

# The American College of Radiology BI-RADS® ATLAS and MQSA: Frequently Asked Questions

(Updated: 9/01/09)

## General

### Q. What is the Breast Imaging Reporting and Database System (BI-RADS®)?

A. **BI-RADS®** is a quality assurance guide designed to standardize breast imaging reporting and facilitate outcome monitoring. **BI-RADS®** serves as a comprehensive guide providing standardized breast imaging terminology, report organization and assessment structure, as well as a classification system for mammography, ultrasound, and magnetic resonance imaging (MRI) of the breast. The BI-RADS® Atlas also includes the fourth edition of the mammography lexicon and audit system. It provides radiologists with guidance on BI-RADS® through the use of illustrated cases, sample reports, statistical definitions, and explanations for performing mammography audits. It is a systematic method for radiologists to report mammogram findings using 7 standardized categories, or levels. Each BI-RADS® category has a follow-up recommendation associated with it to help radiologists and other physicians appropriately manage a patient's care.

Breast Imaging Reporting and Database System (BI-RADS®)		
Category	Assessment	Follow-up Recommendations
<b>a. Assessment is Incomplete</b>		
0	Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison	Additional imaging and/or prior images are needed before a final assessment can be assigned
<b>b. Assessment is Complete – Final Categories</b>		
1	Negative	Routine annual screening mammography (for women over age 40)
2	Benign Finding(s)	Routine annual screening mammography (for women over age 40)
3	Probably Benign Finding – Initial Short-Interval Follow-Up Suggested	Initial short-term follow up (usually 6-month) examination
4	Suspicious Abnormality – Biopsy Should Be Considered  Optional subdivisions:* 4A: Finding needing intervention with a low suspicion for malignancy 4B: Lesions with an intermediate suspicion of malignancy 4C: Findings of moderate concern, but not classic for malignancy	Usually requires biopsy
5	Highly Suggestive of Malignancy – Appropriate Action Should Be Taken	Requires biopsy or surgical treatment
6	Known Biopsy-Proven Malignancy – Appropriate Action Should Be Taken	Category reserved for lesions identified on imaging study with biopsy proof of malignancy prior to definitive therapy

\* A subdivision may be used **in addition to** the Category 4 final assessment; MQSA does **not** allow a subdivision to replace a Category 4 final assessment. Use of subdivision is at the discretion of the facility it is not required by the FDA.

**Q. Where can I find information about BI-RADS®?**

A. Information about [BI-RADS®](#) is located on the ACR's [website](#) or you can call the ACR at (800) 227-6440.

**Q. Where can I find information on how to purchase the BI-RADS® Atlas?**

A. You can find information on ordering the complete atlas by clicking on [BI-RADS®](#) at the [ACR Store web page](#) or calling Publication Sales at (800) 227-7762. Information on BI-RADS® and other ACR publications is available at this link to the [Materials & Publications Catalog](#).

**Q. How should I reference the ACR BI-RADS® Atlas in a publication I'm preparing?**

A. Please use the following citation in your references:

D'Orsi CJ, Bassett LW, Berg WA, et al: Breast Imaging Reporting and Data System: ACR BI-RADS-Mammography (ed 4), Reston, VA, American College of Radiology, 2003

**Q. What is BI-RADS® Category 6 (Known Biopsy-Proven Malignancy), and when would a facility use it?**

A. BI-RADS® Category 6 has been added for breast findings confirmed to be malignant by biopsy but prior to definitive therapies such as surgical excision, radiation therapy, chemotherapy or mastectomy. This category is also appropriate for second opinions on findings previously biopsied and shown to be malignant or for the monitoring of response to neoadjuvant chemotherapy prior to surgical excision. Unlike BI-RADS® categories 4 and 5, there is no associated intervention required to confirm malignancy.

However, if an exam is performed prior to therapy on a woman with known breast cancer and something other than the original malignancy is seen, the interpreting physician should provide an appropriate final assessment (e.g., Categories 0, 4, and 5) instead of Category 6 so that immediate action can occur.

A major rationale for adding Category 6 is that examinations meriting this assessment should be **excluded from auditing**. Auditing that includes such examinations would inappropriately indicate inflated cancer detection rates, positive predictive values, and other outcomes parameters. More information on Category 6 is available on the [BI-RADS®](#) page on the ACR website.

**Q. Does the ACR have a position on putting universal disclaimers on mammography reports, such as: "X percent of cancers are not detected by mammography." or "Dense breast tissue limits the sensitivity of mammography."?**

A. Page 4 of the introduction to the 2003 ACR BI-RADS® Atlas states: "...universal disclaimers are not necessary since it is well established that a negative mammogram cannot exclude cancer and a clinically suspicious area should be biopsied even if the mammogram is negative." However, it is appropriate to include a statement regarding extremely dense breast tissue. The chapter on Report Organization (p. 179-180) states: "For consistency, breast composition should be described for all patients using the following patterns:

1. The breast is almost entirely fat (<25% glandular)
2. There are scattered fibroglandular densities (approximately 25-50% glandular)
3. The breast tissue is heterogeneously dense, which could obscure detection of small masses (approximately 51-75% glandular)
4. The breast tissue is extremely dense. This may lower the sensitivity of mammography (>75% glandular)."

## BI-RADS<sup>®</sup>, ACR Accreditation & MQSA

### Q. Where can I find information about the ACR's Breast Imaging Accreditation Programs?

A. Information about the ACR's Breast Imaging Accreditation Programs is located on the websites for the [Mammography Accreditation Program](#), the [Breast Ultrasound Accreditation Program](#), and the [Stereotactic Breast Biopsy Accreditation Program](#).

### Q. Where can I go for assistance or clarification of the mammography final assessment categories required by the Mammography Quality Standards Act (MQSA)?

A. The best source of clarification or assistance regarding the MQSA final assessment categories is the FDA. For policy questions, you should check the [FDA's Policy Guidance Help System](#) first. You may also call the FDA Facility Hotline at (800) 838-7715, fax a question(s) to them at (410) 290-6351 or email them at [MQSAhotline@hcmsllc.com](mailto:MQSAhotline@hcmsllc.com).

### Q. Under MQSA, is it necessary to include an assessment code (i.e., 0, 1, 2, 3, 4, 5, or 6) in addition to the assessment category on all mammography reports?

A. No. The FDA regulations only require that each mammographic report include the text corresponding to the overall final assessment category, not the numeric code. These categories are "Negative", "Benign", "Probably Benign", "Suspicious", "Highly Suggestive of Malignancy", and "Incomplete: Need Additional Imaging Evaluation." More recently, the FDA has also approved alternative standards to allow several other final assessment categories: "Known Biopsy Proven Malignancy" and "Post Procedure Mammograms for Marker Placement." The FDA requires that the final assessments be written verbatim as described in their regulations, using phrasing as detailed in the table below. Although the ACR encourages the use of numeric codes along with the final assessment text, there are no requirements that they be assigned to these assessments. For more information, see the [FDA's Policy Guidance Help System](#).

MQSA Final Assessment Category	BI-RADS <sup>®</sup> Category	FDA-Approved Final Assessment Descriptions
Incomplete: Need Additional Imaging Evaluation	0	<ul style="list-style-type: none"> <li>• Incomplete: Need Additional Imaging Evaluation</li> <li>• Incomplete: Needs Additional Imaging Evaluation</li> <li>• Incomplete: Additional Imaging Evaluation Needed</li> <li>• Incomplete: Need Additional Imaging Evaluation - Comparison with Prior Studies</li> <li>• Incomplete: Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison</li> <li>• Incomplete: Need Prior Mammograms for Comparison</li> <li>• Need Additional Imaging Evaluation (<i>the term "Incomplete" can be inferred in this example as this is the only Incomplete BI-RADS<sup>®</sup> assessment category</i>)</li> <li>• Incomplete Mammogram: Need Additional Imaging Evaluation</li> </ul>
Negative	1	<ul style="list-style-type: none"> <li>• Negative</li> <li>• Negative Mammogram</li> </ul>

<b>MQSA Final Assessment Category</b>	<b>BI-RADS® Category</b>	<b>FDA-Approved Final Assessment Descriptions</b>
Benign	2	<ul style="list-style-type: none"> <li>• Benign</li> <li>• Benign Finding</li> <li>• Benign Findings</li> <li>• Benign Abnormality</li> <li>• Benign Abnormalities</li> <li>• Benign Mammogram</li> </ul>
Probably Benign	3	<ul style="list-style-type: none"> <li>• Probably Benign</li> <li>• Probably Benign Finding</li> <li>• Probably Benign Findings</li> <li>• Probably Benign Abnormality</li> <li>• Probably Benign Abnormalities</li> <li>• Probably Benign - Short Interval Follow-up Suggested</li> <li>• Probably Benign Finding - Short Interval Follow-up Suggested</li> <li>• Probably Benign Mammogram</li> </ul>
Suspicious	4	<ul style="list-style-type: none"> <li>• Suspicious</li> <li>• Suspicious Finding</li> <li>• Suspicious Findings</li> <li>• Suspicious Abnormality</li> <li>• Suspicious Abnormalities</li> <li>• Suspicious for Malignancy</li> <li>• Suspicious of Malignancy</li> <li>• Suspicious Abnormality - Biopsy Should Be Considered</li> <li>• Suspicious Finding - Biopsy Should Be Considered</li> <li>• Suspicious Mammogram</li> </ul>
Highly Suggestive of Malignancy	5	<ul style="list-style-type: none"> <li>• Highly Suggestive of Malignancy</li> <li>• Highly Suggestive for Malignancy</li> <li>• Highly Suggestive of Malignancy - Appropriate Action Should Be Taken</li> </ul>
Known Biopsy Proven Malignancy	6	<ul style="list-style-type: none"> <li>• Known Biopsy Proven Malignancy</li> <li>• Known Biopsy Proven Cancer</li> <li>• Known Malignancy</li> <li>• Known Cancer</li> </ul>
Post Procedure Mammograms for Marker Placement	none	<ul style="list-style-type: none"> <li>• Post Procedure Mammograms for Marker Placement</li> </ul>

(This question and answer was adapted from the [FDA's Policy Guidance Help System](#).)

**Q. Is there a new BI-RADS® code for “Post Procedure Mammograms for Marker Placement?”**

A. No, there is no BI-RADS® code for the FDA-approved alternative standard for “Post Procedure Mammograms for Marker Placement.” This is not a BI-RADS® final assessment. This assessment category may only be used for post-procedure mammograms obtained for the purpose of confirming the deployment and position of breast tissue markers, which typically have been placed at the time of core biopsy. In addition, this assessment should be excluded from auditing. For more information, see the [FDA's Policy Guidance Help System](#).

**Q. Does the ACR have sample lay letters for the FDA-approved “Post Procedure Mammograms for Marker Placement” final assessment?**

A. No. Because “Post Procedure Mammograms for Marker Placement” is not a formal BI-RADS® final assessment, the ACR has not developed sample lay letters for these situations. Facilities using this assessment will need to develop their own lay letters for these patients.

**Q. The MQSA regulations require a facility to provide mammography reports to referring healthcare providers and lay summaries to its patients within 30 days of the date of the exam. The regulations also require that if the final assessment is “Suspicious” or “Highly Suggestive of Malignancy”, the facility should provide the mammography report and lay summary as soon as possible (ASAP). The FDA guidance interprets ASAP as within 3 days for the report to the healthcare provider and within 5 days for the lay letter to the patient. Is this guidance timeframe within 3 and 5 days of the patient’s mammography exam?**

A. No. This is within 3 and 5 days of the *report date*, as long as it is no longer than 30 days from the date of the exam.

## Mammography

**Q. We know that we must send our patients the results of their mammograms in writing. Does the ACR have examples of letters for this purpose?**

A. Yes, the ACR has samples of lay letters for all of the BI-RADS® final assessment categories at the following link: [Mammography Sample Lay Report Letters](#).

**Q. Our patient has a palpable abnormality but the mammogram is “Negative.” Should we code the mammogram as a BI-RADS® Category 1 or 0?**

A. Page 254 of the BI-RADS® Atlas recommends that, in general, reports be coded with final assessments based on the imaging findings. Hence, a negative mammogram (no findings to report) should be assessed as negative (Category 1). However, when patient management is influenced by clinical findings, the *management recommendation should take both imaging and clinical findings into consideration and the clinical findings may be detailed in the report*. For example, it would be acceptable to render a negative (Category 1) assessment but describe the presence and nature of a palpable abnormality, with recommendations for annual screening mammography and management of the palpable abnormality based on findings at clinical breast examination.

**Q. Does BI-RADS® Category 0 (Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison) have a subcategory that addresses technical errors on mammograms (e.g., motion, artifacts, insufficient tissue, etc.) to indicate that the mammogram needs repeating (i.e., “technical recall”)?**

A. No, there is no official subcategory for technical errors in BI-RADS® Category 0. You may create your own subcategory for internal analysis purposes. For example, you may want to create a subcategory of “0-TR” for technical recalls and include the technical reasons for the recall in the body of the report. Keep in mind that the FDA regulations require you to assign **only the FDA-approved categories as final assessments**. However, if you provide a subcategory for technical recalls within the overall assessment category of “0,” the technical recalls should not be counted in the medical audit of category “0”s.

**Q. A patient has a diagnostic mammogram with a final assessment of Category 4. The patient then has two biopsies of the same lesion, one core and one surgical. The core biopsy pathology is ADH; the excisional biopsy pathology is malignant. Should the diagnostic**

**mammogram be statistically categorized as both a FALSE POSITIVE and a TRUE POSITIVE, or just a TRUE POSITIVE?**

A. If the exam was a positive and cancer was discovered within the year, it is considered a **true positive** exam. The truth is determined by the discovery of malignancy by any means, **within 365 days** from the exam date.

**Q. We commonly issue addenda and/or comparison reports after initial mammography reports have been issued. Are we required to provide a final assessment category with each of these reports? Must we also send the addendum or comparison report to the referring health care provider and a letter to the patient, even if there is no change in the final assessment category or recommended course of action?**

A. Yes, to both questions. The report issued after additional x-ray testing that is covered under MQSA (i.e., coned, repeat, magnification views) or following comparison with old images must provide a final assessment category for the case. A report **must** be communicated to the referring health care provider or the self-referred patient. In addition, a lay summary of the addendum or comparison report **must** be provided to the patient, even if there is no change in the final assessment category or recommended course of action.

For the specific case where there is no significant change in the report, a simple statement that the comparison has been performed and that there is no overall change (ensuring to include the unchanged final assessment) would satisfy the requirement. If the addendum states that the referring health care provider has been notified of the results of the patient's examination, the addendum lay summary can be a simple statement informing the patient of that fact. *(This question and answer was adapted from the [FDA's Policy Guidance Help System](#).)*

**Q. We wish to use the ACR's Category 4 subdivisions (4A – Finding needing intervention with a low suspicion for malignancy, 4B – Lesions with an intermediate suspicion of malignancy, and 4C – Findings of moderate concern, but not classic for malignancy). Can our reports use these subcategories instead of the Category 4 assessment (Suspicious Abnormality – Biopsy Should Be Considered)?**

A. No. While you have the option of using one of the 3 subcategories **in addition to** a final assessment of "Suspicious", the FDA will **not** allow you to use the subcategories instead of the "Suspicious" assessment category on the mammography report. *(This question and answer was adapted from the [FDA's Policy Guidance Help System](#).)*

**Q. Do mammograms performed on men require a BI-RADS® final assessment and/or code?**

A. Yes, all mammography examinations, regardless of the patient's gender, are required to have a final assessment assigned to them. However, management recommendations may differ from those made for women because annual screening mammography is not usually appropriate for men.

## Ultrasound

**Q. Does MQSA require that BI-RADS® categories be assigned to breast ultrasound examinations?**

A. No, MQSA does not apply to breast ultrasound; however, the ACR does recommend using [BI-RADS®](#) final assessment codes for breast ultrasound examinations. See "Multiple Procedures" section below for discussion on issuing a combined report with mammography.

## MRI

**Q. Does MQSA require that BI-RADS® categories be assigned to MR examinations?**

A. No, MQSA does not apply to MRI; however, the ACR does recommend using [BI-RADS®](#) final assessment codes for MR examinations.

**Q. A patient's breast MRI exam resulted in a BI-RADS® Category 2 assessment (Benign Finding(s)); her mammography exam resulted in a BI-RADS® Category 4 assessment (Suspicious Abnormality – Biopsy Should Be Considered). The patient has a previous history of malignancy following lumpectomy, and her physician believes that the area needs biopsy. In cases where the mammography report disagrees with the breast MRI exam, is it appropriate to recommend a biopsy in the impression of the breast MRI report based on the positive mammogram?**

A. Yes, you may include a recommendation for biopsy in your breast MRI report. If your report system has a combined module that includes all three lexicons (mammography, ultrasound, and breast MRI), appropriate letters will be sent to clinicians and patients based on the most serious BI-RADS® category (in this case "4"). Also, as a general rule, imaging studies should not be used to contradict a biopsy from another breast imaging study.

## Multiple Procedures

**Q. Does MQSA require an "Overall Assessment" for multiple procedures?**

A. No, an overall assessment summarizing multiple procedures is not required under MQSA. You may visit the [FDA's Policy Guidance Help System's](#) section on "Medical Records and Reports/Contents of Records and Reports" for more information.

**Q. If we perform a "non-mammographic" breast imaging study on the same day as the mammographic examination, are we required to issue a separate mammography report with its own final assessment category and recommendations? Or, may we issue a combined report whose final assessment category and recommendations represent the overall assessment of all the breast imaging studies that were performed that day?**

A. The facility has the option of issuing either separate or combined reports. (You may want to check with your billing office first; some third party payers may require individual reports.)

Ideally, the report of diagnostic mammographic views and ultrasound should be included in the same report (with separate paragraphs detailing each) and one integrated final assessment that takes into consideration all breast imaging findings. (This is allowable under MQSA; see [FDA's Policy Guidance Help System](#) for more information.) If a single final assessment is issued, it should be based on the interpreting physician's review of all studies. The hierarchy of the BI-RADS® categories is as follows: 5, 4, 0, 3, 2, 1. The [BI-RADS®](#) Atlas provides several examples of such combined reports (see page 221 "Illustrated Case #4" in the Mammography section, and page 11 in the "Illustrated Cases-Combined" section).

**Q. Under Centers for Medicare and Medicaid Services (CMS) guidelines, we can now charge for screening and diagnostic exams done on the same patient on the same day. May we combine the two exams into one report or must we issue two separate reports?**

A. The FDA allows the facility to have the option of issuing either separate or combined reports. If two reports are issued, each must contain its own overall final assessment. The facility can report both exams on the "same piece of paper." If the facility decides to issue a single combined report, the facility needs to be aware of the following:

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1. A single combined report must contain a single overall final assessment.
2. The combined report should make it clear to the referring physician that it is combining the results of the screening and diagnostic studies. This is also important if questions ever arise about whether the exams were billed correctly.
3. Issuing a single report with a single final assessment will skew the facility's medical audit results unless the exam is audited as both screening category 0 and diagnostic using the final assessment category rendered.
4. Though some computerized reporting systems may consider this a single exam (rather than two), FDA would still allow facilities to count both exams toward meeting the continuing experience requirement.

However, the ACR strongly recommends that a final assessment be given for **each procedure** if a single report with a single overall final assessment is issued for multiple procedures.

(This question and answer was adapted from the [FDA's Policy Guidance Help System](#).)

**Q. If the final assessment of a mammography exam is "incomplete" (BI-RADS® Category 0) and the woman is referred for additional testing, does MQSA require the facility to revise or amend the original report if, as a result of this referral, the assessment is changed to one of the other categories?**

A. No. Furthermore, it is critical that the "incomplete" (BI-RADS® Category 0) assessment is not changed in order to accurately perform the medical audit. However, if the other test uses x-rays and is covered under MQSA (e.g., mammographic coned or magnification views), the facility performing these views **must** issue a report (either separately or as an addendum to the original mammography report) reflecting the final assessment.

The ACR BI-RADS® Atlas provides further recommendations on this topic: "An incomplete assessment requires further evaluation with additional mammographic views, comparison films, ultrasound or, less commonly, MRI. When additional imaging studies are completed, a final assessment is rendered. **Ideally**, the report of diagnostic mammographic views and ultrasound will be included in the **same report**, with separate paragraphs detailing each, and **one integrated final assessment** that takes into consideration all breast imaging findings."

**Q. An original screening mammogram received a BI-RADS® Category 0 assessment (Need Additional Imaging Evaluation and/or Prior Mammograms for Comparison) due to an abnormal asymmetry. The subsequent diagnostic mammogram was also BI-RADS® Category 0. An ultrasound exam was performed and received a BI-RADS® Category 1 (Negative) assessment. Even though the ultrasound was negative, I want to further evaluate this patient with MRI since the mammogram was of concern. If I issue a combined final assessment for all of the procedures, how should I determine the appropriate BI-RADS® code to use to ensure proper care?**

A. This question implies two non-recommended uses of BI-RADS® Category 0.

First, BI-RADS® Category 0 should generally **not be used for diagnostic mammograms**; typically, it should be used only for screening mammograms. Therefore, if diagnostic mammography is performed in conjunction with ultrasound, an **overall BI-RADS® assessment should be given** (based on the final assessments of each exam). The overall final assessment would depend on the mammographic and sonographic imaging findings and whether these are described in the diagnostic breast imaging report. See examples:

- If no findings are described in either the mammography or ultrasound portions of the report, BI-RADS® Category 1 (Negative) is the appropriate overall final assessment.

- If specific benign findings are described in either the mammography or ultrasound portion of the report, BI-RADS® Category 2 (Benign Finding(s)) is the appropriate overall final assessment.
- If diagnostic mammography depicts a focal asymmetry with no associated mass, calcifications, or architectural distortion; if there is no sonographic or palpable correlate to the mammographic finding; and if there are no previous mammograms available for comparison, it may be appropriate to render a BI-RADS® Category 3 (Probably Benign Finding – Initial Short-Interval Follow-Up Suggested) overall final assessment.
- If diagnostic mammography indicates the presence of a suspicious abnormality despite absence of a sonographic correlate, BI-RADS® Category 4 (Suspicious Abnormality – Biopsy Should Be Considered) is the appropriate overall final assessment.

Second, BI-RADS® Category 0 should ***not be routinely used for diagnostic breast imaging findings that warrant further evaluation with MRI***. Rather, the radiologist should issue a BI-RADS® ***final*** assessment for the integrated mammography and ultrasound report ***before*** the MRI is performed. If further evaluation with MRI is warranted, the radiologist should incorporate this recommendation into the patient management recommendations within the impression of the integrated mammography and ultrasound report. This provides the following advantages:

- If the recommended MRI examination is not performed, the overall diagnostic breast imaging report will stand as issued.
- On the other hand, if MRI is performed as recommended, it would not be necessary to re-interpret the mammogram and ultrasound. A negative or benign MRI assessment will sustain a similar assessment made for mammography and ultrasound. If the MRI exam shows more abnormal findings than those identified by mammography and ultrasound, the MRI assessment would supersede that made for mammography and ultrasound.

Also note that breast MRI is ***not*** appropriate follow-up in many situations including:

- In lieu of biopsy of a suspicious finding on mammography and/or ultrasound
- As an alternative to short interval follow-up of probably benign findings on mammography and/or ultrasound
- In lieu of biopsy of a suspicious finding on mammography and/or ultrasound (i.e., suspicious calcifications)
- To further evaluate findings which should be recognized as benign on mammography and/or ultrasound, such as gynecomastia or multiple bilateral partially circumscribed, partially obscured masses; most lymph nodes and fat necrosis can be so recognized mammographically and/or sonographically

MRI is rarely helpful in further evaluations of possible distortion which is too vague to target for stereotactic or sonographic biopsy.

**Q. Axillary adenopathy is seen on screening mammography with no suspicious findings in the breasts. What should the BI-RADS® final assessment be?**

A. In the absence of known infectious or inflammatory cause, isolated ***unilateral axillary adenopathy*** should receive a BI-RADS® Category 4 assessment (Suspicious Abnormality – Biopsy Should Be Considered). Unilateral axillary adenopathy suggests occult breast carcinoma or, much less commonly, metastatic melanoma, ovarian cancer, or other metastatic cancer. Consequently:

- A careful search of the ipsilateral breast images is warranted
- Bilateral axillary ultrasound should be performed first to help confirm that the finding is asymmetric/unilateral

- Clinical evaluation for infection or inflammation in the ipsilateral breast, axilla, arm, and hand is recommended at the time of ultrasound, as mastitis, breast abscess, an infected skin lesion, and cat scratch fever are all potential sources of benign unilateral axillary adenopathy

If no known infectious or inflammatory sources are present, a BI-RADS® Category 4 assessment (Suspicious Abnormality – Biopsy Should Be Considered) is appropriate, with intent to biopsy after further evaluation and review of clinical history. It is then appropriate to proceed with ultrasound-guided fine needle aspiration biopsy (FNAB) or core biopsy, and it may be advisable to perform ipsilateral whole breast ultrasound during that visit to search for an occult primary breast carcinoma.

If a benign cause can be elucidated, BI-RADS® Category 2 (Benign Finding(s)) is a reasonable assessment.

**Bilateral axillary adenopathy** should be assessed as BI-RADS® Category 2 (Benign Finding(s)) in some situations and as BI-RADS® Category 4 (Suspicious Abnormality – Biopsy Should Be Considered) in others.

- Bilateral axillary adenopathy is frequently reactive/infectious in origin such as with inflammatory conditions (sarcoid, systemic lupus erythematosus, psoriasis, other) and HIV. In such situations, the finding is BI-RADS® Category 2 (Benign Finding(s)).
- Patients with known lymphoma may also have bilateral axillary adenopathy. In this situation, the BI-RADS® assessment should be based on the breasts themselves, but should indicate known lymphoma (e.g., “BI-RADS® Category 2 (Benign Finding(s)) with known lymphoma”). It may be helpful to contact the referring healthcare provider to clarify whether or not there is such a history before issuing a final report.

If there is no known explanation for the bilateral adenopathy, and particularly if it is new, then it may be a sign of lymphoma and a BI-RADS® Category 4 assessment (Suspicious Abnormality – Biopsy Should Be Considered) rendered with a recommendation for ultrasound-guided FNAB or core biopsy. [Note: Ideally the specimen should be kept in saline or RPMI 1640 if lymphoma is suspected, to facilitate fluorescence-activated cell sorting.].

## Medical Audits

**Q. Does the ACR have information regarding physician mammography outcome analysis software?**

A. Yes, the ACR has a list of licensed vendors on our website at [BI-RADS® Software Vendors List](#). All have medical audit software.

**Q. Are there more recent benchmarks, than those provided in the 2003 ACR BI-RADS® Atlas, for auditing my mammography practice?**

A. Yes. Audit results from actual practice of the Breast Cancer Surveillance Consortium (BCSC) participants were published in 2006. This study included results from 807 radiologists at 187 facilities and over 2.5 million screening mammographic examinations (1). Results have also been analyzed from the diagnostic mammography practice in this consortium for 646 radiologists at 151 facilities and over 332,000 examinations (2). In general, the audit is designed for screening, though some practices audit their overall practice, including diagnostic examinations. If a facility’s audit includes both screening and diagnostic mammograms, expected outcomes will vary depending on the percent of exams which are diagnostic. Suggested outcomes from combined studies can be found in Sohlich et al (3).

The table below summarizes the BCSC results for pure screening, exams recalled from screening (BI-RADS® Category 0) for additional evaluation, and pure diagnostic examinations for patients with a palpable lump. The following definitions are used:

- Stage 0 Cancers – ductal carcinoma in situ (DCIS)
- Stage I Cancers – invasive cancer ≤ 2 cm in size and negative nodes
- Minimal Cancers – includes DCIS and invasive cancer ≤ 1 cm in size
- Cancer Detection Rate – # of women with examinations called positive (BI-RADS® Categories 0, 4, or 5 on screening; BI-RADS® Categories 4 or 5 on diagnostic workup) who are diagnosed with cancer, divided by the total number of examinations] times 1000
- Recall Rate – # of positive examinations on screening (BI-RADS® Categories 0, 4, and 5) divided by the total number of examinations.
- Sensitivity – percentage of women called positive (BI-RADS® Categories 0, 4, or 5 on screening; BI-RADS® Categories 4 or 5 on diagnostic workup) who are diagnosed with cancer within one year of screening
- PPV2 – percentage of women with examinations recommending biopsy (BI-RADS® Categories 4 or 5) which have a tissue diagnosis of cancer within one year

	<b>Screening</b>	<b>Screening Recalls</b>	<b>Diagnostic (Lump)</b>
Stage 0 or I Cancers	76 %	83 %	40 %
Minimal Cancer	52 %	63 %	16 %
Positive Axillary Node(s)	19 %	16 %	33 %
Cancer Detection Rate	4.4	3.1	47
Recall Rate	9.7 %	N/A	N/A
Sensitivity	80 %	86 %	84 %
Mean Invasive size (cm)	1.3	1.1	2.1
PPV2	25 %	23 %	48 %

The following should be considered when auditing one's practice:

- A clinically useful audit includes calculation of several rather than only one or two metrics, the more the better.
- For low-volume practices, and especially for individual radiologists who work in low-volume practices, some metrics will lack precision because the number of cancers is small. The workaround is to audit for the most recent two or three years rather than just the most recent year.
- Most practices will not be able to acquire sufficiently accurate data on false-negative cases to accurately calculate sensitivity. Linkage with a regional tumor registry or a captive non-mobile patient population (such as found in a large HMO) is necessary to obtain such information.
- Practices which use integrated BI-RADS® assessments for concurrently-performed diagnostic mammography/ultrasound examinations should expect different outcomes from published benchmarks. The above published data involves the performance of mammography alone.

Current National Cancer Institute Breast Cancer Surveillance Consortium Performance Benchmarks for Screening and Diagnostic Mammography are available at:

(<http://breastscreening.cancer.gov/data/benchmarks/screening/>) and  
(<http://breastscreening.cancer.gov/data/benchmarks/diagnostic.html>).

References:

1. [Rosenberg RD, et al., Performance benchmarks for screening mammography, Radiology 2006; 241:55-66.](#)
2. [EA Sickles, et al., Performance benchmarks for diagnostic mammography, Radiology 2005; 235:775-790.](#)
3. [Sohlich RE, Sickles EA, Burnside ES, Dee KE. Interpreting data from audits when screening and diagnostic mammography outcomes are combined. AJR Am J Roentgenol 2002; 178:681-686.](#)

**Q. Is it necessary for a facility to separate the medical audit into screening and diagnostic patients?**

A. No. Although a facility will obtain more statistically relevant information by separating their analyses for screening and diagnostic examinations, FDA regulations allow the facility to combine all patients into one group of audit data. The ACR strongly recommends that screening and diagnostic examinations be audited separately.

**Q. Does MQSA require follow up of Category 0 patients?**

A. Not at this time. FDA regulations specify that facilities must “collect and review outcome data for all mammograms performed, including follow up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician.” The FDA considers mammograms with final assessments of “Suspicious” or “Highly suggestive of malignancy” to be positive. Therefore, the FDA does not require facilities to follow-up other cases such as those recommended for short-term follow up or ultrasound, or cases that are in the assessment category of “Incomplete, Need additional imaging evaluation.” (For more information, see the [FDA's Policy Guidance Help System.](#))

However, the ACR believes that a meaningful audit of **screening** examinations requires that the recommendations for recall imaging (BI-RADS® Category 0) also be considered “positive” and thus recommends that the facility collect and review outcome data on Category 0 exams.

**Q. When doing medical audits, are pathology-proven “high risk lesions” described on page 300 in the BI-RADS® Atlas (i.e., Atypical ductal hyperplasia, Atypical lobular hyperplasia, Lobular carcinoma in-situ, Peripheral duct papillomas, and Phylloides tumor) considered positive?**

A. No, these are considered **negative** pathology results.

**Q. We always do a post-procedure mammogram after an ultrasound-guided biopsy. We bill for the mammogram separately from the biopsy procedure and use the FDA’s final assessment of “Post Procedure Mammograms for Marker Placement.” However, because this final assessment is not included in the current ACR BI-RADS® Atlas, our software vendors have not provided this option in their medical audit software. Consequently, we cannot include these studies in our annual medical audit. Do you have any suggestions how we can include these cases?**

A. Some facilities consider the post-clip mammogram as part of the ultrasound interventional procedure and consequently will not bill for it or code it. Other facilities that choose to code it (and bill for it) separately wait for the result of the biopsy and then code the mammogram accordingly. For example, if the pathology was benign, they would code the mammogram as a Category 2; if the pathology was malignant, they would code the mammogram as a Category 6. In either case, it is not appropriate to include these outcomes in your medical audit because the purpose of the examination

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is only to assess for successful treatment (proper clip placement) rather than to assess for presence or absence of malignancy.

## Implants

**Q. A patient with implants has a mammography examination which is interpreted as BI-RADS® Category 2 (Benign Finding(s)). However, there is an implant rupture. Should this be considered a BI-RADS® 3 (Probably Benign Finding – Initial Short-Interval Follow-Up Suggested) because of the rupture? Should the lay letter to the patient inform her of the ruptured implant?**

A. No to the first question. Since “implant rupture” is a benign finding, the mammogram should receive a BI-RADS® Category 2 (Benign Finding(s)) final assessment. However, the recommendations usually associated with this assessment would **not** be correct in this situation. We suggest including something other than “routine follow-up” in the body of your report. This should not be a problem since no patient follow-up recommendations are part of this assessment category as they are with the malignancy categories (i.e., Categories 4 and 5). Yes, you should also clarify the follow-up for the patient in her lay letter. This issue is currently under consideration by the ACR BI-RADS® committee.

## Miscellaneous

**Q. Are there BI-RADS® assessments and recommendations available for breast PET scans and breast-specific gamma imaging (BSGI) exams? Are there plans to include these in the BI-RADS® Lexicon in the future?**

A. No, because these procedures are so new, the ACR currently does not have assessments and recommendations for breast PET scans and BSGI exams. The ACR will update the BI-RADS® Atlas with new modalities as they become more established and widely available. However, the language for mammography, ultrasound and MRI assessment categories may be used for such exams as long as recommendations for patient management are clearly stated in the reports.

**Q. We performed a stereotactic core biopsy that demonstrated a small focus of atypical lobular hyperplasia (ALH). As part of this procedure, we performed a post-clip placement mammogram. Should we code the mammogram as a BI-RADS® 6 (Known Biopsy-Proven Malignancy) or a BI-RADS® 4 (Suspicious Abnormality) since we may be recommending a surgical excisional biopsy of the stereotactic biopsy site? Do we need to send the patient the results of this mammogram?**

A. No to both questions. Since this mammogram is part of the interventional procedure, it is not required to have a final assessment category. For the same reason, a patient lay letter is not required. By the way, the diagnosis of ALH is considered benign (negative) rather than malignant (positive).