CONTRAST ENHANCED MAMMOGRAPHY (CEM)

(A supplement to ACR BI-RADS® Mammography 2013)

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PREFACE

The introduction of the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS®) has revolutionized breast imaging interpretation and reporting and serves as the model for optimal reporting of radiologic studies.

As the field of breast imaging has evolved to include newer technologies, so too has the BI-RADS® atlas evolved. When first introduced in 1992, BI-RADS® was little more than a pamphlet dealing only with mammography. As experience with mammography grew and terms were validated by evidence, subsequent editions were released refining terms. The 4th edition of BI-RADS®, which was published in 2003, included sections on ultrasound and magnetic resonance imaging (MRI) in addition to mammography. The 5th and current edition, released in December 2013, has continued to refine terms and expand on areas such as auditing and reporting.

Contrast enhanced mammography (CEM) was first approved by the Food and Drug Administration (FDA) in 2011 and its use is increasing. CEM has been shown to be more sensitive than mammography or ultrasound for the detection of malignancy. Given that utilization is increasing, it is important that a lexicon be available to allow for consistency in reporting and also to allow for validation of standardized terms through studies looking at the performance of CEM in a variety of clinical settings. The next edition of BI-RADS® is under development but rather than waiting to issue a section on CEM until the release of the new edition, this supplement is available to facilitate the interpretation and reporting of CEM studies.

This is the first version of the BI-RADS® lexicon for CEM and will undergo revisions and alterations as more experience is gained with this modality and as studies to validate terms are performed. Until then, as with other sections of BI-RADS®, we encourage consistent usage of the lexicon to promote increased clarity and precision in reporting and accuracy in reaching final assessments.

Carol Lee, MD, FACR
Chair, Workgroup on BI-RADS® CEM Supplement

INTRODUCTION

To perform CEM, intravenous iodinated contrast is administered and two exposures (low- and high-energy) are made using the standard mammography projections of craniocaudal (CC) and mediolateral oblique (MLO) with kVp settings that straddle the k-edge of iodine. The low- and high- energy images are then recombined and processed to indicate tissue that enhances with iodine. The low energy (LE) image serves as the standard digital mammogram and reporting for this portion of the CEM examination should be no different than reporting for a standard mammogram. The mammography lexicon should be used for reporting the LE images. For the recombined (RC) image, the lexicon is similar but not identical to that used for MRI as outlined in this document.

A significant finding on a CEM examination might be seen on the LE images only, on the RC images only, or on both. Therefore, separate descriptions of the LE and RC images as well as an overall description should be included.

CEM is a relatively new technology and revisions to the lexicon will occur. If you would like to propose a substantive change, please submit it by e-mail (BI-RADS@acr.org) to the ACR for review by the BI-RADS® committee. However, please first visit the ACR BI-RADS web page at: https://www.acr.org/-/media/ACR/Files/RADS/BI-RADS/BIRADSFAQ.pdf, which displays committee-approved responses to suggestions already submitted.

SECTION ORGANIZATION

The ACR BI-RADS® – CEM is divided into four sections:

SECTION I: General considerations and image acquisition parameters

SECTION II: Breast Imaging Lexicon – CEM

SECTION III: Reporting System

SECTION IV: Guidance

Appendix I: ACR BI-RADS® – CEM Lexicon Classification Form (for recombined images)

Appendix II: Images

The following are brief summaries of each section

I. General considerations and image acquisition parameters

The potential indications for the examination, workflow considerations, and acquisition parameters are discussed.

II. Breast Imaging Lexicon – CEM

The lexicon for the LE image portion of the CEM is the same as the mammography lexicon. For the RC images, terms are adopted from the MRI section but modified to cover situations unique to CEM. Each descriptor is illustrated by images.

III. Reporting System

In addition to the usual organization of the breast imaging report, the LE and the RC images should be described separately, and the final assessment should be based on the most abnormal findings on each of these components.

IV. Guidance

Because CEM is a relatively new modality, many unanswered questions may arise in its performance. This section will discuss some questions that are commonly encountered in performing and interpreting these examinations.

Appendix

The appendix contains a form for easily noting the findings on the RC images of a CEM examination with the appropriate BI-RADS® terminology in a simple checklist. This form also contains the BI-RADS® assessment categories. For findings on the LE images, whether or not they are seen on the RC images, please refer to the appendix in the BI-RADS® mammography section.

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SECTION I: GENERAL CONSIDERATIONS

GENERAL CONSIDERATIONS

Contrast enhanced mammography is referred to by several different names including contrast enhanced digital mammography and contrast enhanced spectral mammography. The preferred term which avoids overlap with proprietary names is contrast enhanced mammography (CEM).

The post-processed combination of low-and high-energy images should be referred to as the recombined images (RC images).

When starting to utilize this technique, it is prudent to decide for which indications and clinical settings the study will be used. There is some evidence that CEM may be useful for a variety of indications including determination of extent of disease in newly diagnosed breast cancer, response to neoadjuvant chemotherapy, problem solving, and intermediate and high-risk screening. CEM has also been proposed as an alternative to MRI when the patient is not a candidate for MRI.

For any proposed indication, it is worthwhile to have a predetermined workflow for evaluation of (RC) imaging findings that have no correlate on conventional mammography or ultrasound. Although CEM–guided biopsy devices are FDA approved, these findings are commonly pursued with MRI and MRI biopsy as there is currently limited availability of CEM-guided biopsy. If MRI or MRI-guided biopsy is not available or cannot be tolerated by the patient, an alternative approach for these findings will be needed and this should be recognized before CEM is performed. If neither CEM-guided nor MRI-guided biopsy are available, possible options, depending on the level of suspicion of the finding could include short interval follow-up CEM, stereotactic biopsy using landmarks, or in rare circumstances image guided localization using landmarks followed by surgical excision.

CEM requires the use of intravenous iodinated contrast and patients should be evaluated for risks for contrast reaction. In addition, personnel at facilities that offer CEM should be fully trained and equipped to deal with contrast reactions. For patients who report prior contrast reactions, premedication can be considered to reduce the possibility of subsequent reaction. However, the data on reducing severe reactions has not been consistently demonstrated. Overall, the potential benefit of performing CEM in these patients should be weighed against the possibility of a serious contrast reaction or side effects of the pre-medication.

Many facilities choose to screen patients for impaired renal function or other relative contraindications to IV contrast. If this is elected by a facility, criteria for who should be screened prior to the CEM examination should be the same as those used prior to CT studies that require contrast. Also, any screening to determine suitability for contrast administration should happen at the time of scheduling so that lab work assessing renal function, if required, can be obtained before the patient's CEM visit. For patients with compromised renal function, the benefit of CEM should be weighed against the risk of contrast induced nephropathy prior to scheduling the exam. For a full discussion of the use of intravenous contrast please refer to the ACR Manual on Contrast Media available on the ACR website (https://www.acr.org/Clinical-Resources/Contrast-Manual).

WORKFLOW AND IMAGE ACQUISITION:

There is little data that supports timing of CEM during any particular phase of the menstrual cycle. For MRI, the recommendation has been to schedule during week 2, but several studies have shown that outcomes may not be affected by the stage of the menstrual cycle, and this may also be true for CEM.

Ready availability of personnel to start an intravenous line is critical to ensure timely performance of the study. To facilitate this, facilities should consider setting aside dedicated CEM time slots.

The usual dose for CEM will depend on the patient's body weight and the concentration of iodine in the agent used. Contrast is generally delivered with a power injector at a rate of 3 ml/sec. After a delay of approximately 2 minutes, the patient is positioned in the standard four mammography projections and two exposures are taken for each projection, one right after the other. The LE image is obtained at a kVp in the range of standard mammography, generally 28 to 32 kVp, and the high energy image typically between 45 and 49 kVp. A post-processed RC image is generated from the LE and high-energy images.

The order of the projections obtained varies with the facility. In general, for a bilateral study, the same view is alternated between the breasts so at least one view of each breast is obtained while contrast is maximally present. If there is one breast that requires particular attention, for example a case of newly diagnosed breast cancer, both views of that breast can be obtained first. Also, if it is known that an additional non-standard view of one breast is needed, for example an exaggerated CC view, it can be obtained before imaging of the contralateral breast. The total time available to obtain images before contrast washes out is between 7 to 10 minutes, so ideally the entire CEM should performed within that time frame.

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SECTION II:
BREAST IMAGING LEXICON - CONTRAST ENHANCED DIGITAL MAMMOGRAPHY

Table 1: CEM Lexicon Overview

Breast Tissue	Terms	
A. Breast Composition	a. Almost entirely fatty b. Scattered areas of fibroglandular density c. Heterogeneously dense d. Extremely dense	
B. Background parenchymal enhancement (BPE)	1. Level	a. Minimal b. Mild c. Moderate d. Marked
	2. Symmetric or Asymmetric	a. Symmetric b. Asymmetric

FINDINGS ON LOW ENERGY IMAGES ONLY: Refer to mammography BI-RADS® lexicon

FINDINGS ON RECOMBINED IMAGES ONLY:

Finding	Terms	
A. Mass	1. Shape	a. Oval b. Round c. Irregular
	2. Margins	a. Circumscribed b. Not circumscribed i. Irregular ii. Spiculated
	3. Internal Enhancement Characteristics	a. Homogeneous b. Heterogeneous c. Rim enhancement

B. Non-mass Enhancement (NME)	1. Distribution	a. Diffuse b. Multiple regions c. Regional d. Focal e. Linear f. Segmental
	2. Internal Enhancement Pattern	a. Homogeneous b. Heterogeneous c. Clumped
C. Enhancing Asymmetry	Internal Enhancement Pattern	a. Homogeneous b. Heterogeneous
D. Lesion Conspicuity	a. Low b. Moderate c. High	

FINDINGS ON LOW ENERGY IMAGES WITH ASSOCIATED ENHANCEMENT ON RECOMBINED IMAGES:

Morphology	Refer to mammography lexicon
Internal Enhancement Pattern	a. Homogeneous b. Heterogeneous c. Rim
Extent of Enhancement	a. Mammographic lesion partially enhances b. Mammography lesion completely enhances c. Enhancement extends beyond mammographic lesion d. No enhancement of the mammographic lesion but enhancement in the adjacent tissue
Lesion Conspicuity	a. Low b. Moderate c. High

ASSOCIATED FEATURES:

Associated Features	a. Nipple retraction b. Nipple invasion c. Skin retraction d. Skin thickening e. Skin invasion f. Axillary adenopathy

1. **Breast composition:** Breast composition should be assessed on the low energy images and characterized using categories similar to conventional mammography. The report should include a description of the breast composition using one of the following terms:

   a. Almost entirely fatty

   b. Scattered areas of fibroglandular density

   c. Heterogeneously dense

   d. Extremely dense

2. **Background Parenchymal Enhancement (BPE):** The presence of background parenchymal enhancement of the normal breast tissue should be described. As CEM is performed with intravenous contrast, fibroglandular breast parenchyma may demonstrate normal enhancement. BPE is not necessarily directly related to the amount of fibroglandular tissue and should be described as:

   a. Minimal

   b. Mild

   c. Moderate

   d. Marked

   As is the case with MRI, BPE should be described relative to the amount of the fibroglandular tissue and not the entire volume of the breast.

   e. Symmetric vs Asymmetric:

      i. Symmetric BPE denotes similar levels and distribution of BPE between the two breasts.

      ii. Asymmetric BPE denotes a greater level of more broad distribution of enhancement in one breast than in the other. This may be seen after radiation therapy, with the radiated breast showing less BPE. If asymmetric BPE is seen without a known cause, it should be evaluated as it may represent a pathologic process such as diffuse inflammation or diffuse malignancy in the breast with the asymmetrically higher BPE.

3. **Findings seen on CEM are divided into three broad categories:** Those seen on the LE images only, those presenting as areas of enhancement only seen on the RC images, and those seen on the LE images with associated enhancement on the RC images. It should be clearly stated in the report whether a finding is seen on the low energy images only, on the recombined images only, or on both. If there are separate findings on the LE and RC images, this should be clearly stated.

   a. Finding on low energy images only: A finding apparent on the low-energy images only should be described using the BI-RADS® mammography lexicon. For example, masses that demonstrate no enhancement may be described by their shape, margin, and density. Calcifications should be described as benign or if not classically benign, by their morphology and distribution.

b. Enhancement on RC images only: A finding visualized only on the RC images may be described as a mass, non-mass enhancement, or an enhancing asymmetry. The descriptors for areas of enhancement on CEM are in general the same as those used for MRI. However, the CEM lexicon includes fewer descriptors than the MRI lexicon due to the lower resolution of CEM. In addition, unlike MRI, there are cases in which abnormal enhancement is seen on one view only. This should be called an "enhancing asymmetry." The conspicuity of the lesion, reflecting the degree of enhancement relative to background parenchymal enhancement may also be described.

i. Mass: A mass is a 3-D space occupying lesion with a convex-outward contour. There may or may not be an identifiable correlate on the low energy images. If there is no LE correlate, the mass shape/margin and internal pattern of enhancement should be characterized on the recombined images.

1. Shape/margin: Descriptors for mass shape and margin are the same as for MRI, and include oval, round, or irregular shape, with circumscribed or not circumscribed (irregular, spiculated) margin.

2. Internal pattern of enhancement: A mass may demonstrate homogeneous, heterogeneous, or rim enhancement.

ii. Non-mass enhancement (NME): Enhancement that is neither a mass nor an enhancing asymmetry is classified as non-mass enhancement. NME should be classified according to its distribution and described as focal, linear, segmental, regional, multiple regions, or diffuse. However, unlike with MRI, the internal enhancement pattern of NME may not be clearly discernible due to the lower resolution of CEM compared to MRI. If visible, internal enhancement pattern may be described as homogeneous, heterogeneous, or clumped.

iii. Enhancing asymmetry: This term should be used for a finding seen on only one view on the RC images. If desired, the internal enhancement pattern of an asymmetry can be described as homogeneous or heterogeneous. If a one-view asymmetry is seen on the LE image and exhibits enhancement, it can also be described as an enhancing asymmetry.

iv. Lesion conspicuity (relative to background): Degree of enhancement relative to background may be described as low, moderate, or high. These are subjective qualitative descriptors relative to the degree of background parenchymal enhancement. Low refers to enhancement equal to or slightly greater than BPE, high if the enhancement is much greater than BPE, and moderate if the enhancement is in between low and high. For CEM, there is no data yet to correlate lesion conspicuity with likelihood of malignancy. Terms for conspicuity are included in the lexicon to allow for future research.

c. Findings seen on low-energy images with associated enhancement on recombined images: for enhancing lesions with a correlate on LE images (mass asymmetry, focal asymmetry, architectural distortion, or calcifications); the LE finding should be described using the BI-RADS® mammography lexicon. If the LE finding that enhances is not a mass (asymmetry,

architectural distortion, or calcifications) and the area enhances, the characteristics of the enhancement should be described using the CEM lexicon. For masses seen on the LE images that also enhance, it is not always necessary to further describe the mass shape and margin as seen on the RC images. Other descriptors besides shape and margin for enhancement seen on RC images include:

i. Internal pattern of enhancement: homogeneous, heterogeneous, rim.

ii. Extent of enhancement

1. The mammographic lesion partially enhances
2. The mammographic lesion completely enhances
3. The enhancement extends beyond the mammographic lesion
4. There is no enhancement of the mammographic lesion but there is surrounding enhancement in the tissue adjacent to the lesion. This commonly occurs with inflamed cysts or fat necrosis.

iii. Lesion conspicuity: Low, moderate, or high as described in section 3.b.iv.

4. Associated Features: These are generally seen on the LE images and can also sometimes be appreciated on the RC images.

a. Nipple retraction: Nipple retraction is when the nipple is pulled in. New nipple retraction is associated with increased suspicion of underlying.

b. Nipple invasion: Tumor is contiguous and invades the nipple.

c. Skin retraction: Skin is pulled in abnormally.

d. Skin thickening: Skin thickening is defined as being greater than 2-3 mm in thickness. Skin thickening without enhancement may represent post treatment related changes (such as surgery and/or radiation) or a systemic process if bilateral and diffuse. However, diffuse skin thickening, with or without areas of enhancement, may also be secondary to lymphatic obstruction from malignancy or locally advanced breast cancer.

e. Skin invasion: Skin invasion may be seen with direct tumor invasion or with inflammatory cancer.

f. Trabecular thickening

g. Axillary adenopathy: Enlarged axillary lymph nodes may warrant comment, clinical correlation and additional evaluation, especially if they are new or considerably larger or rounder when compared to prior studies.

5. Lesion location: The location of a suspicious lesion should be described using standard clock-face clinical orientation. Similar to mammography, the side is given first, followed by the quadrant, clock-face location, and the depth of the lesion (anterior, middle, or posterior third).

SECTION III: REPORT ORGANIZATION

The reporting system should be concise and organized and include any pertinent clinical history that may affect interpretation of the examination. The report should include a description of the amount of fibroglandular tissue and the degree of background parenchymal enhancement (BPE). Significant findings on the LE and on the RC images should be described and an assessment rendered based on the most suspicious finding. For any given finding, it is important to state clearly whether it is seen on the LE images only, the RC images only, or both.

Report Structure	
1.	Indication for examination
2.	CEM technique
3.	Comparison to previous examination(s)
4.	Succinct description of overall breast composition
5.	Clear description of any important findings
6.	Assessment
7.	Management

1. INDICATION FOR EXAMINATION

The indication for examination should contain a concise description of the patient's clinical history, including:

a. Reason for performing the exam (e.g., screening, staging, problem solving)

b. Clinical abnormalities, if any including laterality and duration

2. CEM TECHNIQUE

Give a brief description of the protocol.

a. Laterality (right, left, bilateral) and views.

b. Name of contrast agent

c. Dosage (mmol/kg) and volume (in cc)

d. Presence or absence of complications/contrast reaction; if there is a reaction, include a description of the reaction, management and disposition of the patient. Contrast reactions and recommendations for further management should also be detailed in the final recommendation section to be certain it is noted by the referring clinician.

3. COMPARISON TO PREVIOUS EXAMINATION(S)

Include a statement indicating that the current examination has been compared to previous studies including the type of exam [CEM, digital mammogram, etc. with specific date(s)]. If no prior exams are available for comparison this should be stated. Correlation with other breast imaging such as ultrasound, MRI should be reported if performed. The status of any finding that is reported should be detailed, whether stable, increased, decreased, or new.

4. SUCCINCT DESCRIPTION OF OVERALL BREAST COMPOSITION

This should include an overall description of the breast composition as determined by the LE images.

Breast Composition Categories
a. Almost entirely fatty
b. Scattered areas of fibroglandular tissue
c. Heterogeneously dense
d. Extremely dense

The amount of background parenchymal enhancement on the recombined images

a. Minimal

b. Mild

c. Moderate

d. Marked

On bilateral examinations, describe whether the pattern is asymmetric or symmetric, if appropriate.

If an implant is present, it should be so stated in the report. Note that CEM has not been studied in patients with implants and like standard mammography is not accurate for assessment of silicone implant integrity.

5. CLEAR DESCRIPTION OF ANY IMPORTANT FINDINGS

Significant findings on the LE and RC images should be reported and correlated. If there is an abnormality on the LE images, a statement as to whether it is seen on the RC images and vice versa should be included. When there is a finding on the LE images, descriptors using the mammography lexicon should be used. When there is a finding on the RC images descriptors as outlined in the CEM lexicon section should be used. If the finding is present on both the LE and RC images, descriptors of both using the lexicon should be reported

Abnormal enhancement is unique and separate from BPE. Its description should indicate the breast in which the abnormal enhancement occurs, the lesion type, and modifiers.

The report of any significant finding should include:

a. Size

b. Location

   i. Right, left, or bilateral

   ii. Breast quadrant and clock-face position (or central, retroareolar, and axillary tail descriptors)

   iii. Depth (anterior, mid, or posterior)

c. Descriptors for abnormal enhancement. If a mass is seen on both the LE and RC images, the shape and margin should be described using the mammography lexicon. Repeating the descriptors for the findings on the RC image is not necessary.

   i. Mass

   - shape (if seen on RC image only)
   - margin if evaluable (if seen on RC image only)
   - internal characteristics, if evaluable
   - lesion conspicuity

   ii. Non-mass

   - distribution
   - internal characteristics, if evaluable
   - lesion conspicuity

   iii. Enhancing asymmetry

   - lesion conspicuity

d. Artifacts if severe enough to potentially affect interpretation

6. ASSESSMENT

All reports should include an assessment category. This should reflect the most abnormal **finding whether on LE images, RC images, both, or neither.**

ASSESSMENT CATEGORIES

Category 0: Incomplete — Need Additional Imaging Evaluation and/or prior mammograms for comparison

This category is used when there is a finding for which additional imaging evaluation is needed. Category 0 can be used if additional mammographic views, ultrasound, or MRI are desired to make a final assessment. However, the use of category 0 for CEM is discouraged, particularly if the finding is seen on the LE images, unless the examination is read off-line, and the patient needs to be

recalled for the additional imaging. For these cases, the CEM is analogous to a screening mammogram and the use of BI-RADS® 0 is appropriate.

Additionally, unlike MRI, where most of the information needed to make a final assessment is included in the standard protocol for the exam, this is not necessarily true for CEM, and there will be cases for which additional imaging such as ultrasound or MRI will be necessary to make a final assessment. This generally pertains to findings seen on the recombined images only and not seen on the low-energy images which cannot be fully characterized based on the RC images alone. For these cases, a category 0 assessment may be most appropriate.

Keep in mind that there are problems associated with the use of category 0. If category 0 is assigned and the patient does not have the recommended additional imaging, or if the additional imaging is not correlated with the CEM findings, a significant abnormality may be missed.

If category 0 is assigned, the type of recommended additional imaging should be clearly stated in the report. Subsequent management should also be included in the report, should the additional imaging prove to be negative. For example, if there is an enhancing mass on the RC images with negative LE images and ultrasound or MRI is recommended, the report should state what should be done if the subsequent imaging is negative. If a suspicious enhancing lesion is seen on CEM but CEM-biopsy capability is not available and MRI is needed to direct the biopsy, the case should be assigned a BI-RADS® category 4 or 5, not BI-RADS® category 0. This situation is analogous to a suspicious finding on MRI for which biopsy is warranted but for which targeted ultrasound is recommended to attempt to identify a correlate. If the abnormality is not seen on MRI, further management can then be decided based on the findings on both the CEM and MRI. Giving these cases an assessment of 4 or 5 decreases the possibility of a suspicious finding on CEM falling through the cracks.

As with other imaging modalities, there should be a mechanism in place to resolve cases assigned a BI-RADS® category 0.

Category 1: Negative

There is nothing to comment on. This is a normal examination. Category 1 includes a normal description of breast composition and the degree of BPE. It should be emphasized that BPE is a normal finding, and short-term follow-up is not necessary to assess BPE for stability.

Category 2: Benign

Like category 1, this is a normal assessment, but in these cases the interpreter chooses to describe a benign finding such as intramammary lymph node, implants, metallic foreign bodies (such as core biopsy and surgical clips), enhancing and non-enhancing fibroadenomas, cysts, old non-enhancing scars, or recent scars; postoperative collections, fat-containing lesions (such as oil cysts, lipomas, galactoceles, and hamartomas). The interpreter may choose not to describe such findings, in which case the examination should be assessed as negative (category 1). Both category 1 and 2 assessments indicate that there is no evidence of malignancy. The difference is that category 2 should be used when describing one or more specific benign findings in the report, whereas category 1 would be used when such findings are not described (even if they are present).

Category 3: Probably Benign

A finding assessed using this category should have a ≤ 2% likelihood of malignancy but greater than the essentially 0% likelihood of malignancy of a characteristically benign finding. Typical findings on mammography that are appropriately assigned a probably benign assessment are well-established. For findings seen only on the recombined images, however, there is no data to guide which lesions fall into this category. In the absence of data, the use of category 3 for RC image findings remains intuitive.

BPE, a benign finding on nearly all CEM examinations, should not be the reason for a probably benign assessment.

In general, a BI-RADS® category 3 assessment should not be given directly from a screening CEM study, as is the case for standard screening mammography. Ideally, any finding or questionable finding should be fully worked up before a category 3 assessment is assigned. However, given the lack of data concerning BI-RADS® category 3 assessments on CEM, there may be instances where it is used without the addition of further imaging evaluation.

Recommendations will likely undergo future modifications as more data accrue regarding the validity of using category 3 assessments for CEM, the follow-up interval required, and the type of findings that warrant this assessment.

Careful auditing of the use of category 3 assessments should be performed and publication of outcomes data is strongly recommended.

Category 4: Suspicious

This category is used for findings that have ≥ 2% but < 95% chance of malignancy and for which biopsy is recommended. Thus, almost all recommendations for breast interventional procedures will come from assessments made using this assessment category. In CEM, assessment category 4 is not currently divided into subcategories 4A, 4B, and 4C.

Category 4 is used for the majority of findings for which tissue diagnosis is desired. These biopsies can usually be performed percutaneously, by US or stereotactic guidance, or by MRI guidance for lesions not visible at either US or mammography. As cysts rarely pose a problem in interpretation at CEM, diagnostic aspiration is not commonly performed.

In many patients with a suspicious finding on the RC image only, targeted US will identify a corresponding abnormality so that US-guided biopsy can be performed. US-guided biopsies are faster, more comfortable for the patient, and more cost effective than MRI-guided biopsies so should be the chosen method when possible. If CEM-directed biopsy is not available and the RC-only finding is not visible on US, then an MRI-guided biopsy may be required. If the finding that was deemed suspicious on CEM is not visible by MRI, follow-up CEM may be reasonable, similar to suspicious MRI findings that are not visible on MRI at the time of attempted MRI-guided biopsy. If the interpreter feels that the CEM finding is sufficiently suspicious to warrant an attempt at biopsy despite a negative MRI, biopsy using landmarks on the LE images could be attempted.

Category 5: Highly Suggestive of Malignancy

These assessments carry a very high probability (≥ 95%) of malignancy. This category initially was established to include lesions for which 1-stage surgical treatment was considered without preliminary biopsy. Given the widespread acceptance of imaging-guided percutaneous biopsy, 1-stage surgery is rarely performed. Therefore, the current rationale for using a category 5 assessment is to identify lesions for which any non-malignant percutaneous tissue diagnosis is considered discordant, resulting in a recommendation for repeat (usually surgical) biopsy.

No single CEM descriptor is sufficiently predictive of malignancy to produce the ≥ 95% probability required for a category 5 assessment. Just as in mammography and US, an appropriate combination of suspicious findings is needed to justify a category 5 assessment at CEM. It is recommended that category 5 assessments be audited separately to verify a ≥ 95% PPV, thereby validating that the assessment is not being overused.

Category 6: Known Biopsy-Proven Malignancy

This category is reserved for examinations performed after biopsy proof of malignancy (imaging performed after percutaneous biopsy) but prior to surgical excision, in which there are no abnormalities other than the known cancer present that might need additional evaluation. That is, a cancer diagnosis has already been established, a lesion is depicted at CEM, and this lesion corresponds to the previously biopsied cancer.

In the setting of CEM after neoadjuvant chemotherapy, if no abnormal enhancement is seen, the case should still be assigned a BI-RADS® category 6 because definitive surgery is still the standard of care despite an apparent imaging response as determined by imaging.

7. MANAGEMENT

All CEM examinations should include a management recommendation. If the assessment is incomplete (category 0), a specific suggestion for the next course of action should be rendered. This could include obtaining prior mammograms or performing additional imaging such as ultrasound or MRI. If additional imaging is recommended, the course of action should the additional imaging prove to be negative should be clearly stated. With few exceptions, the management recommendations should be linked to the assessment category as described below.

Concordance Between BI-RADS® Assessment Categories and Management Recommendations.

Assessment	Management	Likelihood of Cancer
Category 0: Incomplete — Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison	Recall for additional imaging and/or comparison with prior examinations	N/A
Category 1: Negative	Routine screening	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine screening	Essentially 0% likelihood of malignancy
Category 3: Probably Benign	Short-interval (6-month) follow-up	≥ 0% but ≤ 2% likelihood of malignancy
Category 4: Suspicious	Tissue diagnosis	> 2% but < 95% likelihood of malignancy
Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	≥ 95% likelihood of malignancy
Category 6: Known Biopsy-Proven Malignancy	Surgical excision when clinically appropriate	N/A

WORDING THE REPORT

The current examination should be compared to prior examinations when appropriate. The indication for examination, such as screening or diagnostic, should be stated. The report should be organized with a brief description of the composition of the breast and any pertinent findings, followed by the assessment and management recommendations. All discussions between the interpreting physician and the referring clinician or patient should be documented in the original report or in an addendum to the report.

If a contrast reaction has occurred, a full description of the type of reaction, treatment if any, and management of the patient should be clearly stated in the body of the report and referred to in the report conclusion to be certain the referring physician is aware. In addition, recommendations for possible need for pre-treatment if intravenous contrast needs to give in the future should be made.

The report should be succinct, using terminology from the approved lexicon without embellishment. Do not use definitions of the lexicon terms in the report narrative; use only the descriptors themselves. Following the impression section and the (concordant) management recommendations section of the report, the terminology for the assessment category should be stated, as well as its category number. Other aspects of the report data should comply with the ACR Practice Parameter for Communication of Diagnostic Imaging Findings
https://www.acr.org/Clinical-Resources/Practice-Parameters-and-Technical-Standards.

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SECTION IV: GUIDANCE

Summary

This section provides additional guidance for how to use the new CEM BI-RADS® lexicon and reporting system in a variety of different clinical scenarios.

Lexicon

As of this publication, the lexicon used to report findings appreciated on the low-energy (LE) and recombined (RC) images of CEM exams are adapted from conventional mammography and breast MRI descriptors. It is important to characterize any abnormality based on both its LE and RC imaging appearance. However, if a mass seen on LE images also enhances, the primary descriptors should be those of the mammography lexicon. It is not necessary to repeat descriptors for the shape and margin of the same mass on the RC images. If appropriate, descriptors for internal enhancement characteristics (homogenous, heterogeneous, rim) and degree of conspicuity of the enhancement may be described.

If an abnormality has suspicious features on LE but has no RC correlate, it should still be pursued as a suspicious imaging finding. This is particularly true for suspicious calcifications seen on the LE images without corresponding enhancement [1,2]. Similarly, if there is enhancement on recombined images only, without LE correlate, it should be pursued as an indeterminate finding.

Interpreting CEM can be very straightforward when there is a solitary finding seen on both LE and RC images in the setting of minimal background parenchymal enhancement. However, there are circumstances when interpreting the RC images, can be challenging. We have outlined some methods for navigating these circumstances below.

Technical Considerations

As with all imaging, it is important to first ensure the CEM images are technically adequate for interpretation. This includes (1) confirming contrast was appropriately administered, (2) ensuring your hanging protocol has LE images superimposed with RC images, and (3) appropriately setting window and level to reveal contrast enhancement.

To start, it is important to confirm that all of the contrast agent was safely and completely administered to the patient. Unlike breast MRI which employs a relatively small volume of gadolinium-based contrast material, CEM uses a larger quantity of an iodinated contrast agent that is administered at a dose of 1.5cc/kg with variable institutional maximums. As a result, the technologist performing the CEM should be able to visibly appreciate if contrast agent leaks from the tubing or if the patient is experiencing discomfort from contrast extravasation into their soft tissues. Any contrast event should be communicated to the responsible radiologist who will determine next steps including whether the study is interpretable. Otherwise, it is reasonable to assume that contrast has been appropriately administered to the patient and abnormal enhancement, if present, should be seen. While it is true that variations in hemodynamic blood flow could impact contrast visibility, the technical parameters of the CEM have been determined to allow for this.

The acquired CEM images could be impacted should contrast material get on a patient's skin or on the imaging equipment. Contrast contamination has the appearance of punctate hyperdensities overlying the breasts, similar to calcifications, but are often only seen on the recombined images [3,4,5] To minimize this artifact, personnel should wash hands after handling contrast material. Alternatively, personnel can consider wearing gloves when handling the contrast material and changing or removing the gloves when performing the imaging portion of the CEM exam.

Hanging protocols for CEM can vary from institution to institution. One key element that should be maintained across sites is the superimposition of LE and RC images during viewing. This allows direct correlation of LE imaging findings with enhancement on RC images. Similarly, it allows readers to identify a LE correlate should an unexpected abnormality be seen on the RC images. Some vendor equipment has improved functionality that allows for the phasing in and out of the LE and RC images, however, this is not critical for exam review.

Lastly, a common challenge is adjusting the window and level to maximize contrast visibility. The internal contrast and brightness of the CEM images are determined at the time of acquisition. They are impacted by different conditions, such as breast tissue thickness and breast composition. Viewing workstations typically maintain the same technical parameters from acquisition and may not be optimized for interpretation. Manual adjustment of image brightness (level) and contrast (window) should be performed to improve visibility of any abnormal enhancement. A series of window and level settings may also be established so manual adjustment is less necessary.

Background Parenchymal Enhancement (BPE)

BPE is defined as the normal enhancement of glandular elements of the breast. The literature suggests that a majority of women imaged with CEM have minimal or mild background parenchymal enhancement [6,7]. It has yet to be determined whether timing CEM with the stage of the menstrual cycle will affect the accuracy of interpretation. The MRI literature suggests that for MRI, performing the study during a specific stage of the menstrual cycle does not affect sensitivity [8,9].

It can be difficult to differentiate BPE from artifacts that are seen on recombined images. The most common artifact that is appreciated is called rim artifact, also known as breast-within-a-breast, halo artifact, or matrix artifact. This artifact is due to scattered radiation that occurs within the breast during image acquisition. The result is an apparent enhancing halo just deep to the skin surface and can often be seen in the upper breast.

The literature suggests that moderate or marked BPE may be associated with increased risk for malignancy [6], however, this needs to be studied further before formal associations are made. Studies are also examining whether BPE is related to false negative CEM exams (cancer not identified on CEM) and false positive CEM exams. Until results are available, it is important to remember that CEM is a planar imaging exam, and consequently small benign or malignant abnormalities may blend with BPE when it is moderate or marked. Along these lines, any enhancement that stands out above BPE on CEM should not be dismissed.

The approach for maximizing detection of abnormal enhancement in the setting of increased BPE is similar to that for MRI interpretation. The RC image can be viewed as you might a maximum intensity projection. Look for areas of asymmetric enhancement between the two breasts with special attention to areas separate from the BPE. Correlation with the LE images is critical to determine if an associated morphologic abnormality is present. If none, additional evaluation with targeted ultrasound and possibly MRI would be recommended.

Mass

Masses on LE images may have associated enhancement on RC images. It is important to recognize that the presence of enhancement does not necessarily mean that the mass is malignant. Several benign entities can be associated with an enhancing mass including fibroadenoma, papilloma, and radial scar. When determining management strategies for these enhancing masses, it is important to use information from both the LE and RC images. If the mass has suspicious features on LE images, such as having irregular margin or increased density, or having developed over time, the finding should be viewed with suspicion. On the other hand, should the mass be stable over time with circumscribed margin, further evaluation may not be necessary.

Masses on LE images may also be absent of enhancement. Similar to MRI, non-enhancing masses are often benign. Masses that have a thin rim of enhancement but are otherwise associated with decreased enhancement relative to surrounding breast tissue are typically benign. This imaging appearance is termed the 'eclipse sign' or negative contrast enhancement and is classic for benign cysts [10].

However, it may not be possible to definitively say that a mass is non-enhancing in the setting of moderate or marked BPE. Remember that CEM is a planar exam, and the RC images reflect enhancement occurring throughout the breast. While the mass itself may not be enhancing, it may appear to have enhancing portions due to superimposed enhancing breast parenchyma. In this circumstance, the RC images are not helpful in classifying the mass as benign or malignant and ultrasound or possibly MRI may be necessary for further characterization.

Architectural Distortion

Similar to masses, architectural distortion on LE images may or may not be associated with enhancement. Although preliminary results for CEM and MRI suggest it may be possible to differentiate benign from malignant distortion based on enhancement [11], there is insufficient published data to confidently make this distinction. As a result, the LE assessment becomes crucial for interpretation. Should unexplained distortion persist on LE and conventional mammographic and tomosynthesis images, it should be pursued with percutaneous biopsy regardless of its enhancement pattern.

Calcifications

The published literature suggests that the presence or absence of enhancement on RC imaging cannot be used to classify calcifications as benign or malignant [1,2]. Studies have shown that DCIS and invasive carcinoma can present as calcifications on LE images without abnormal enhancement on RC images. For this reason, any suspicious calcifications should be worked up according to their appearance on LE, conventional mammographic and tomosynthesis views.

Asymmetry

As with standard mammography, a one-view only finding should be called an asymmetry until its 3-dimensional nature can be confirmed with additional imaging. Also, in keeping with standard mammography, a 2-view finding that does not fulfill the criteria for a mass on LE images should be termed a focal asymmetry. Asymmetries on the LE images, including focal, global, and developing asymmetries should be evaluated and managed as on any mammogram whether or not they enhance.

Recombined (RC) Image-Only Findings

A primary benefit of CEM is the ability to detect lesions based on vascularity that would otherwise not be seen on conventional mammography or tomosynthesis. However, managing RC image-only enhancement on CEM can be challenging. Unlike MRI that has multiple sequences that help characterize abnormalities as benign or malignant, RC images often only provide binary information as to whether enhancement is present or not. As of this publication, additional features of RC image-only enhancement such as margin, distribution, and internal enhancement characteristics are often not specific enough to differentiate benign from malignant. As a result, it can be difficult to determine which RC image-only enhancement requires additional imaging work-up. In addition, RC image-only enhancement may be difficult to localize on two views. This can further complicate the diagnostic evaluation. The suggestions below can be used to help navigate some of these circumstances.

To start, the CEM lexicon should be used to describe the RC image-only enhancement as a mass, non-mass enhancement, or enhancing asymmetry. This enhancement should then be directly correlated with the LE images to see whether there is any associated abnormality. If there is a LE correlate, then it can be used to help determine the probability of malignancy. If the LE correlate is new, then the enhancement remains indeterminate. On the other hand, if the LE correlate has been present over many years and the LE appearance is morphologically benign, then the enhancement can be classified as benign. If a LE correlate is not clearly noted, it may also be useful to correlate with any additional mammographic views and ultrasound.

In addition, it is worth evaluating how the RC image-only enhancement compares with background parenchymal enhancement. As mentioned earlier, it should be determined whether the enhancement is asymmetric between breasts or whether it is more conspicuous or discrete than the BPE. If this is the case, then the enhancement should be viewed as suspicious and further evaluated. A first step in further evaluation of an enhancing finding could be ultrasound. If, however, there is continued uncertainty with how to manage RC image-only enhancement, the best approach is to analogize to breast MRI. Published data have shown that findings on MRI and CEM have a similar appearance [12,13,14]. For this reason, when unsure how to handle incidental enhancement, consider how a similar finding might be handled on breast MRI and follow that plan.

Enhancing Asymmetry

Unlike MRI where abnormal enhancement can generally be localized within the breast, it is not uncommon to see potentially abnormal enhancement on only one RC image without LE correlate. These should be termed "enhancing asymmetries" and managed as one would manage an asymmetry seen on a standard mammogram. As with conventional mammography, a one-view-only enhancing finding cannot be dismissed simply because it is seen on only one view.

Reporting Organization

It is important to remember that CEM is made up of LE and RC images. The report, management plan, and BI-RADS® assessment should include an interpretation of both. If a suspicious abnormality is seen on either the LE or the RC images, it should be pursued with additional diagnostic evaluation. For example, if there is a suspicious morphologic finding noted on LE images (mass, distortion, calcifications) this should be further evaluated, even in the absence of enhancement. Similarly, RC image-only enhancement without a LE correlate should be pursued.

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SECTION V: FAQ

1. **When US is needed after diagnostic CEM does US get incorporated into the report? If US is not incorporated into the report – how do you code?**

   As with standard mammography, it is preferable to report both the CEM and the US together if done on same day. If US is reported separately, it should be given a BI-RADS® assessment based on the sonographic findings with an added statement referring to the CEM findings. For example, if there is a mass on the CEM study and ultrasound is done at a later time and is negative, the US can be assigned a BI-RADS® 1 with additional recommendation of how to manage the finding on the CEM. If ultrasound is recommended based on CEM findings and done at a later time, the CEM report should always include a management recommendation if the ultrasound is negative.

2. **I don't have access to MRI. How should I handle RC image only findings?**

   Targeted ultrasound should be performed to see if there is a sonographic correlate. If US is negative and the RC image finding is low suspicion, a short interval follow-up CEM may be appropriate. If the RC image finding is very suspicious, biopsy using stereotactic guidance and landmarks could be attempted. Alternatively, pre-operative localization, again using landmarks, followed by surgical excision could be undertaken for very suspicious findings.

3. **Can we use dynamics of enhancement to help determine probability of malignancy?**

   Although there has been some work on using kinetics in CEM, the protocol at most facilities does not allow for sequential post-contrast imaging so dynamics cannot be used.

4. **When does the exam become non-diagnostic? How much time do I have?**

   Ideally, imaging should be completed with 8-9 minutes after injection. After that time, contrast may have washed out sufficiently to render RC images unreliable.

5. **What should I do if the full contrast dose doesn't get administered?**

   In these circumstances, it depends on how much contrast was actually delivered. If only a small amount of contrast was given, the study can be rescheduled. Alternatively, the exam could be done with the understanding that the RC images may not be reliable and only the LE images are read as a regular mammogram. In general, if there is any doubt as to the adequacy of contrast administration, the examination should be read as a standard LE examination.

6. If I have a choice between CEM and MRI, when is each imaging exam better?

It has been shown that MRI has a higher sensitivity for detection of breast cancer but lower or comparable specificity than CEM. MRI also offers better visualization of areas typically not well seen on mammography including far posterior locations or axilla. MRI is more expensive than CEM, not always covered by insurance, and not as easily tolerated for most women. MRI is recommended for very high-risk patients (such as BRCA mutation carriers, lifetime risk of ≥ 20 Currently, CEM is not approved by the FDA for screening so using this examination for this indication would be considered an off-label use. Facilities that choose to use CEM for screening are encouraged to have strict criteria for who will be screened and carefully audit their results.

7. I want to tell the tech to do extra images (XCC, cleavage view, etc.) because a suspected finding is in the outer or inner portion of the breast. When should I do these extra images?

These can be done along with the standard images of the breast in question, followed by imaging of the contralateral breast. All imaging should be accomplished within the 8–9-minute time frame following contrast injection.

8. Should I be timing CEM with menstrual cycle?

There is no data that outcomes of CEM are influenced by the stage of the menstrual cycle in which the study is done. For MRI, there is evidence that important outcomes are unrelated to the stage of the menstrual cycle in which the study was performed.

9. The RC image-only finding barely enhances. Do I have to work this up?

In general, any enhancement that is not considered to be background should be fully evaluated, even if the level of enhancement is low. As more experience is gained with CEM and more data becomes available, better guidance on findings that can be safely ignored may become evident.

10. I see an RC image-only finding on only one view. What do I do next?

First, it should be determined whether the enhancing asymmetry is a true lesion or simply part of background. If it is felt to be a real finding, targeted ultrasound can be attempted. If that is unrevealing, MRI may be the best option for further evaluation. MRI can often characterize the finding as benign, probably benign (such as a likely fibroadenoma), or suspicious. If suspicious, an MRI guided biopsy can be performed. If the enhancement seen on CEM is not seen on MR, a 6-month follow-up CEM can be the management strategy.

11. Should we place radiopaque markers on the breast to indicate scars, skin lesions, or clinical abnormalities?

Markers that are usually placed for standard mammograms should also be placed for CEM studies.

12. What should I call a finding seen only on one view and only on the RC image? If it has the shape of a mass, can I call it a mass? Do these one-view findings with no LE correlate always have to be evaluated?

Enhancement without a corresponding finding on LE images and seen on only one RC view is not an uncommon occurrence in CEM. This should be termed an "enhancing asymmetry" even if it has a geometric shape on the single view, similar to standard mammography. It should not be called a mass unless seen on orthogonal views. These one view RC image findings are often simply asymmetric BPE but can sometimes represent a true finding and even malignancy so should not be dismissed simply because they are seen on only one view.

13. If an asymmetry is seen on only one LE view but shows enhancement on the corresponding RC image, would it also be called an "enhancing asymmetry?"

Yes, such a finding could be called an enhancing asymmetry. It can also be described as an asymmetry with corresponding enhancement.

14. Why is the term "focus" not included in the CEM lexicon as it is for MRI?

"Focus" was included in the MRI lexicon to describe dots of enhancement too small to characterize further in terms of margins or kinetics. The term is not included in the mammography lexicon. The resolution of enhancing findings on CEM is lower than for standard mammography or MRI and kinetics are not used with CEM. Therefore, these small areas of enhancement are more analogous to small masses seen on standard mammography rather than dots on MRI and the term "mass" should be used regardless of size.

15. The descriptors for mass margins are different for LE findings and RC only findings. If a mass is seen on both the LE and RC images, is it necessary to give separate descriptors for the margin?

No. If a mass is seen on the LE images, the mammography lexicon should be used to describe shape and margin regardless of whether or not it enhances. If appropriate, additional descriptors for the enhancement such as internal characteristics (homogeneous, heterogeneous, rim) and lesion conspicuity can be used.

16. What are appropriate uses for BI-RADS® category 0 for CEM? When should BI-RADS® category 0 not be used?

If additional imaging is needed to evaluate a definite or questioned CEM finding, the use of BI-RADS® category 0 is appropriate.

If BI-RADS® category 0 is used, the type of additional imaging and the management should the additional imaging prove to be negative should be stated in the report. Additionally, there should be a mechanism in place to resolve all cases assigned a category 0.

BI-RADS® category 0 should not be used if there is a suspicious finding on CEM but for which CEM-guided biopsy is not available and for which MRI is needed to guide intervention. In this case, a BI-RADS® category 4 or 5 assessment is correct, with recommendation made for MRI-guided biopsy.

APPENDIX I: CLASSIFICATION FORM

ACR BI-RADS® - CEM Lexicon Classification Form for Recombined Images

For each of the following categories, select the term that best describes the dominate lesion feature. Whenever possible, definitions used in BI-RADS® for mammography and/or MRI schould be used.

Breast Tissue		
A. Background parenchymal enhancement (BPE): Refers to the normal enhancement of fibroglandular tissue seen on the recombined images		
1. Level	a. Minimal	
	b. Mild	
	c. Moderate	
	d. Marked	
2. Symmetric or asymmetric (report for bilateral studies)	a. Symmetric	Enhancement in both breasts
	b. Asymmetric	More enhancement in one breast than the other
Findings		
B. Seen on low energy images	1. Yes	
	2. No	
C. Lesion Conspicuity (relative to background)	1. Low	Enhancement equal to or less than background
	2. Moderate	Enhancement is between low and high
	3. High	Enhancement is much greater than background
D. Masses: 3-D, space occupying lesion, convex-outward contour		
1. Shape	a. Oval (includes lobulated)	Elliptical or egg-shaped (may include two or three undulations
	b. Round	Spherical, ball-shaped, circular, or globular
	c. Irregular	Neither round nor oval
2. Margin	a. Circumscribed	Entire margin is sharply demarcated with abrupt transition between the lesion and surrounding tissue
	b. Not circumscribed	
	i. Irregular	Uneven or jagged edges (but not spiculated
	ii. Spiculated	Characterized by lines radiating from the mass
3. Internal enhancement characteristics	a. Homogeneous	Confluent uniform enhancement
	b. Heterogeneous	Nonuniform enhancement with variable density
	c. Rim enhancement	Enhancement more pronounced at periphery of mass

E. Non-mass enhancement (NME): Enhancement that is neither a mass nor an enhancing asymmetry

1. Distribution	a. Diffuse	Enhancement distributed randomly throughout the breast
	b. Multiple regions	Enhancement in at least two large volumes of tissue not conforming to a ductal distribution and separated by normal tissue, multiple geographic areas, patchy in appearance
	c. Regional	Enhancement that encompasses more than a single duct system
	d. Focal	In a confined area, less than a breast quadrant volume with fat or normal glandular tissue interspersed between the abnormally enhancing components (exception: focal homogeneous enhancement)
	e. Linear	Enhancement arrayed in a line (not necessarily a straight line) or a line that branches
	f. Segmental	Triangular or cone-shaped region of enhancement. Apex at the nipple
2. Internal enhancement characteristics	a. Homogeneous	Confluent uniform enhancement
	b. Heterogeneous	Nonuniform enhancement in a random pattern separated by normal breast parenchyma or fat
	c. Clumped	Cobblestone enhancement of varying shapes and sizes with occasional confluent areas

F. Enhancing asymmetry

1. Internal enhancement pattern	a. Homogeneous	Confluent uniform enhancement
	b. Heterogeneous	Nonuniform enhancement in a random pattern separated by normal breast parenchyma or fat

G. Intramammary lymph node: Circumscribed, homogeneously enhancing masses, reniform, generally < 1 cm

H. Skin lesion: Benign enhancing lesions of skin

I. Associated features

1. Nipple retraction	Nipple is pulled in. Do not confuse with nipple inversion	
2. Nipple invasion	Tumor directly invades and is contiguous with the nipple	
3. Skin retraction	The skin is pulled in abnormally	
4. Skin thickening	May be focal or diffuse, > 2mm in thickness	
5. Skin invasion	Abnormal enhancement within the skin, which is thickened	
	a. Direct invastion	The skin enhances where the tumor directly invades
	b. Inflammatory cancer	The enhancement may be diffuse or focal depending on the extent of invasion of dermal lymphatics
6. Axillary adenopathy	Enlarged lymph nodes may warrant comment, clinical correlation, and additional evaluation especially if new or considerably larger or rounder compared to previous examination	
7. Pectoralis muscle invasion	Abnormal enhancement extending into the adjacent pectoralis muscle	
8. Architectural distortion	As an associated feature, may be used in conjunction with another finding to indicate distortion or retraction of parenchyma adjacent to the other finding	

K. Location of Lesion: An important lesion (assessed as anything other than benign) must always be triangulated so that its 3-D location within the breast is known

1. Location	Describe right, left, or both breasts Use quadrant location (upper outer, upper inner, lower outer, lower inner and clock face position or Use retroareolar, central, and axillary tail preceded by right, left, or both breasts.
2. Depth	Indicate depth (anterior, middle, posterior thirds). Include centimeters from nipple or skin as appropriate

ASSESSMENT CATEGORIES (select one)		
Incomplete Assessment	**Management**	**Likelihood of Cancer**
Category 0: Incomplete – Need Additional Imaging Evaluation	Recommend additional imaging: mammographic views (including tomosynthesis) ultrasound, MRI	N/A
Final Assessment	**Management**	**Likelihood of Cancer**
Category 1: Negative	Routine annual mammography (with or without contrast as appropriate)	Essentially 0% likelihood of malignancy
Category 2: Benign	Routine annual mammography (with or without contrast as appropriate)	Essentially 0% likelihood of malignancy
Category 3: Probably Benign	Short-interval (6-month) follow up	> 0% but ≤ 2%
Category 4: Suspicious	Tissue diagnosis	> 2 but < 95% malignancy
Category 5: Highly Suggestive of Malignancy	Tissue diagnosis	≥ 95% malignancy
Category 6: Known Biopsy Proven Malignancy	Surgical excision when clinically appropriate	N/A

APPENDIX II: IMAGES

A. BACKGROUND PARENCHYMAL ENHANCEMENT:

1. LEVEL

    a. Minimal

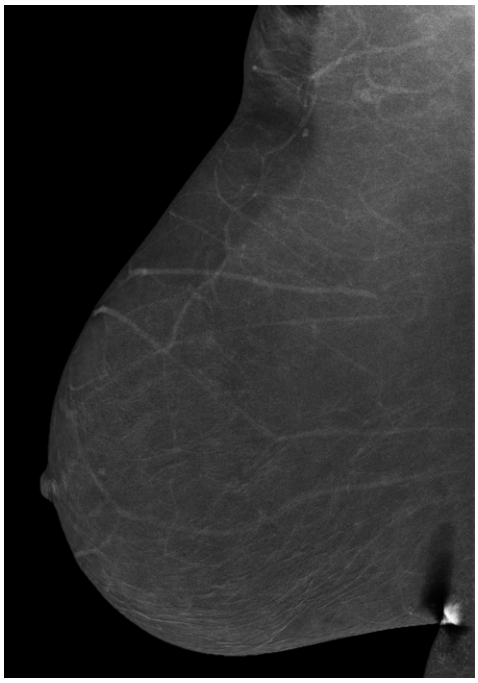

Figure 1 – BACKGROUND PARENCHYMAL ENHANCEMENT: MINIMAL. Recombined image.

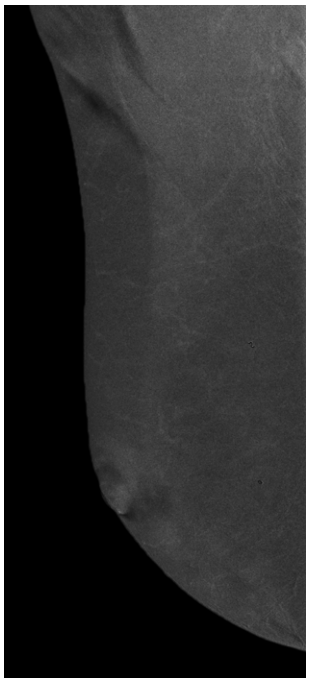

Figure 2 – BACKGROUND PARENCHYMAL ENHANCEMENT: MINIMAL. Recombined image.

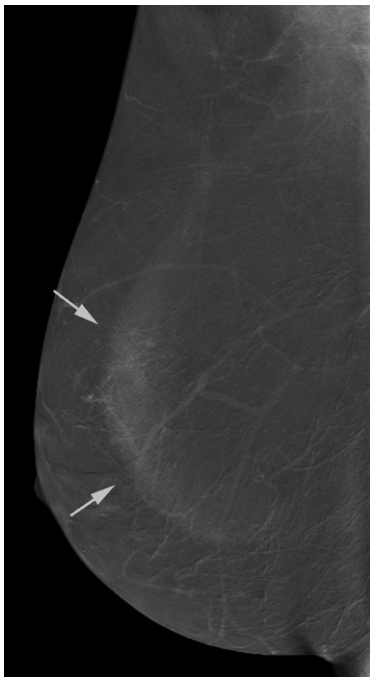

Figure 3 – BACKGROUND PARENCHYMAL ENHANCEMENT: MINIMAL. Note the rim artifact (arrows) caused by scattered radiation within the breast during image acquisition. Recombined image.

A. BACKGROUND PARENCHYMAL ENHANCEMENT:

1. LEVEL

   b. Mild

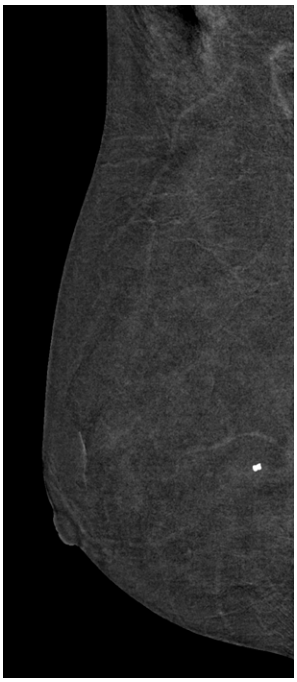

Figure 4 – BACKGROUND PARENCHYMAL ENHANCMENT: MILD. Recombined image.

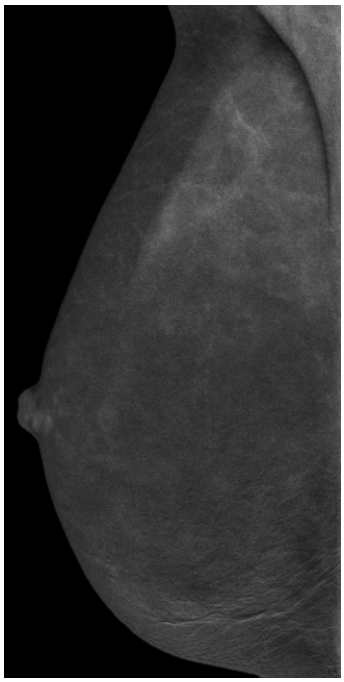

Figure 5 – BACKGROUND PARENCHYMAL ENHANCEMENT: MILD. Recombined image.

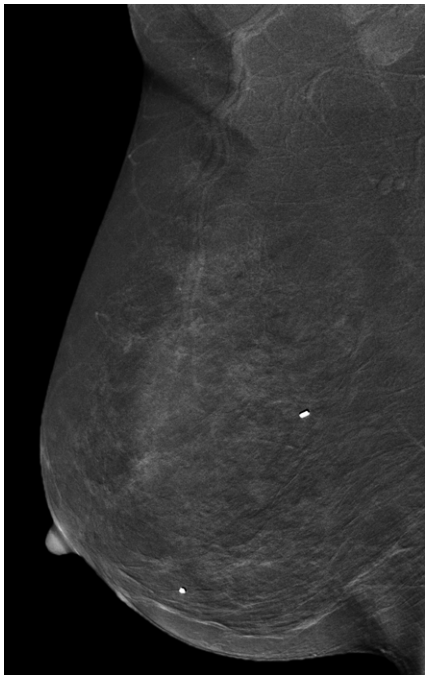

Figure 6 – BACKGROUND PARENCHYMAL ENHANCEMENT: MILD. Recombined image.

A. BACKGROUND PARENCHYMAL ENHANCEMENT:

1. LEVEL

    c. Moderate

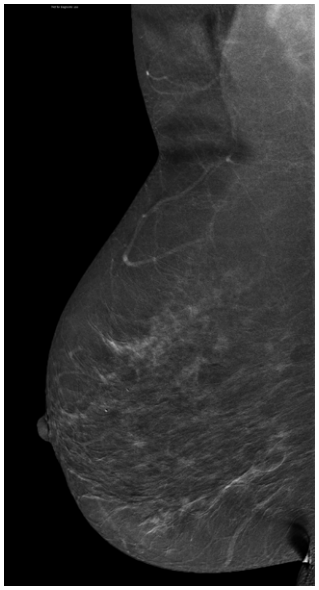

Figure 7 – BACKGROUND PARENCHYMAL ENHANCEMENT: MODERATE. Recombined image.

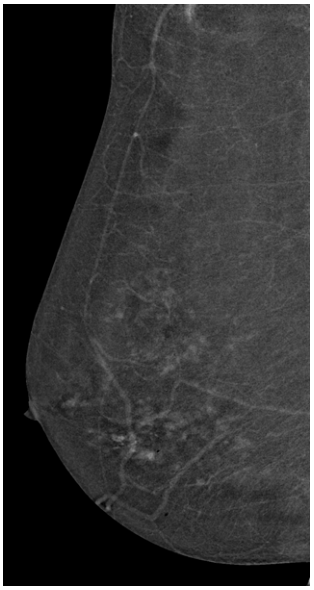

Figure 8 – BACKGROUND PARENCHYMAL ENHANCEMENT: MODERATE. Recombined image.

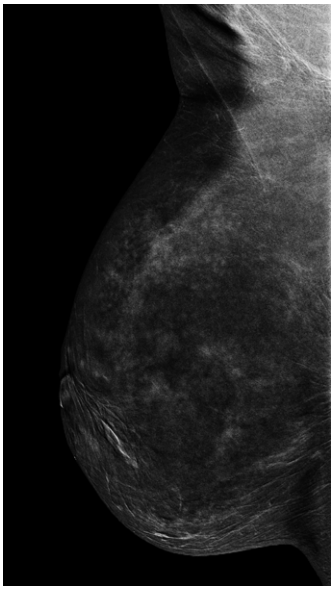

Figure 9 – BACKGROUND PARENHCHYMAL ENHANCEMENT: MODERATE. Recombined image.

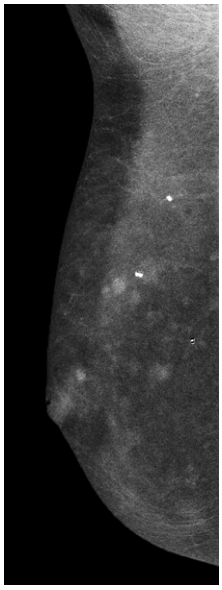

Figure 10a – BACKGROUND PARENHCHYMAL ENHANCEMENT: MODERATE. Right breast, recombined image. The multiple bilateral dots of enhancement should not be called multiple foci.

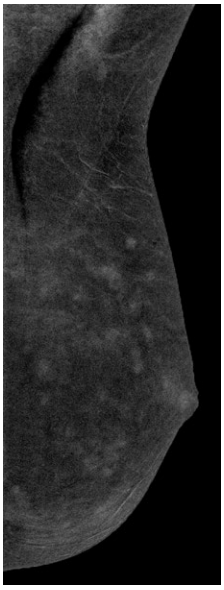

Figure 10b –BACKGROUND PARENHCHYMAL ENHANCEMENT: MODERATE. Left breast, recombined image. The multiple bilateral dots of enhancement should not be called multiple foci.

A. BACKGROUND PARENCHYMAL ENHANCEMENT:

1. LEVEL

   d. Marked

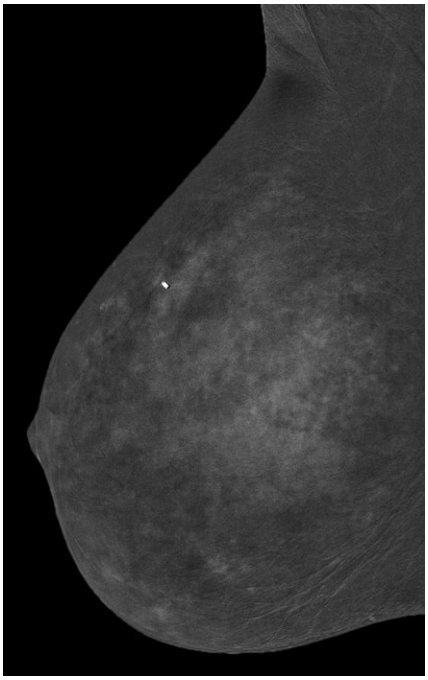

Figure 11 – BACKGROUND PARENCHYMAL ENHANCEMENT: MARKED. Recombined image.

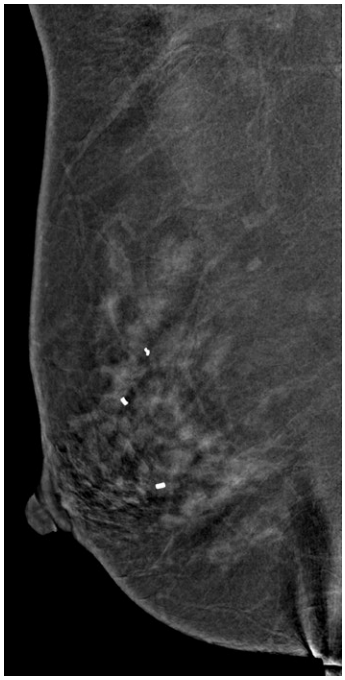

Figure 12 – BACKGROUND PARENCHYMAL ENHANCEMENT: MARKED. Recombined image.

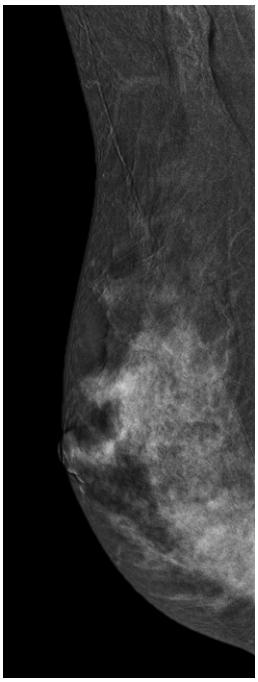

Figure 13 – BACKGROUND PARENCHYMAL ENHANCEMENT: MARKED. Recombined image.

A. BACKGROUND PARENCHYMAL ENHANCEMENT:

2. SYMMETRIC OR ASYMMETRIC

   a. Symmetric

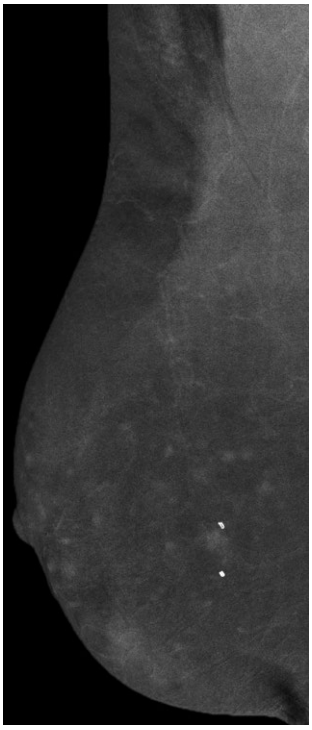

Figure 14a – BACKGROUND PARENCHYMAL ENHANCEMENT: SYMMETRIC. BPE is moderate and symmetric in both breasts. Right breast recombined image.

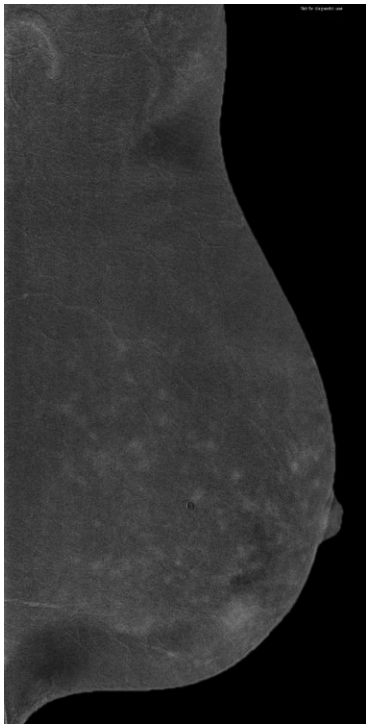

Figure 14b – BACKGROUND PARENCHYMAL ENHANCEMENT: SYMMETRIC. BPE is moderate and symmetric in both breasts. Left breast recombined image.

A. BACKGROUND PARENCHYMAL ENHANCEMENT:

2. SYMMETRIC OR ASYMMETRIC

b. Asymmetric

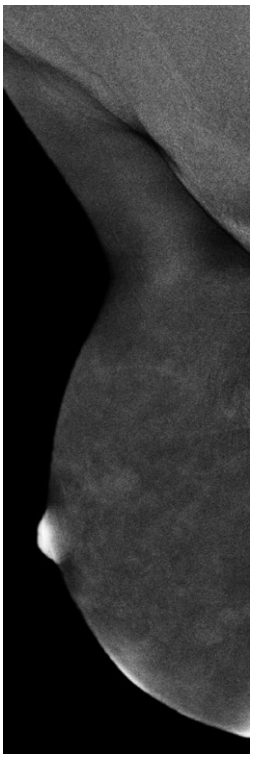

Figure 15a – BACKGROUND PARENCHYMAL ENHANCEMENT: ASYMMETRIC. Minimal BPE right breast, moderate BPE left breast in a patient with a history of right breast cancer status post breast—conservation surgery and radiation therapy. Right MLO recombined image.

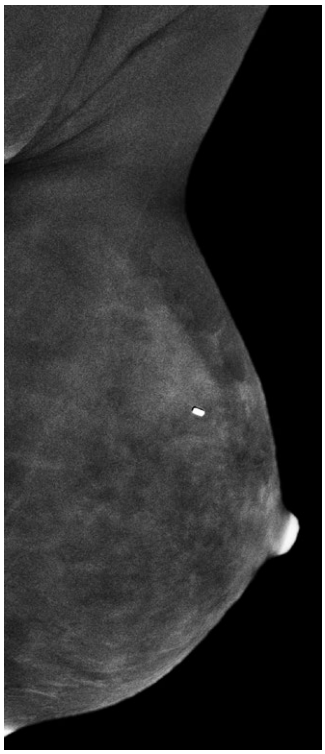

Figure 15b – BACKGROUND PARENCHYMAL ENHANCEMENT: ASYMMETRIC. Minimal BPE right breast, moderate BPE left breast in a patient with a history of right breast cancer status post breast—conservation surgery and radiation therapy. Marker clip on the left from remote ultrasound-guided biopsy of a 7 mm mass yielding fibroadenoma. Left MLO recombined image.

C. LESION CONSPICUITY (relative to background)

1. LOW

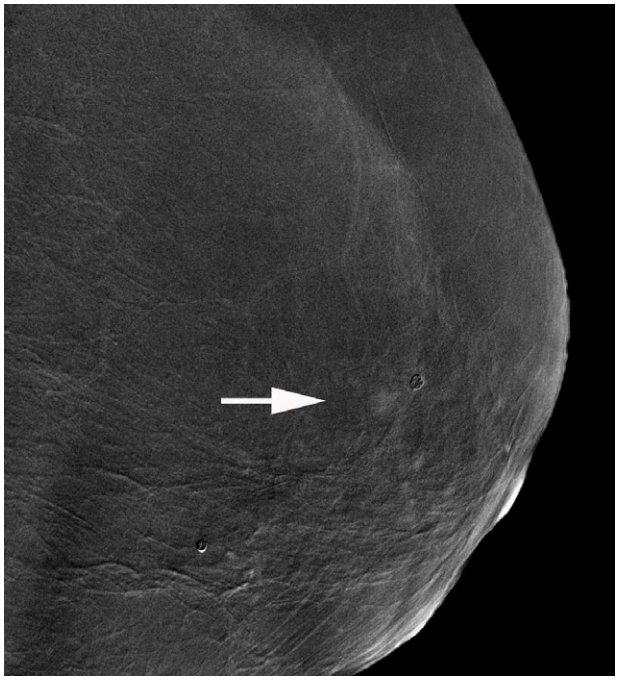

Figure 16a – LESION CONSPICUITY: LOW: Small round mass with irregular margin (arrow). Left MLO recombined image.

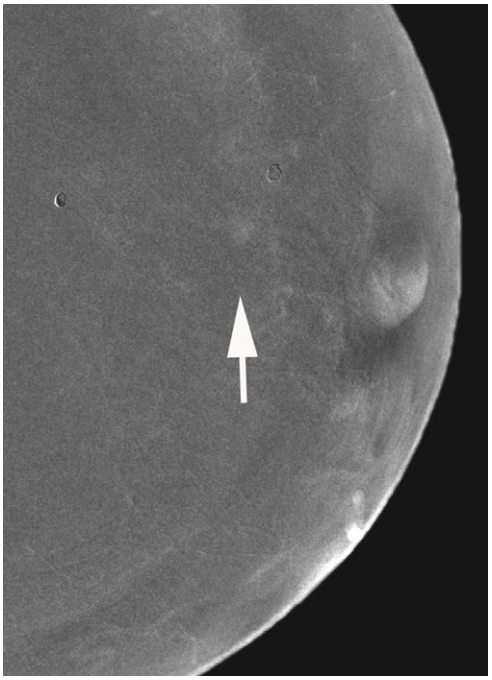

Figure 16b – LESION CONSPICUITY: LOW: Small round mass with irregular margin. Same patient as seen in 16a. Left CC recombined image. Pathology: invasive ductal carcinoma despite low conspicuity.

C. LESION CONSPICUITY (relative to background)

2. MODERATE

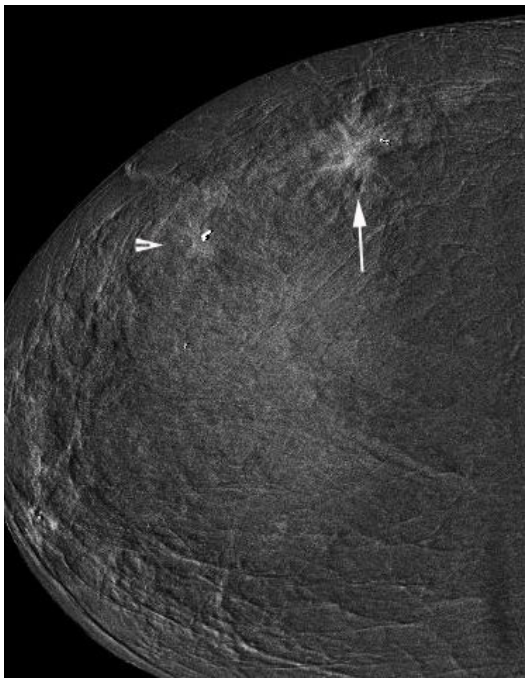

Figure 17 – LESION CONSPICUITY: MODERATE: Focal non-mass with homogeneous internal enhancement (arrow). Second lesion (arrowhead) has low conspicuity. Recombined image. Pathology: invasive ductal carcinoma for both.

C. LESION CONSPICUITY (relative to background)

3. HIGH

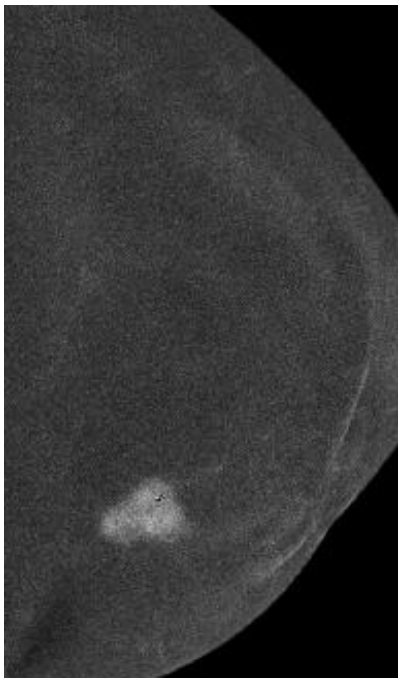

Figure 18 – LESION CONSPICUITY: HIGH: Oval mass with circumscribed margin, heterogeneous internal enhancement. Recombined image. Pathology: fibroadenoma.

D. MASSES

1. SHAPE

    a. Oval (includes lobulated)

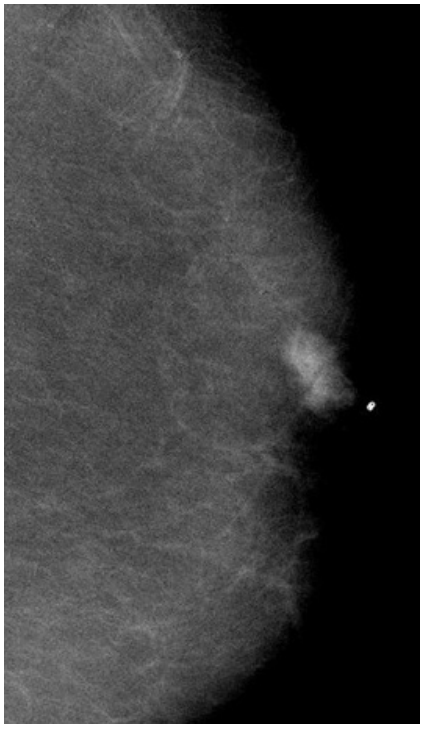

Figure 19 – MASS SHAPE: OVAL. Indistinct margin, heterogeneous internal enhancement. The mass was palpable. Recombined image. Pathology: invasive ductal carcinoma.

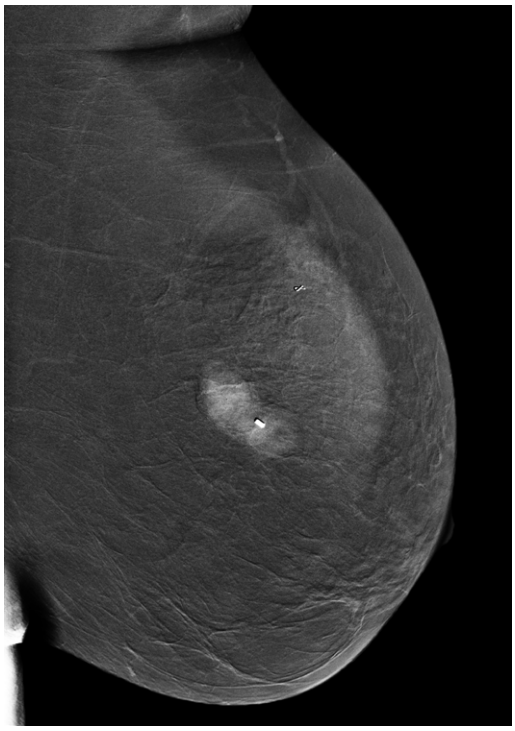

Figure 20 – MASS SHAPE: OVAL. Circumscribed margin, heterogeneous internal enhancement. Recombined image. Pathology: invasive ductal carcinoma.

D. MASSES

1. SHAPE

   b. Round

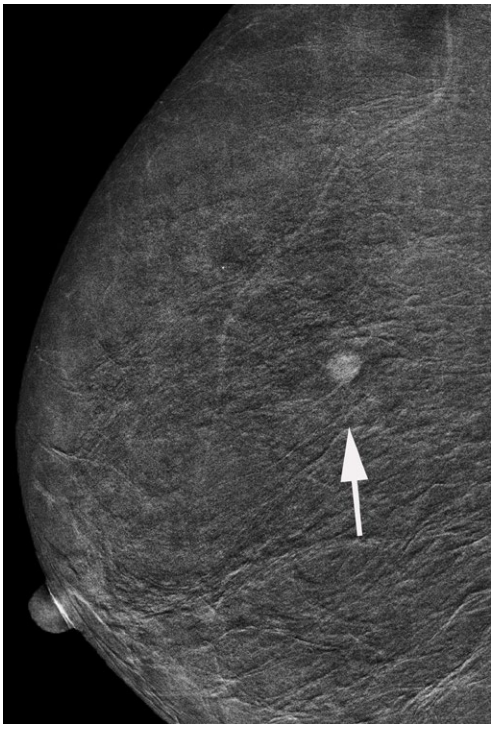

Figure 21 – MASS SHAPE: ROUND Circumscribed margin, homogeneous internal enhancement (arrow) Recombined image. Pathology: lymph node.

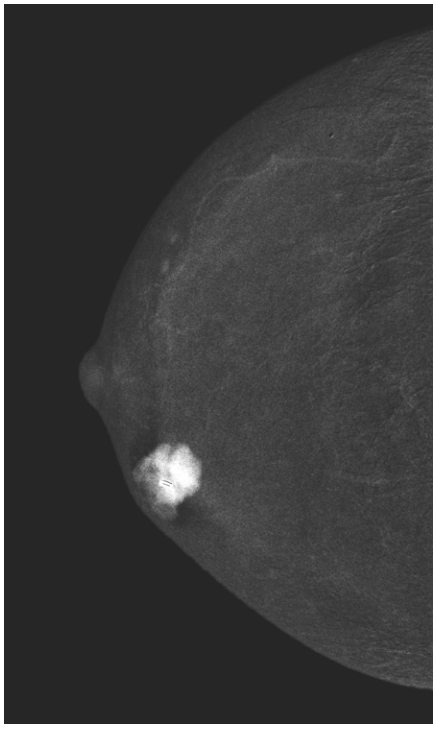

Figure 22 – ROUND. Circumscribed margin, heterogeneous internal enhancement. Recombined image. Pathology: fibroadenoma.

D. MASSES

1. SHAPE

    c. Irregular

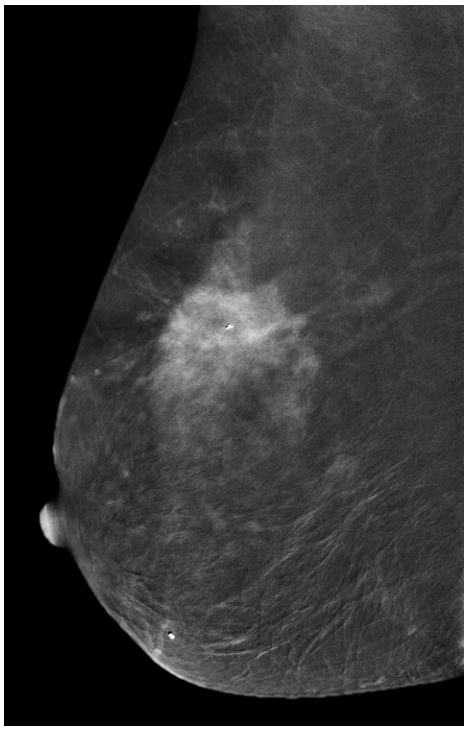

Figure 23 – MASS SHAPE: IRREGULAR. Irregular margin, heterogeneous internal enhancement. Recombined image. Pathology: invasive ductal carcinoma.

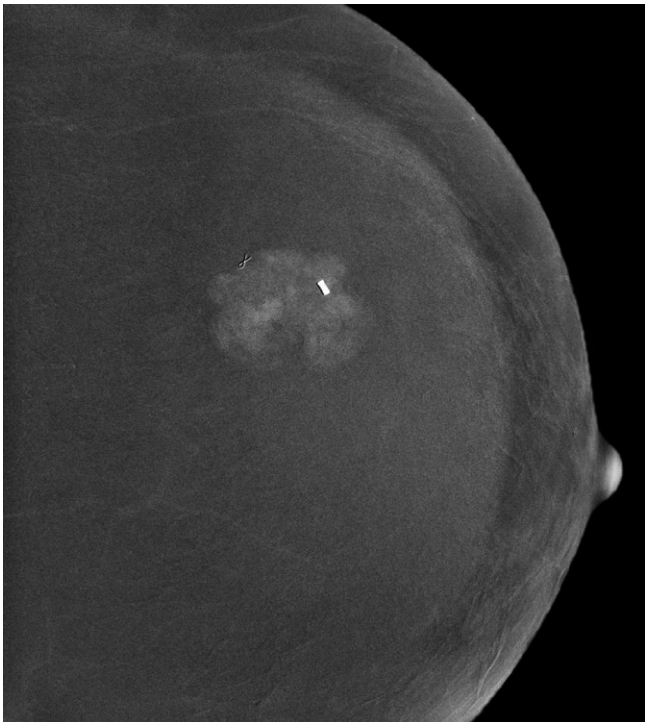

Figure 24 – MASS SHAPE: IRREGULAR. Irregular margin, heterogeneous internal enhancement. Recombined image. Pathology: invasive ductal carcinoma.

D. MASSES

2. MARGIN

a. Circumscribed

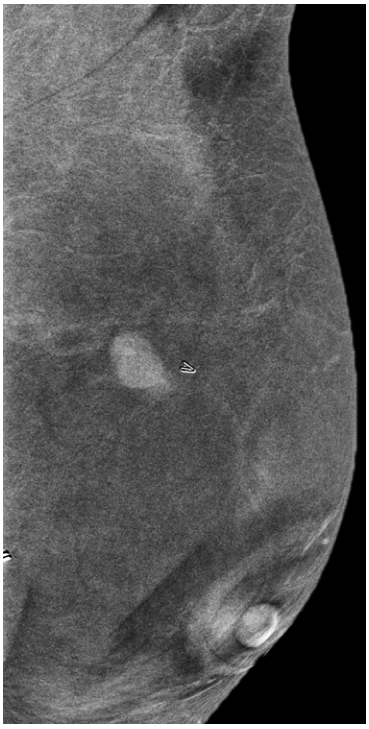

Figure 25 – MASS MARGIN: CIRCUMSCRIBED. Oval shape with homogeneous internal enhancement. Recombined image. Pathology: fibroadenoma.

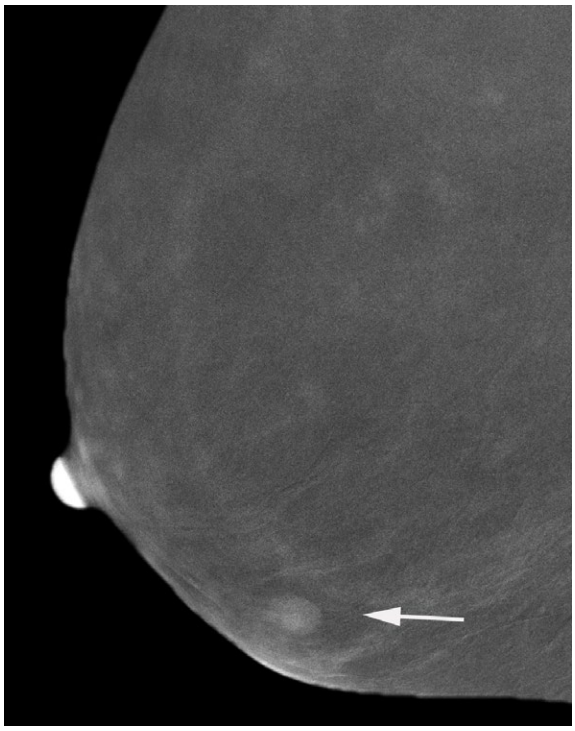

Figure 26 – MASS MARGIN: CIRCUMSCRIBED. Oval shape with homogeneous internal enhancement (arrow). Recombined image. Pathology: none. Presumed benign, long-term stability.

D. MASSES

2. MARGIN

b. Not Circumscribed

i. Irregular

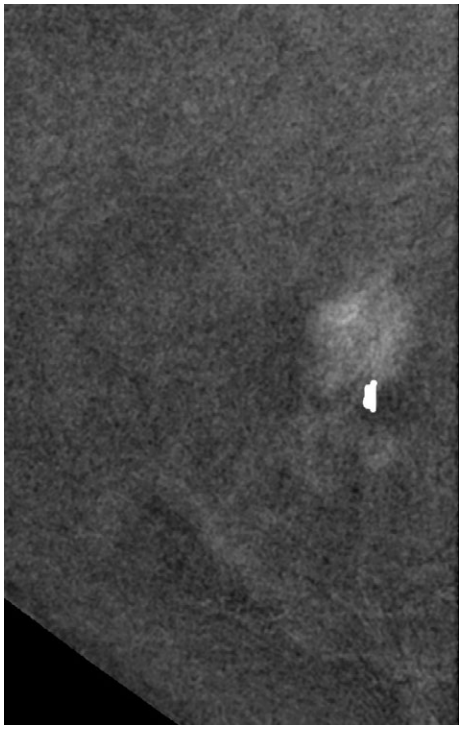

Figure 27 – MASS MARGIN: NOT CIRCUMSCRIBED, IRREGULAR. Irregular shape with homogeneous internal enhancement. Recombined image. Pathology: Invasive ductal carcinoma.

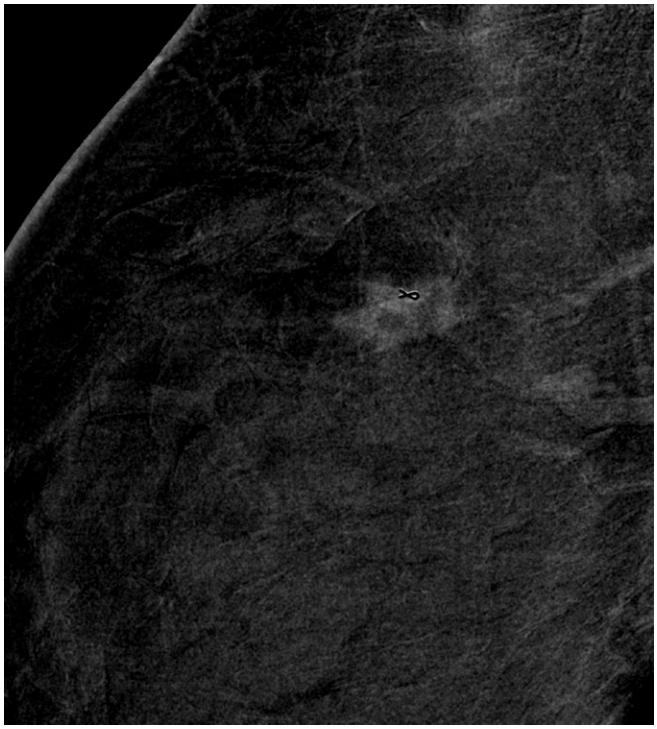

Figure 28 – MASS MARGIN: NOT CIRCUMSCRIBED: IRREGULAR. Irregular shape heterogeneous internal enhancement. Recombined image. Pathology: invasive ductal carcinoma.

D. MASSES

2. MARGIN

b. Not Circumscribed

ii. Spiculated

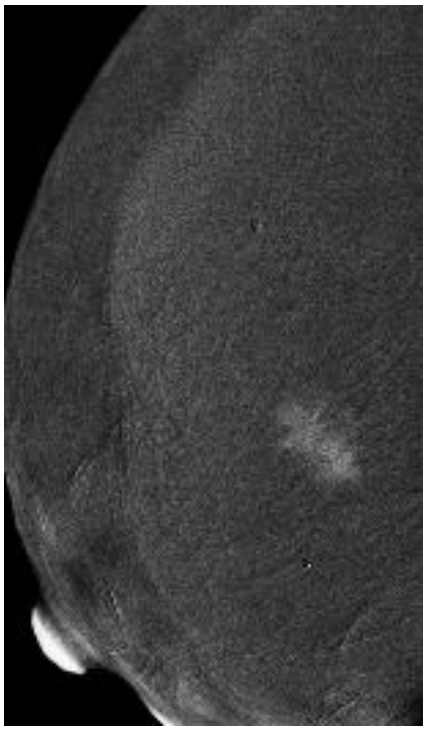

Figure 29 – MASS MARGIN: NOT CIRCUMSCRIBED: SPICULATED. Irregular shape, homogeneous internal enhancement. Recombined image. Pathology: invasive ductal carcinoma.

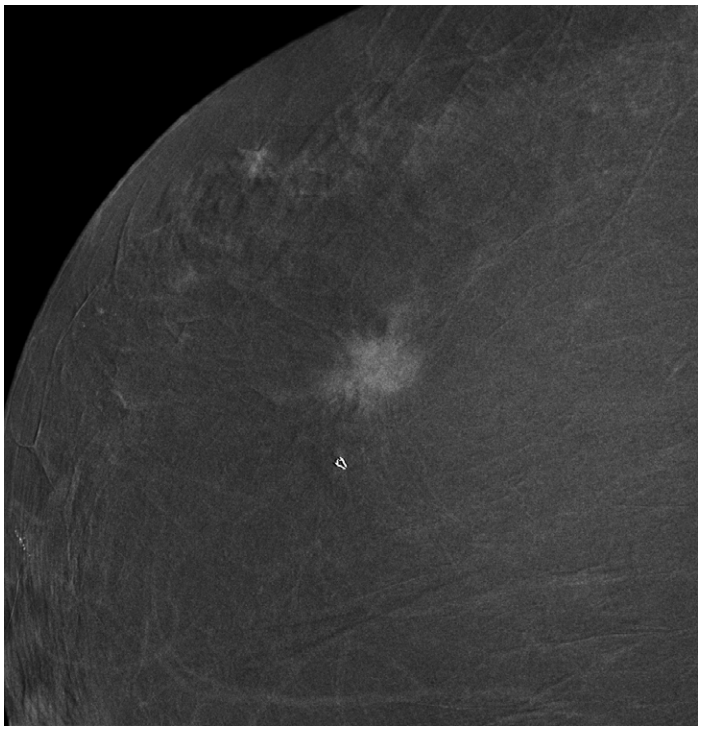

Figure 30 – MASS MARGIN: NOT CIRCUMCRIBED: SPICULATED. Oval shape, homogeneous internal enhancement. Recombined image. Pathology: invasive ductal carcinoma.

D. MASSES

3. INTERNAL ENHANCEMENT CHARACTERISTICS

   a. Homogeneous

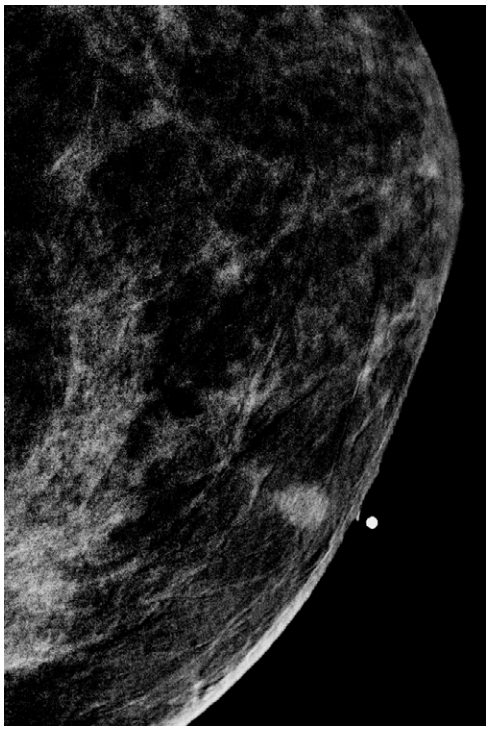

Figure 31 – MASS INTERNAL ENHANCEMENT: HOMOGENEOUS: Oval shape, circumscribed margin. Recombined image. Pathology: benign papilloma.

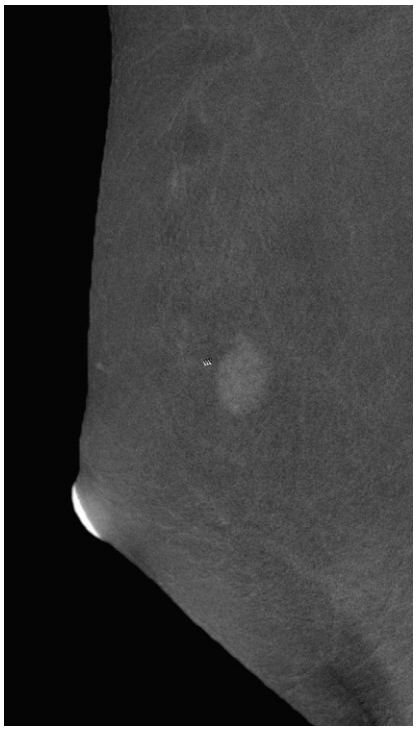

Figure 32 – Oval shape, circumscribed margin. Recombined image. Pathology: fibroadenoma.

D. MASSES

3. INTERNAL ENHANCEMENT CHARACTERISTICS

   b. Heterogeneous

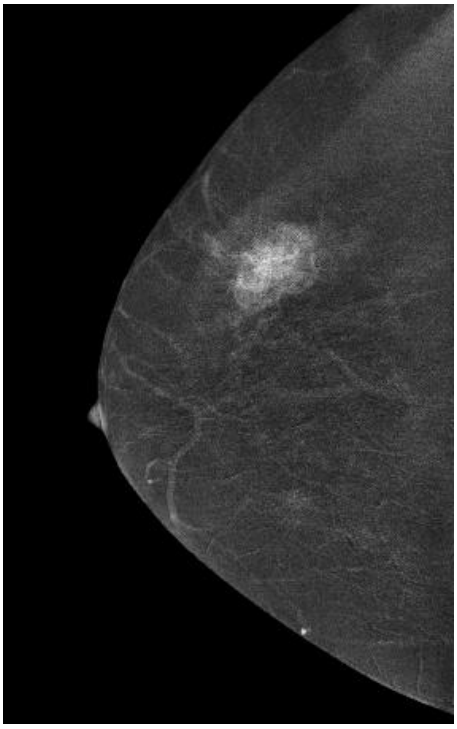

Figure 33 – MASS INTERNAL ENHANCEMENT: HETEROGENEOUS. Oval shape, irregular margin. Recombined image. Pathology: invasive ductal carcinoma.

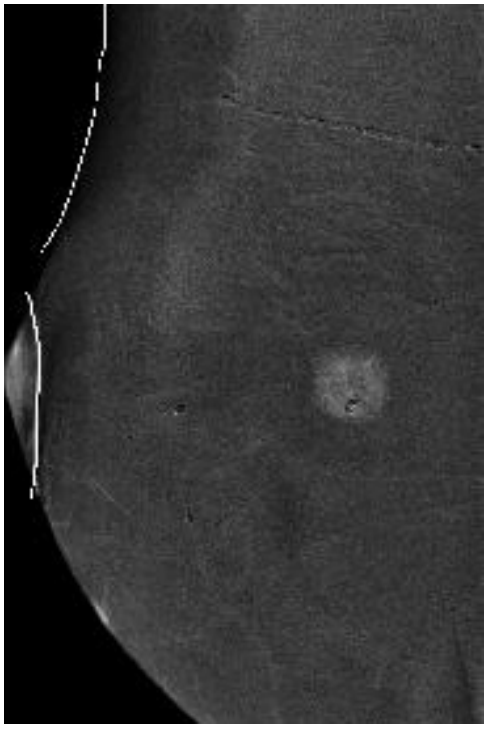

Figure 34 – MASS INTERNAL ENHANCEMENT: HETEROGENEOUS. Round shape, irregular margin. Recombined image. Pathology: invasive ductal carcinoma.

D. MASSES

3. INTERNAL ENHANCEMENT CHARACTERISTICS

   c. Rim Enhancement

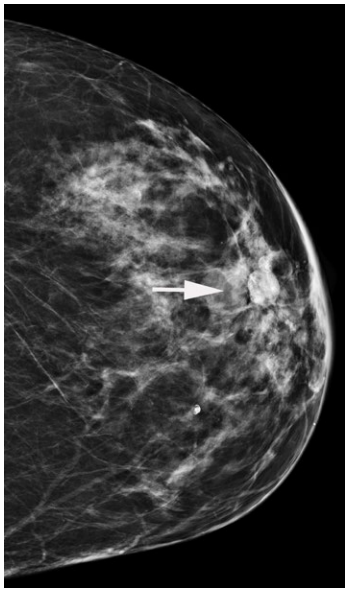

Figure 35a – MASS INTERNAL ENHANCEMENT: RIM: Round circumscribed mass on LE image (arrow).

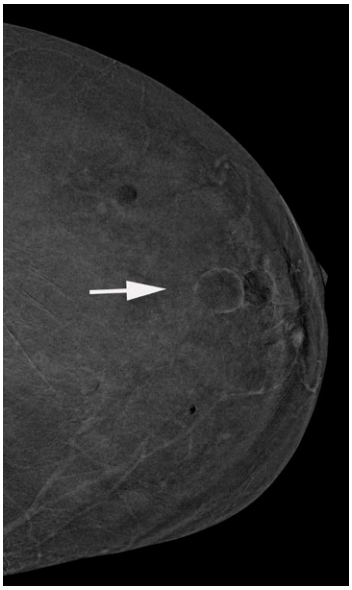

Figure 35b – MASS INTERNAL ENHANCEMENT: RIM: Rim enhancement on RC image (arrow). Pathology: none. Simple cyst by ultrasound.

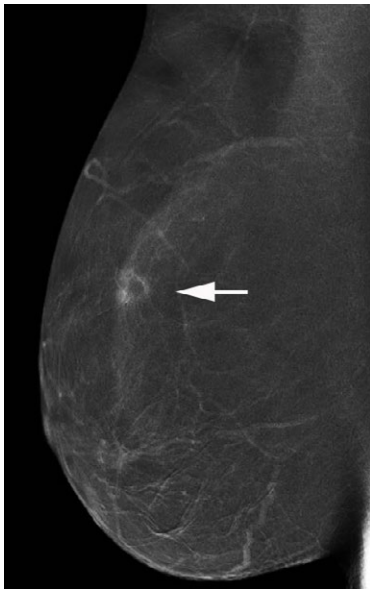

Figure 36a – MASS INTERNAL ENHANCEMENT: RIM: Rim enhancing mass at prior lumpectomy site on recombined image (arrow). Surgery was 18 months earlier.

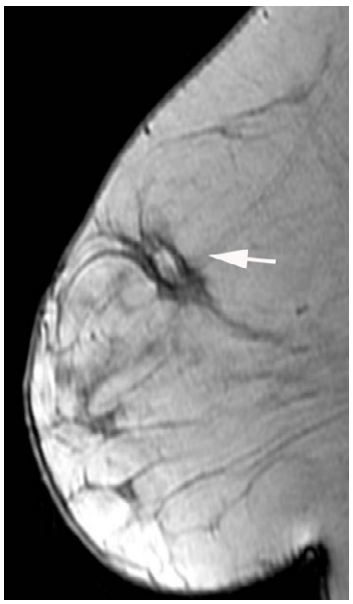

Figure 36b – MASS INTERNAL ENHANCEMENT: RIM: T1 weighted image without fat suppression on MRI shows fat in the mass (arrow). This is a typical benign finding at a lumpectomy site with fat necrosis.

E. NON-MASS ENHANCEMENT

1. DIFFUSE

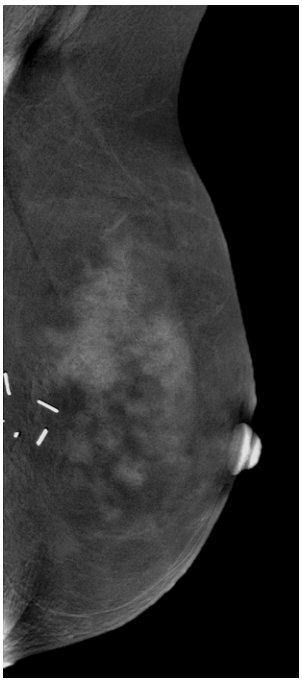

Figure 37 – NON-MASS DISTRIBUTION: DIFFUSE: Patient with prior history of breast cancer and previous lumpectomy and radiation on the left. Recombined image. Pathology: invasive mammary carcinoma (recurrent).

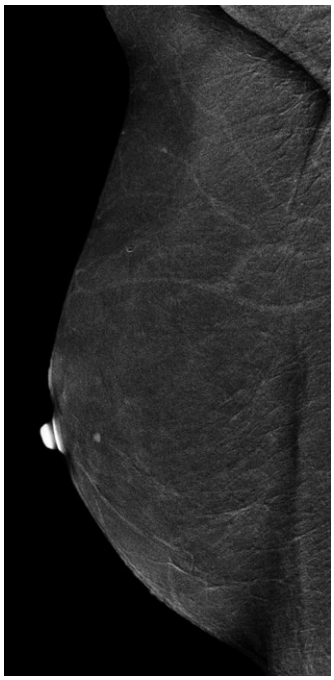

Figure 38a – NON-MASS DISTRIBUTION: DIFFUSE: Minimal enhancement right breast. RMLO recombined image.

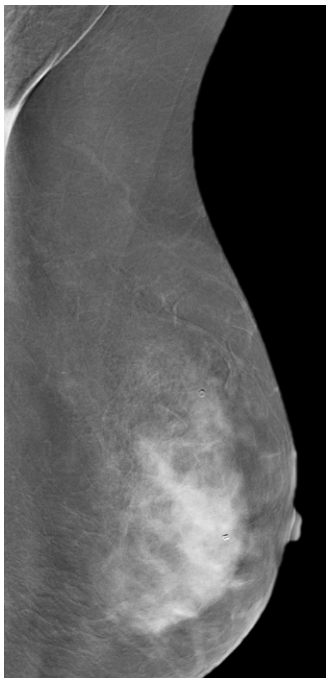

Figure 38b – NON-MASS DISTRIBUTION: DIFFUSE: No history of surgery or radiation. LMLO recombined image. This should not be consumed with asymmetric background enhancement. Pathology: diffuse invasive lobular cancer.

E. NON-MASS ENHANCEMENT

1. DISTRIBUTION

   b. Multiple Regions

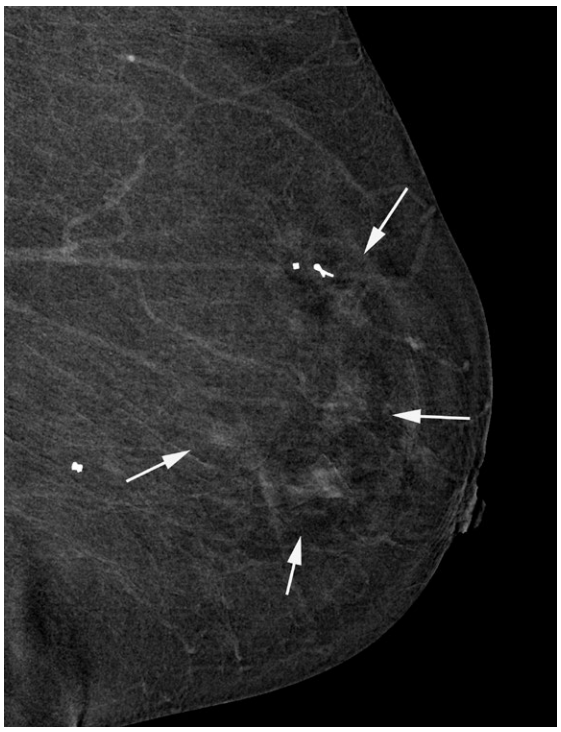

Figure 39 – NON-MASS DISTRIBUTION: MULTIPLE REGIONS (arrows). Recombined image. Pathology: multicentric invasive ductal carcinoma and DCIS.

E. NON-MASS ENHANCEMENT

1. DISTRIBUTION

   c. Regional

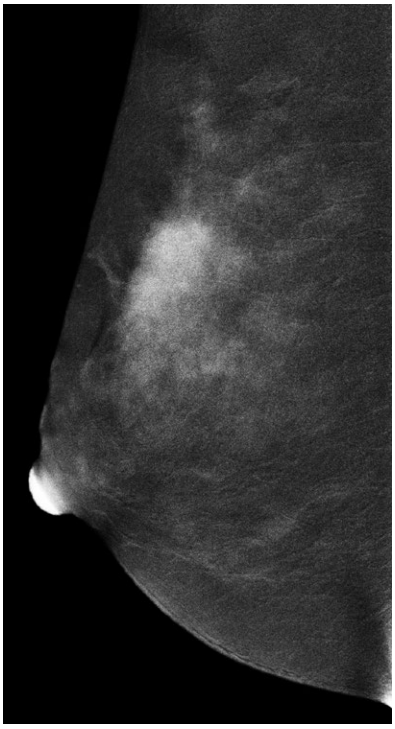

Figure 40 – NON-MASS DISTRIBUTION: REGIONAL: Homogeneous non-mass. Recombined image. Pathology: Pseudoangiomatous stromal hyperplasia (PASH).

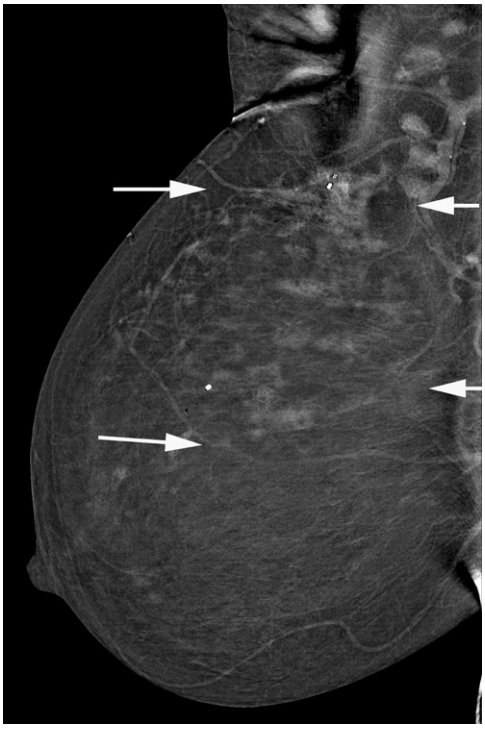

Figure 41 – NON-MASS DISTRIBUTION: REGIONAL (arrows): Clumped non-mass. Recombined image. Pathology: invasive ductal carcinoma and DCIS.

E. NON-MASS ENHANCEMENT

1. DISTRIBUTION

   d. Focal

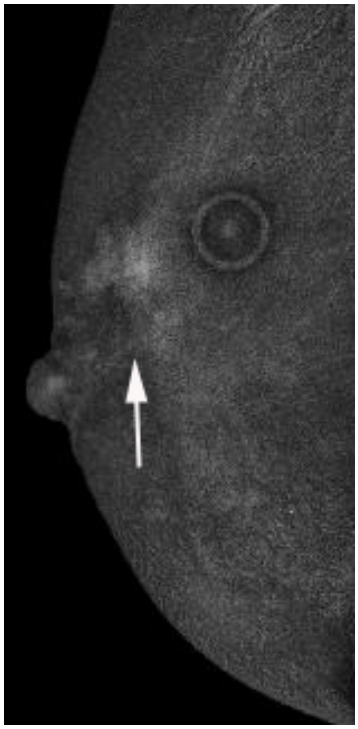

Figure 42 – NON-MASS DISTRIBUTION: FOCAL (arrow). Heterogeneous internal enhancement. Recombined image. Pathology: invasive ductal carcinoma and DCIS.

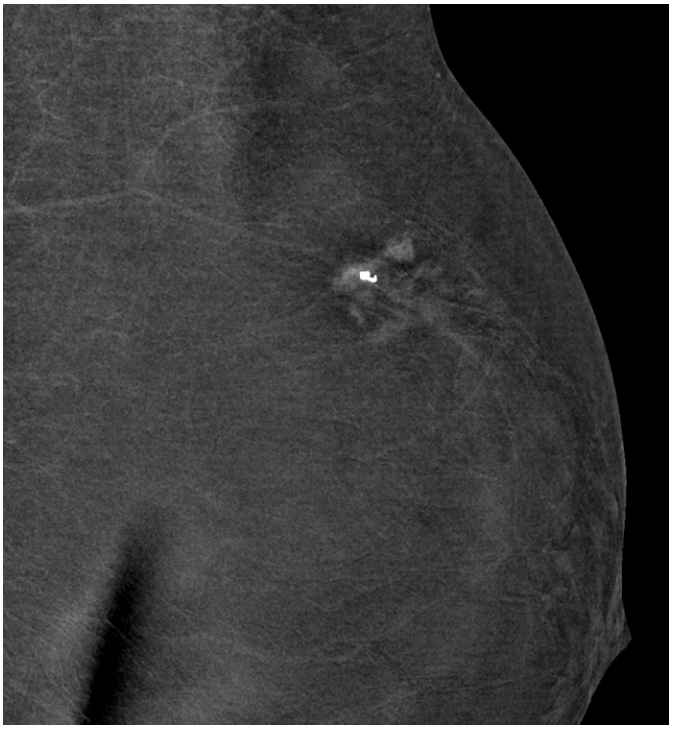

Figure 43 – NON-MASS DISTRIBUTION: FOCAL: Recombined image. Pathology: invasive ductal carcinoma.

E. NON-MASS ENHANCEMENT

1. DISTRIBUTION

   e. Linear

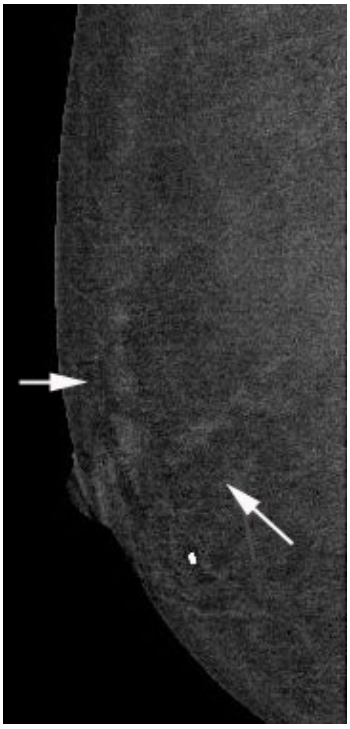

Figure 44 – NON-MASS DISTRIBUTION: LINEAR (arrows): Recombined image. Pathology: DCIS.

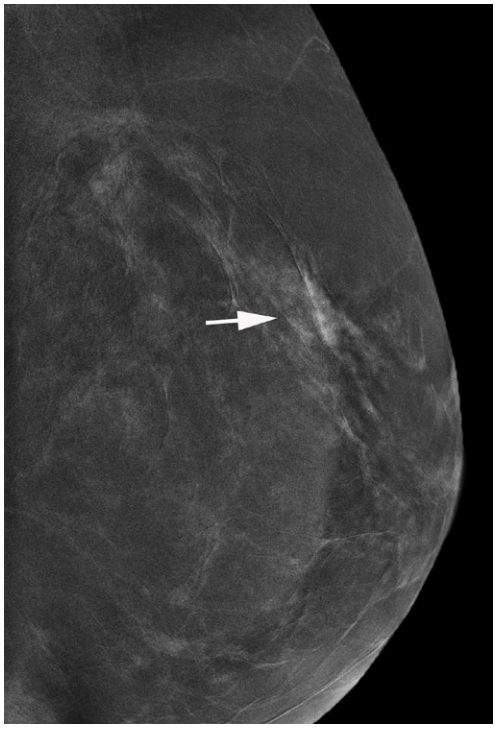

Figure 45 – NON-MASS DISTRIBUTION: LINEAR (arrow): Recombined image. Pathology: DCIS with microinvasion.

E. NON-MASS ENHANCEMENT

1. DISTRIBUTION

   f. Segmental

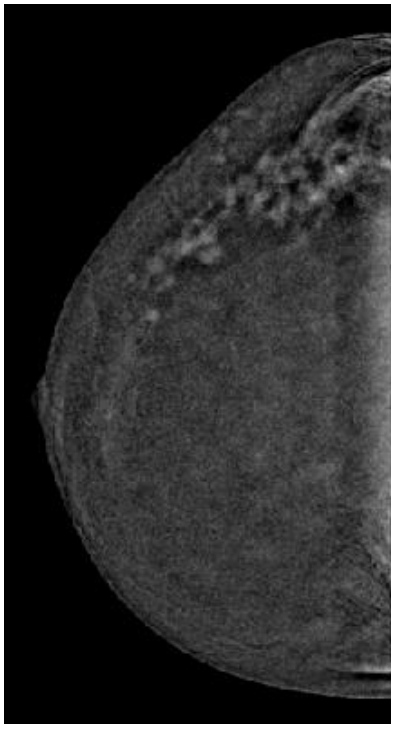

Figure 46 – NON-MASS DISTRIBUTION: SEGMENTAL: Clumped non-mass. Recombined image. Pathology: invasive lobular carcinoma.

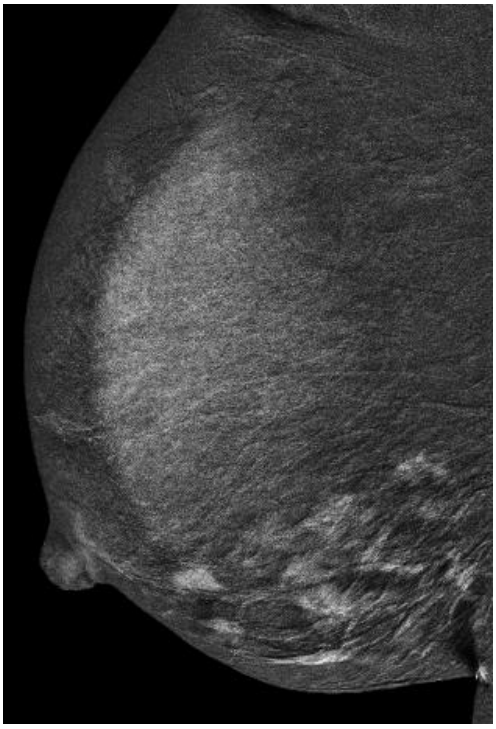

Figure 47 – NON-MASS DISTRIBUTION: SEGMENTAL: Clumped non-mass. Recombined image. Pathology: invasive lobular carcinoma.

E. NON-MASS ENHANCEMENT

2. INTERNAL ENHANCEMENT CHARACTERITICS

a. Homogeneous

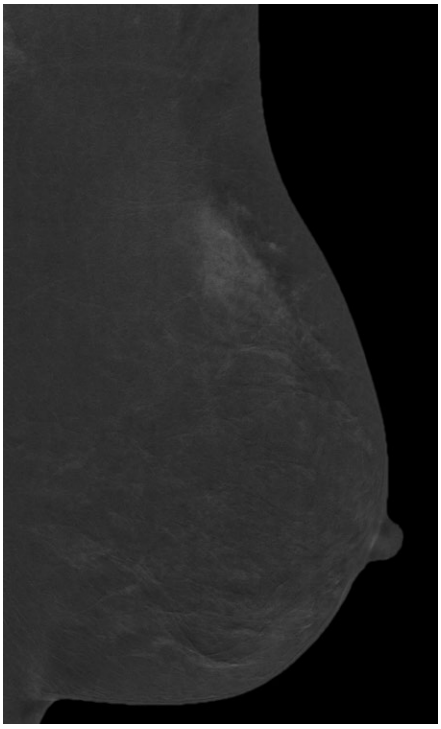

Figure 48 – NON-MASS INTERNAL ENHANCEMENT: HOMOGENEOUS: Regional non-mass enhancement. Recombined image. Pathology: none. Benign based on long term stability.

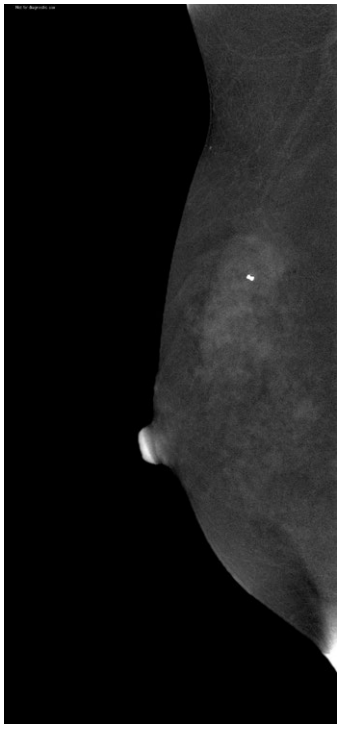

Figure 49 – NON-MASS INTERNAL ENHANCEMENT PATTERN: HOMOGENEOUS: Segmental non-mass enhancement. Recombined image. Pathology: invasive ductal carcinoma.

E. NON-MASS ENHANCEMENT

2. INTERNAL ENHANCEMENT CHARACTERITICS

b. Heterogeneous

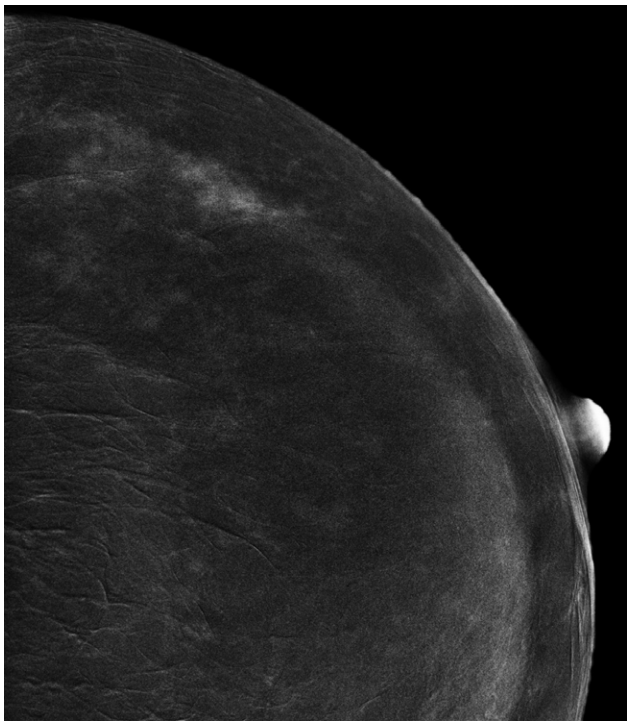

Figure 50 – NON-MASS INTERNAL ENHANCEMENT PATTERN: HETEROGENEOUS: Segmental non-mass enhancement. Recombined image. Pathology: DCIS with microinvasion.

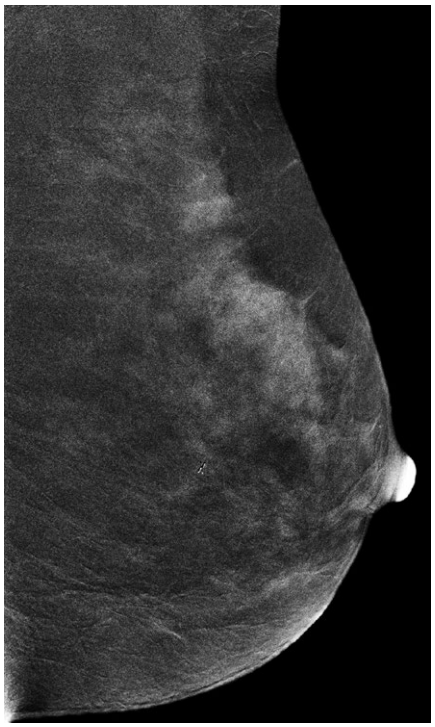

Figure 51 – NON-MASS INTERNAL ENHANCEMENT PATTERN: HETEROGENEOUS: Segmental non-mass enhancement. Recombined image. Pathology: invasive ductal carcinoma.

E. NON-MASS ENHANCEMENT

2. INTERNAL ENHANCEMENT CHARACTERITICS

c. Clumped

Figure 52 – NON-MASS INTERNAL ENHANCEMENT PATTERN: CLUMPED: Regional non-mass enhancement. Recombined image. Pathology: invasive ductal carcinoma.

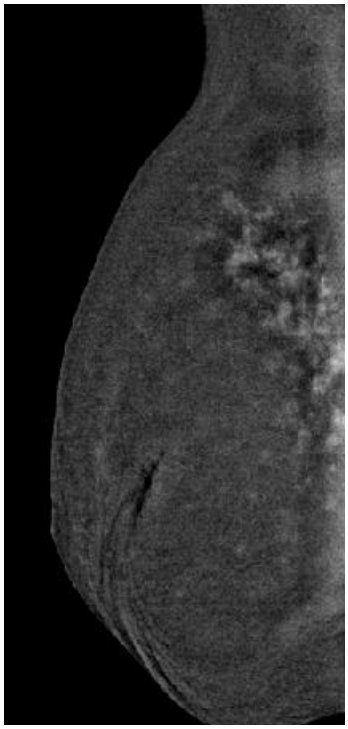

Figure 53 – NON-MASS INTERNAL ENHANCEMENT PATTERN: CLUMPED: Segmental non-mass enhancement. Recombined image. Pathology: invasive lobular carcinoma.

F. ENHANCING ASYMMETRY

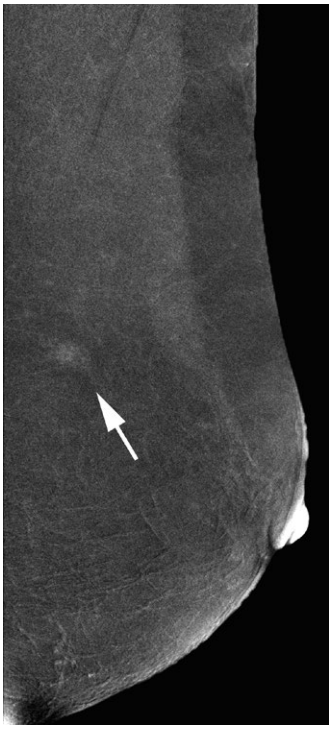

Figure 54a – ENHANCING ASYMMETRY – Seen only on left MLO recombined image (arrow).

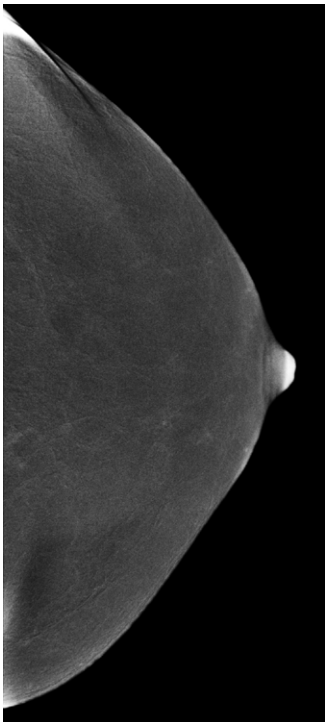

Figure 54b – ENHANCING ASYMMETRY – Not seen on left CC recombined image, perhaps because of deep location.

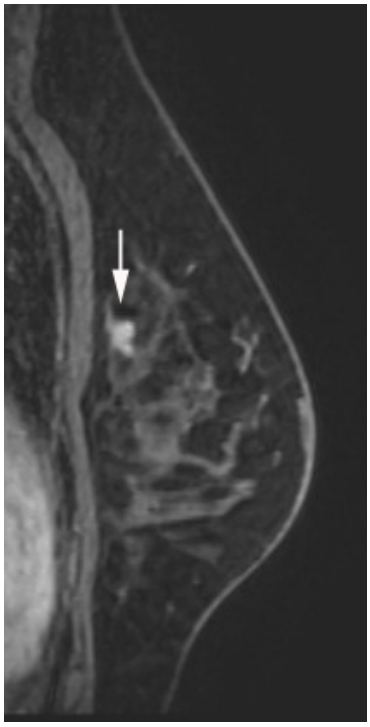

Figure 54c – ENHANCING ASYMMETRY – Seen as enhancing mass on post contrast T1-weighted MRI sagittal image (arrow). Pathology: invasive ductal carcinoma.

F. ENHANCING ASYMMETRY

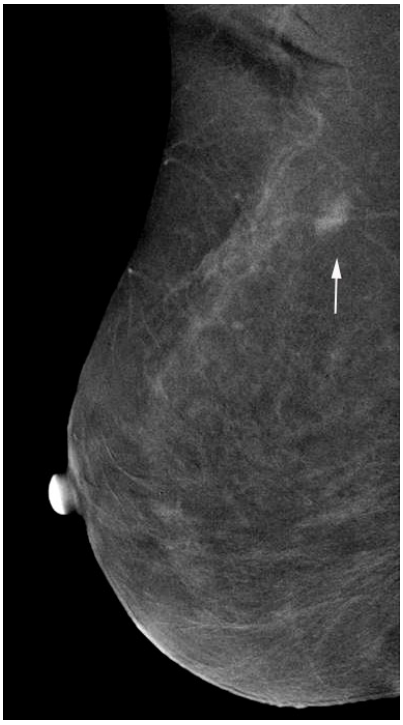

Figure 55a – ENHANCING ASYMMETRY – Seen only on right MLO recombined image (arrow).

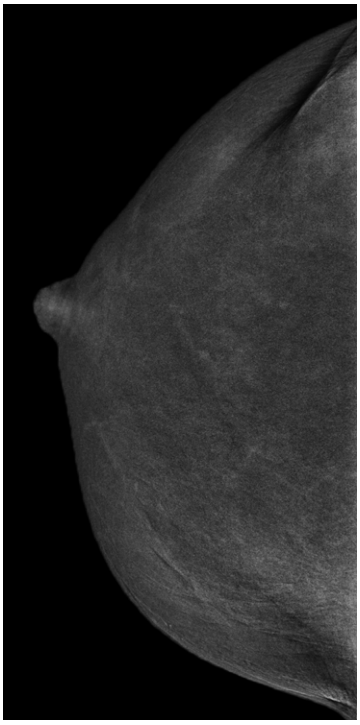

Figure 55b – ENHANCING ASYMMETRY – Not seen on right CC recombined image, perhaps because of posterior location.

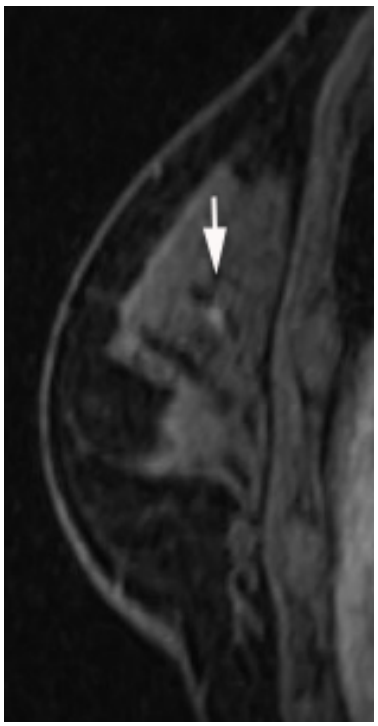

Figure 55c – ENHANCING ASYMMETRY – Seen as enhancing mass on post contrast T1 weighted MRI sagittal image (arrow). Pathology: invasive ductal carcinoma.

ABNORMALITY SEEN ON BOTH LOW ENERGY AND RECOMBINED IMAGES

1. MASS

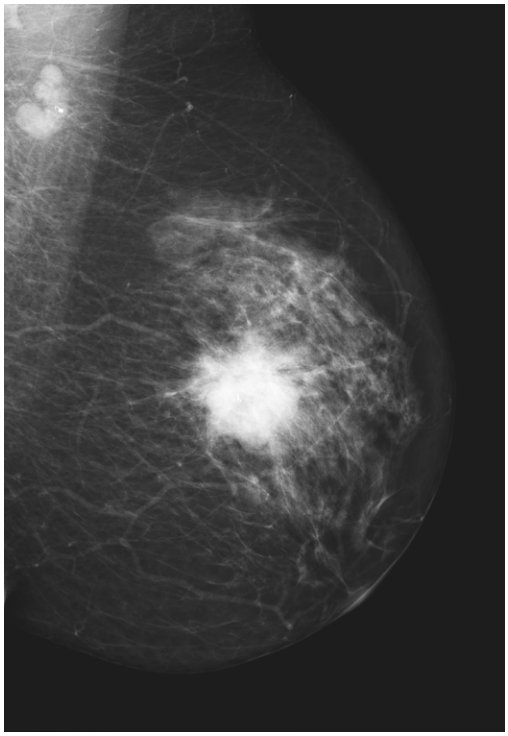

Figure 56a – ABNORMALITY SEEN ON BOTH LOW ENERGY AND RECOMBINED IMAGES: MASS. On the low energy image (a) a round, high density mass with spiculated margin.

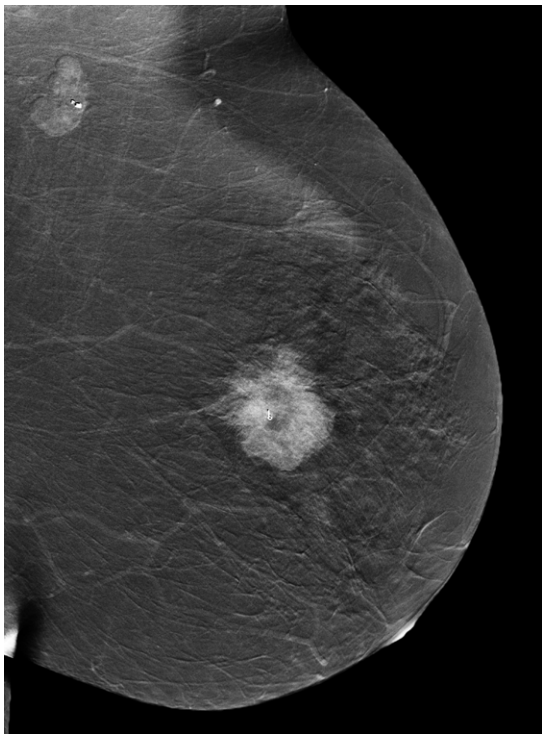

Figure 56b – ABNORMALITY SEEN ON BOTH LOW ENERGY AND RECOMBINED IMAGES: MASS. On the recombined image (b), heterogeneous internal enhancement. When a mass is seen on both the LE and RC images, shape and margin should be described according to the mammography lexicon. It is not necessary to separately describe the shape and margin on the RC image. Internal enhancement and, if desired, conspicuity can be described.

ABNORMALITY SEEN ON BOTH LOW ENERGY AND RECOMBINED IMAGES

2. ARCHITECTURAL DISTORTION

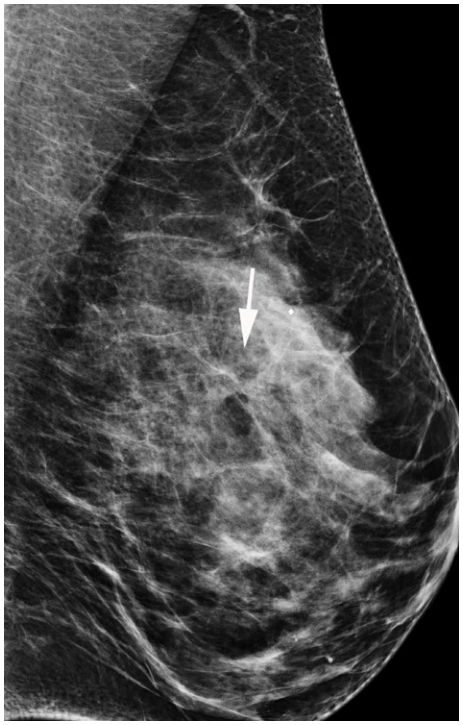

Figure 57a – ABNORMALITY SEEN ON BOTH LOW ENERGY AND RECOMBINED IMAGES: ARCHITECTURAL DISTORTION. On low-energy recombined image (a) an area of architectural distortion (arrow).

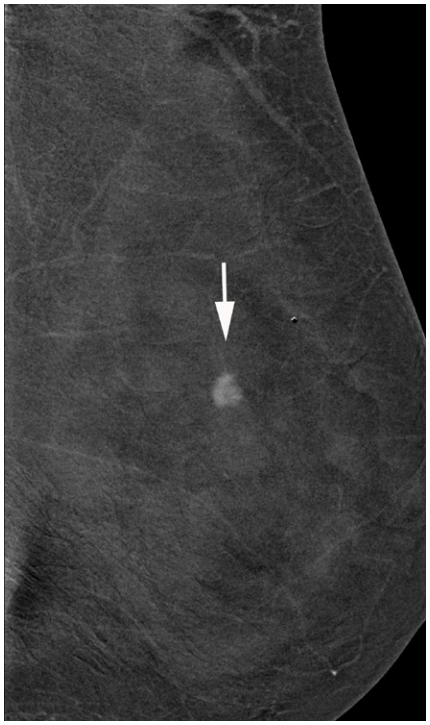

Figure 57b – ABNORMALITY SEEN ON BOTH LOW ENERGY AND RECOMBINED IMAGES: ARCHITECTURAL DISTORTION. Recombined LMLO image shows focal non-mass enhancement with heterogeneous enhancement (arrow). If the finding on the LE image is anything other than a mass, terms from the mammography lexicon should be used to describe the LE finding and terms from the CEM lexicon should be used to describe the enhancement on RC image. Pathology: invasive ductal carcinoma.

ABNORMALITY SEEN ON BOTH LOW ENERGY AND RECOMBINED IMAGES

3. CALCIFICATIONS

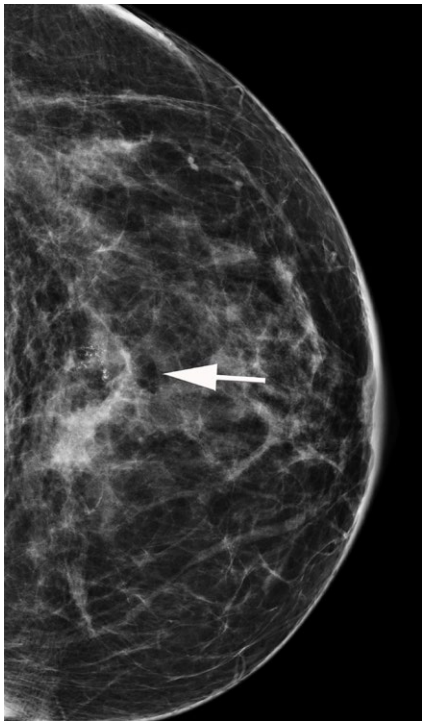

Figure 58a – ABNORMALITY SEEN ON BOTH LOW ENERGY AND RECOMBINED IMAGES: CALCIFICATIONS. On low energy CC view (a), regional fine pleomorphic calcifications with associated asymmetry seen (arrow).

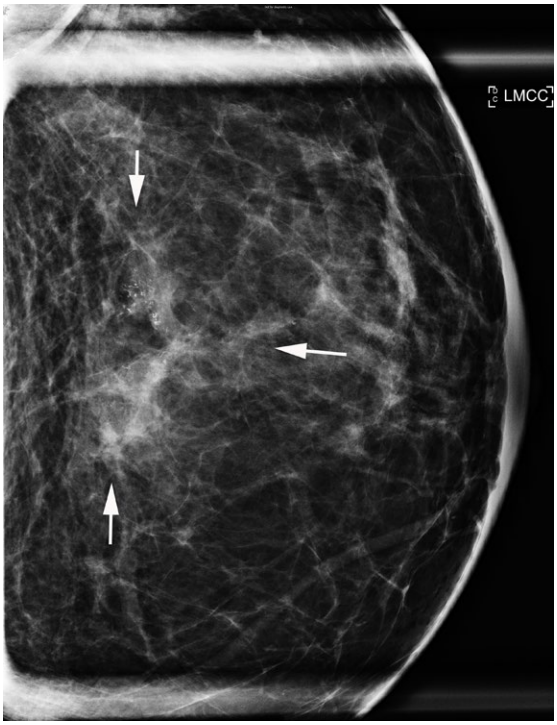

Figure 58b – ABNORMALITY SEEN ON BOTH LOW ENERGY AND RECOMBINED IMAGES: CALCIFICATIONS. On low energy CC view with magnification (b), regional fine pleomorphic calcifications with associated asymmetry seen (arrows).

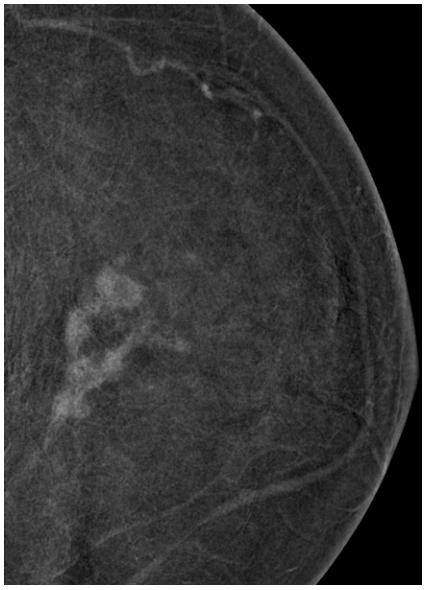

Figure 58c – ABNORMALITY SEEN ON BOTH LOW ENERGY AND RECOMBINED IMAGES: CALCIFICATIONS. On recombined image (c) regional non-mass enhancement. Pathology: DCIS.

ABNORMALITY ON LOW ENERGY BUT NOT RECOMBINED IMAGE

3. CALCIFICATIONS

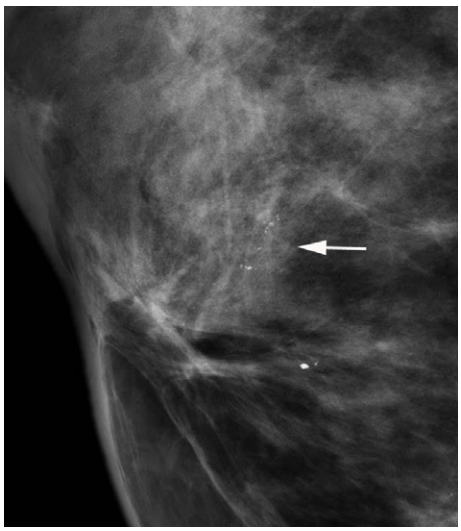

Figure 59a – ABNORMALITY ON LOW ENERGY BUT NOT RECOMBINED IMAGE: CALCIFICATIONS. Magnification ML view shows grouped amorphous calcifications (arrow).

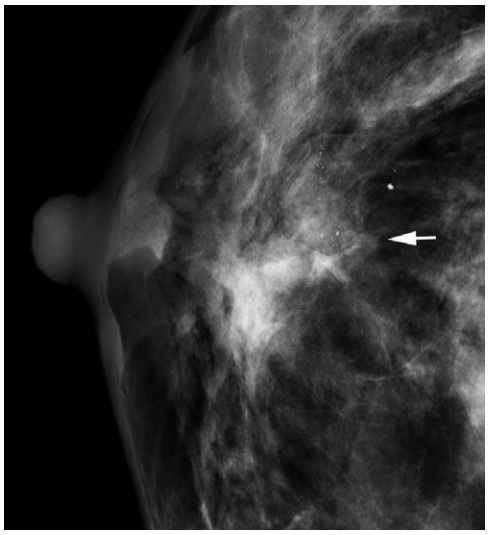

Figure 59b – ABNORMALITY ON LOW ENERGY BUT NOT RECOMBINED IMAGE: CALCIFICATIONS. Magnification CC view shows grouped amorphous calcifications (arrow).

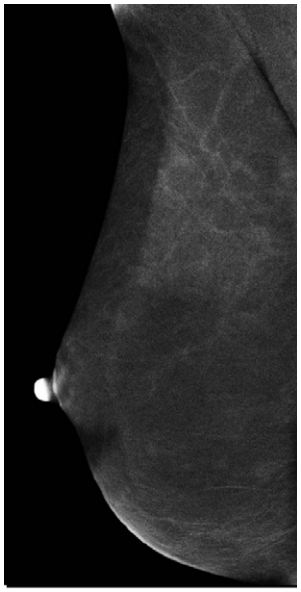

Figure 59c – ABNORMALITY ON LOW ENERGY BUT NOT RECOMBINED IMAGE: CALCIFICATIONS. No abnormal enhancement seen on recombined MLO image.

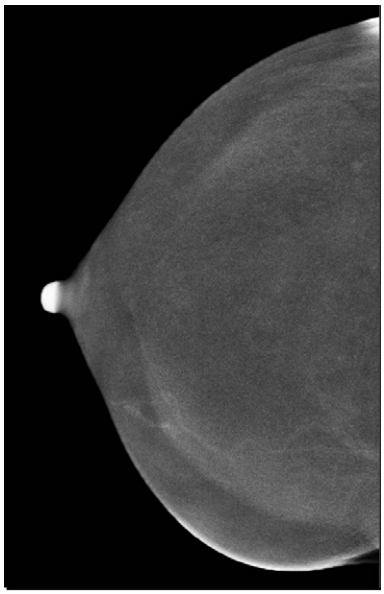

Figure 59d – ABNORMALITY ON LOW ENERGY BUT NOT RECOMBINED IMAGE: CALCIFICATIONS. No abnormal enhancement seen on recombined CC image. Pathology: DCIS with microinvasion.