D. FREQUENTLY ASKEDQUESTIONS

(*Indicates an update on September 10, 2024**)***

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

   No. FDA regulations require only that each mammography report include the text corresponding to the overall assessment category, not the numeric code. These categories are "Incomplete: Need Additional Imaging Evaluation," Incomplete: Need Prior Mammograms for Comparison," "Negative," "Benign," "Probably Benign," "Suspicious," "Highly Suggestive of Malignancy," "Known Biopsy-Proven Cancer," and "Post Procedure Mammograms for Marker Placement." The FDA requires that the assessment category be written verbatim as described in their regulations. However, it has generally exercised enforcement discretion when similar terminology that does not change the intended meaning is used. It has signaled that it will continue to allow equivalent wording as outlined in Table 8 below. Use of any wording not specifically listed in the table would be in violation of FDA regulations.

   Recent amendments to the MQSA regulations, which took effect on Sept. 10, 2024, resulted in the creation of two new assessment categories under Category 0 (replacing the previous combined descriptive verbiage of "Category 0: Incomplete — Need Additional Imaging Evaluation and/or Prior Imaging for Comparison"). As described above, the two new categories are: Category 0-Incomplete: Need Additional Imaging Evaluation, used to indicate that the examination is incompletely evaluated, and the recommendation is for additional imaging evaluation (i.e., supplementary mammographic views and/or US); and Category 0-Incomplete: Need Prior Mammograms for Comparison, to be used if retrieval of previous examinations for comparison is indicated before a final assessment can be rendered.

   The 2023 Amendments to the MQSA Regulations additionally codified another assessment category (which had already been in common clinical use): "Post-Procedure Mammogram for Marker Placement." This assessment was derived from the prior 2003 alternate standard and is to be used on mammograms whose specific purpose is to delineate the presence of a tissue marker, exempting it from requirements for auditing, as with the "Known Biopsy-Proven Malignancy" category. An accompanying numerical code has not been assigned by ACR to this assessment category.

   Note that while the addition of an alphanumeric code is not prohibited by MQSA, it may not be used as the sole method to indicate the final assessment category. The above outlined language must be included in mammogram reports.

***Table 8. FDA-Approved Equivalent Wording for BI-RADS® Assessment Categories**

BI-RADS® Assessment Category	BI-RADS® Numeric Code	FDA–Approved Equivalent Wording
Incomplete: Need Additional Imaging Evaluation or Incomplete: Need Prior Mammograms for Comparison	0 0	➢ Incomplete: Needs Additional Imaging Evaluation ➢ Incomplete: Additional Imaging Evaluation Needed ➢ Need Additional Imaging Evaluation (the term "Incomplete" can be inferred in this example) ➢ Incomplete Mammogram: Need Additional Imaging Evaluation ➢ Incomplete: Needs Prior Mammograms for Comparison ➢ Incomplete: Comparison with Prior Mammograms Needed ➢ Need Prior Mammograms for Comparison (the term "Incomplete" can be inferred in this example) ➢ Incomplete Mammogram: Need Prior Mammogram for Comparison
Negative	1	➢ Negative Mammogram
Benign	2	➢ Benign Finding ➢ Benign Findings ➢ Benign Abnormality ➢ Benign Abnormalities ➢ Benign Mammogram
Probably Benign	3	➢ Probably Benign Finding ➢ Probably Benign Findings ➢ Probably Benign Abnormality ➢ Probably Benign Abnormalities ➢ Probably Benign — Short Interval Follow-up Suggested ➢ Probably Benign Finding — Short Interval Follow-up Suggested ➢ Probably Benign Mammogram
Suspicious	4	➢ Suspicious Finding ➢ Suspicious Findings ➢ Suspicious Abnormality ➢ Suspicious Abnormalities ➢ Suspicious for Malignancy ➢ Suspicious Finding — Biopsy Should Be Considered ➢ Suspicious Abnormality — Biopsy Should Be Considered ➢ Suspicious Mammogram
Highly Suggestive of Malignancy	5	➢ Highly Suggestive for Malignancy ➢ Highly Suggestive of Malignancy — Appropriate Action Should Be Taken
Known Biopsy-Proven Malignancy	6	➢ Known Biopsy-Proven Cancer ➢ Known Malignancy ➢ Known Cancer

2. ***Is there a new numeric code in BI-RADS® for "Post Procedure Mammograms for Marker Placement"?***

   No. There is no numeric code for the FDA-approved assessment category for "Post Procedure Mammogram for Marker Placement." This assessment may be used only for postprocedure 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. Note that there is no FDA-approved equivalent wording for this assessment category other than "Post Procedure Mammogram for Marker Placement."

3. ***In my practice 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?***

   Yes, to both questions. FDA regulations require that the report issued after additional mammography (i.e., repeat, spot-compression, magnification, other additional views) or following comparison with prior mammography examinations 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 in which there is no significant change in a comparison 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, accompanied by a comparison lay summary informing the patient of that fact. For the specific case in which an addendum report is issued that merely states that the referring health care provider has been notified of the results of the patient's examination, then the addendum lay summary may be a simple statement informing the patient of that fact.

4. ***My practice uses the BI-RADS® category 4 subdivisions (4A – low suspicion for malignancy, 4B – moderate suspicion for malignancy, 4C – high suspicion for malignancy). May our reports use these subdivisions as assessment categories instead of the category 4 assessment (suspicious)?***

   No. While you have the option of using one of the three subdivisions of category 4 in addition to a final assessment of Suspicious, the FDA will not allow you to use the subcategories instead of the Suspicious assessment category in the mammography report.

5. ***Do mammography examinations performed on men require a BI-RADS® final assessment and/or numeric code?***

   Yes. All mammography examinations, regardless of the patient's gender, are required to have a final assessment category (not a numeric code) in the mammography report. However, management recommendations may differ from those made for women because annual screening mammography is not usually appropriate for men.

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

   The mammography facility has the option of issuing either separate or combined reports. (You may want to check with your billing office; some third-party payers may require individual reports.) If two reports are issued, each must contain its own overall final assessment. The facility may report both examinations 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:

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

7. ***If the final assessment of a screening mammography examination is "Incomplete" (BI-RADS® category 0) and the woman then undergoes additional imaging evaluation, does the FDA require the mammography facility to revise or amend the original report if, as a result of the additional imaging, the assessment is changed to any of the final assessment categories?***

   First, for auditing purposes, the original screening assessment must remain category 0. However, if the additional imaging includes mammography (and therefore is covered under MQSA), the facility performing these additional mammographic views also ***must*** issue a report (either separately or as an addendum to the original mammography report) that reflects the final assessment. The BI-RADS® Atlas provides further recommendations on this topic. "When more than one type of [diagnostic] examination is performed concurrently (on the same day), it is ***preferable*** that the examinations be reported together, with the findings foreach examination described in a separate paragraph, with separate assessments for each examination followed by ***an overall assessment and management recommendations for the combinedexaminations***.

8. A screening mammography examination received an "Incomplete" (BI-RADS® category 0) assessment due to an asymmetry. The subsequent diagnostic mammography examination is also assessed as BI-RADS® category 0, recommending additional US examination. A US examination then is performed showing no abnormal findings, but I want to further evaluate this patient with MRI, which occasionally depicts a cancer not seen at either mammography or US. Is it appropriate to also assess the US examination as BI-RADS® category 0, recommend additional MRI examination?

This question involves two non-recommended uses of BI-RADS® category 0. First, with few uncommon exceptions, category 0 should not be used for diagnostic mammography examinations. Therefore, if diagnostic mammography is performed concurrently with US, an overall BI-RADS® assessment category should be given (rather than a category 0 assessment for the mammography followed by a final assessment for the US). The overall assessment would depend on the mammographic and sonographic findings and whether these are or are not described in the diagnostic breast imaging report. Refer to the following examples.

- If no findings are described in either the mammography or US portions of a combined re- port, the appropriate overall assessment is negative (BI-RADS® category 1).
- If one or more specific benign findings are described in either the mammography or US portions of a combined report, the appropriate overall assessment is benign (BI-RADS® category 2).
- 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 prior mammography examinations available for comparison, it may be appropriate to render a probably benign (BI-RADS® category 3) assessment.
- If diagnostic mammography indicates the presence of a suspicious abnormality despite absence of a sonographic correlate (or vice versa), the appropriate overall assessment is suspicious (BI-RADS® category 4).

Second, BI-RADS® category 0 ***should not be used for diagnostic breast imaging findings that warrant further evaluation with MRI.*** Rather, the radiologist should issue a final assessment for the combined diagnostic mammography and US examinations in a report that is made ***before*** the MRI is performed. If further evaluation with MRI is warranted, the radiologist should incorporate this recommendation into the patient management recommendations in the combined mammography/US report. This provides the following advantages:

- If the recommended MRI examination is not performed, the combined diagnostic breast imaging report will stand as issued.
- If MRI is performed as recommended, it would not be necessary to re-interpret the mammography and US examinations. A negative or benign MRI assessment would sustain a simi- lar assessment made at diagnostic mammography and US. If the MRI examination shows more abnormal findings than those identified at mammography and US, the MRI assessment would supersede that made for mammography and US.

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

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- Instead of biopsy of a suspicious finding at mammography and/or US.
- As an alternative to short-interval follow-up of probably benign findings at mammography and/or US.
- To further evaluate findings that should be recognized as benign at mammography and/ or US, such as gynecomastia or multiple bilateral, mostly circumscribed masses. Also most lymph nodes and fat necrosis may be characterized as benign at mammography and/or US.

MRI is rarely helpful in further evaluation of possible architectural distortion that is too vague to target for stereotactic or sonographic biopsy.

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

In the absence of a known infectious or inflammatory cause, isolated ***unilateral*** axillary adenopathy should receive a suspicious (BI-RADS® category 4) assessment. Unilateral axillary adenopathy suggests occult breast carcinoma or, much less commonly, lymphoma, metastatic melanoma, ovarian cancer, or other metastatic cancer. Consequently, a careful search of the ipsilateral breast images is warranted. Bilateral axillary US should be performed to 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 US, as mastitis, breast abscess, an infected skin lesion, and cat-scratch fever are all potential sources of benign unilateral axillary adenopathy. If a benign cause is elucidated, a benign (BI-RADS® category 2) assessment would be appropriate. In the absence of a known infectious or inflammatory source, a suspicious (BI-RADS® category 4) assessment would be appropriate, with the intent to biopsy after further evaluation and review of clinical history. It is then appropriate to proceed with US-guided fine-needle aspiration (FNA) or core biopsy of the axillary adenopathy, and it may be advisable to perform ipsilateral whole-breast US at that visit to search for an occult primary breast carcinoma.

Bilateral axillary adenopathy would be assessed as benign (BI-RADS® category 2) in some situations and as suspicious (BI-RADS® category 4) in others. Bilateral axillary adenopathy is frequently reactive/infectious in origin, such as with inflammatory conditions (sarcoidosis, systemic lupus erythematosis, psoriasis, etc.) and HIV. In such situations, the appropriate assessment is benign (BI-RADS® category 2). Patients with known lymphoma or leukemia may also have bilateral axillary adenopathy. In this situation, the BI-RADS® assessment should be based on findings in the breasts themselves, but the report also should indicate the presence of adenopathy and the known underlying disease. For example, a report might indicate a negative or benign assessment, followed by "with bilateral axillary adenopathy presumed due to known lymphoma." It may be helpful to contact the referring health care provider or review the electronic medical record to clarify whether or not there is such a history before issuing a final report. If there is no known explanation for bilateral adenopathy, and particularly if it is new, then it may be a sign of lymphoma/leukemia, and a suspicious (BI-RADS® category 4) assessment is warranted, with a recommendation for US-guided FNA or core biopsy. Note that ideally, biopsy specimens should be kept in saline or RPMI 1640 if lymphoma is suspected, to facilitate fluorescence-activated cell sorting.

10. Are there BI-RADS® assessment categories and management recommendations available for breast PET scans and dedicated breast gamma camera imaging examinations? Are there plans to include these in the BI-RADS® Atlas in the future?

No. Because these breast imaging modalities are so new, the BI-RADS® Atlas does not have assessment categories and management recommendations for breast PET scans and dedicated breast gamma camera imaging examinations at this time. The atlas will be updated with new modalities as they become more established and widely available. In the interim, the same assessment categories for mammography, US and MRI may be used for these and other new-modality examinations, so long as recommendations for patient management are clearly stated in the imaging report.