiology if imaging needed. 5. If no imaging needed, send immediately to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | Yes  | 1. Identify tumor and core biopsy site 2. Report to surgeon distances of any gross lesion to margins, and if biopsy site present. 3. Place into formalin and document times* IO.BREASTG (or IO.BREASTFS) | QA as intraoperative error if IDC or DCIS is transected at margin (0.2 cm rules do not apply for DCIS if invasive tumor also present). Invasive carcinomas with extensive intraductal component (EIC) should be discussed at multidisciplinary conferences to determine if further margin re-excisions are needed. |
| Invasive tumor (no DCIS or variant type LCIS) | 1. Document time specimen removed from patient. 2. Surgeon intraoperatively inks lumpectomy specimen or places stitch at 12 o'clock on mastectomy specimen. 3. Order as *** in EPIC. 4. Send to radiology if imaging needed. 5. If no imaging needed, send immediately to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | Yes  | 1. Identify tumor and core biopsy site 2. Report to surgeon distances of any gross lesion to margins, and if biopsy site present. 3. Place into formalin and document times* IO.BREASTG (or IO.BREASTFS) | QA as intraoperative error if invasive tumor is transected at margin. |

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| Margin reexcisions for invasive tumor transected on original lumpectomy margin (status post prior lumpectomy) | 1. Document time specimen removed from patient. 2. Surgeon intraoperatively inks true margin(s) of specimen. 3. Order as *** in EPIC. 4. Send immediately to pathology. | None | Yes  | 1. Identify any residual gross tumor. 2. Determine if frozen section would be indicated. 3. Report to surgeon distances of any gross lesion to margins. 4. Place into formalin and document times* IO.BREASTMARGINREDOG or IO.BREASTMARGINREDOFS | QA as intraoperative error if IDC or DCIS is transected at margin (0.2 cm rules do not apply for DCIS if invasive tumor also present). |
| Margin reexcisions for DCIS (status post prior lumpectomy) | 1. Document time specimen removed from patient. 2. Surgeon intraoperatively inks true margin(s) of specimen. 3. Order as *** in EPIC. 4. Send immediately to pathology. | None | Yes  | 1. Perform frozen section on suspicious or representative tissue. 2. Report to surgeon distances of any DCIS to margins. 3. Place into formalin and document times* IO.BREASTMARGINREDOFS | 1. If invasive component was/is also present: QA as intraoperative error if DCIS is transected at margin (0.2 cm rules do not apply for DCIS if invasive tumor also present). 2. If patient has only DCIS: QA as intraoperative error if DCIS is located less than 0.2 cm from margin. (Exception: if DCIS is less than 0.2 cm from deep margin and deep margin is at fascia per surgeon's op note, no QA error.) |
| Neoadjuvant chemotherapy cases | 1. Document time specimen removed from patient. 2. Surgeon intraoperatively inks lumpectomy specimen or places stitch at 12 o'clock on mastectomy specimen. 3. Order as *** in EPIC. 4. Send to radiology if imaging needed. 5. If no imaging needed, send immediately to pathology. | If specimen was imaged in radiology, radiology must immediately transport specimen to lab. | Yes  | 1. Identify tumor bed, any residual tumor and core biopsy clip (s) with imager. 2. Report to surgeon distances of any identifiable tumor to margins. 3. If gross tumor bed appears transected at margins, report to surgeon (surgeon may or may not request frozen section). 3. Place into formalin and document times* IO.BREASTNEOADJ | QA as intraoperative error if IDC or DCIS is transected at margin |
| Nipple sparing mastectomy for cancer | 1. Document time specimen removed from patient. 2. Surgeon removes nipple ducts from behind nipple and sends to pathology for frozen section. 3. Surgeon places stitch at 12 o'clock and stitch at where nipple was on mastectomy specimen. 4. Order as *** in EPIC. 5. Send mastectomy specimen immediately to pathology for frozen section on nipple region of mastectomy specimen. | None | Yes  | 1. Perform two frozen sections: on separately submitted nipple duct specimen, and on tagged area where nipple was located on breast. 2. Identify tumor and core biopsy site 3. Report to surgeon distances of any gross lesion to margins, and if biopsy site present. 4. Place into formalin and document times* IO.BREASTNIPPLESPARING | QA as intraoperative error if: 1. Incorrect FS DX given on nipple duct specimens. 2. IDC or DCIS is transected at margin. |
| Sentinel lymph nodes for: 1. mastectomy cases 2. neoadjuvant chemotherapy cases (either mastectomies or lumpectomies) 3. lumpectomy cases where surgeon requests frozen based on clinically suspicious nodes | 1. Document time specimen removed from patient. 2. Order as *** in EPIC 3. Send sentinel lymph node specimen immediately to pathology for frozen section. | None | Yes  | 1. Perform frozen section(s) on sentinel nodes. 2. Report to surgeon and document using IO templates (including size of met and if extracapsular extension is present). 3. Place into formalin and document times* IO.SLNNEG or IO.SLNPOS | QA as intraoperative error if: 1. Incorrect FS DX given (if representative cryostat slide does not contain area of interest, document this in comment of report and regard as sampling error). |

* Times pathology will document (on specimens that arrive in pathology for intraoperative review):

- time specimen arrived for pathology review;
- time pathology assessment given to surgeon;
- time specimen placed into formalin.