VI. FREQUENTLY ASKED QUESTIONS CONCERNING BREAST IMAGING AUDITS

A. All Breast Imaging Modalities

1. ***According to the BI-RADS® Atlas, category 0 assessments at screening are considered positive for auditing purposes. Does this apply to examinations for which comparison with prior examination(s) is recommended or to examinations assessed as incomplete due to technical deficiency?***

   As discussed in Section IV, examples #16, #17, and #18 (see pages 45 and 46), when an incomplete (BI-RADS® category 0) screening assessment is rendered with the recommendation to await prior examination(s) for comparison, interpretation of the current examination actually is being deferred until informed by the imaging data provided by the previous examination(s). When such an interpretation ultimately is completed (either when previous examination[s] become available for comparison, or within 30 days if no comparison examination[s] become available), the initial category 0 assessment is ***replaced*** either by a final (category 1–5) assessment or by a category 0 assessment that recommends additional imaging. Hence, category 0 assessments that are made awaiting prior examination(s) for comparison are not included in audits at all (therefore considered neither positive nor negative), because these assessments always are replaced by something else. This same answer also applies to "technical repeat" or "technical recall" examinations. Such examinations, assessed as incomplete (BI-RADS® category 0) due to technical deficiency in image quality, also are not included in audits because they are replaced by examinations of acceptable image quality (for mammography, batch-interpreted screening examinations with poor breast positioning, inadequate breast compression, motion blur, improper exposure, etc.; for breast US, screening examinations with improper setting of focal zone, field-of-view, gray scale gain, etc.; and for breast MRI, examinations with poor breast positioning, inadequate or absent contrast injection, and image artifacts resulting from patient motion, fat-suppression failure, etc.).

2. ***The BI-RADS® Atlas does not indicate whether to consider category 0 assessments at diagnostic imaging as positive or negative for auditing purposes. How should these examinations be audited?***

   It is important to understand that an incomplete (BI-RADS® category 0) assessment should be made only rarely at diagnostic imaging, because such an examination is monitored in real time by the radiologist so that imaging is sufficiently complete to render a final (category 1–5) assessment. However, unusual extenuating circumstances may prevent completion of a diagnostic examination, such as when imaging equipment or technologist personnel are not immediately available, or when the patient is unable or unwilling to wait for completion of a full diagnostic examination. This situation is analogous to the screening examination assessed as incomplete (BI-RADS® category 0) awaiting prior examination(s) for comparison. Interpretation of the current (in this case, diagnostic) examination is deferred until it is completed, at which time the initial category 0 assessment is ***replaced*** by a final (category 1–5) assessment. Hence, category 0 assessments at diagnostic imaging are not included in audits at all (therefore considered neither positive nor negative) because these assessments always are replaced by final assessments.

3. ***When a diagnostic breast imaging examination is completed for a woman who has been recalled after screening examination, should an addendum be made to the screening report changing the assessment from BI-RADS® category 0 to whatever final assessment is made on the basis of the diagnostic imaging examination?***

   No, the assessment at screening has not changed. For purposes of auditing, this screening assessment is considered positive (action before the next routine screening), and the clinical outcome will determine whether this assessment is TP (cancer diagnosis within 1 year of screening) or FP

(no cancer diagnosis within 1 year of screening). If screening assessments were amended to reflect the final assessments made after diagnostic imaging examination, auditing of screening outcomes would not be meaningful.

4. ***Is it necessary for a breast imaging facility to separate the medical audit into screening and diagnostic components?***

   FDA regulations[1] do not require auditing at the level of complexity described in parts of this section, including separate auditing of screening and diagnostic examinations. However, periodic auditing is sound medical practice and the best way for a breast imaging practice and its individual radiologists to determine acceptable clinical performance. The ACR strongly recommends that screening and diagnostic examinations be audited separately because the outcomes of these two types of examination differ significantly.[3,9,13] For practices that are unable to segregate examinations by screening versus diagnostic indication, mathematical models have been developed to provide guidance on how to evaluate combined audit data.[14]

5. ***Published benchmarks for PPV_2 and PPV_3 are similar. Which one is the more accurate indicator of interpretive performance?***

   PPV_2 and PPV_3 are performance measures that relate primarily to diagnostic mammography examination. PPV_2 involves the positive predictive value calculation (percentage of positive examinations that are TP) based on the number of examinations for which tissue diagnosis is recommended, whereas PPV_3 involves the same calculation based on the number of examinations for which tissue diagnosis actually is performed. Because performed biopsies are more likely to yield a cancer diagnosis than biopsies not performed, one would expect the value of PPV_3 to be somewhat higher than that of PPV_2, and this is what is observed in almost all breast imaging audits. PPV_3 is the more accurate indicator of cancer status because biopsy results may be obtained in virtually all cases. Furthermore, the data collected for the PPV_3 calculation are the same as what is required by the FDA regulations[1]. However, the advantage of the PPV_2 calculation is that it relates directly to the performance of the interpreting radiologist (involving all examinations for which tissue diagnosis is recommended), whereas the interpreting radiologist has little if any control in selecting the subset of PPV_2 cases that qualify for the PPV_3 calculation (biopsies actually performed). Therefore, although PPV_3 is the more accurate indicator of cancer status, PPV_2 is the more accurate indicator of interpretive performance.

6. ***Why is it important to use several (rather than just one or two) performance metrics in conducting a breast imaging audit?***

   A breast imaging audit is clinically relevant to the extent that it provides meaningful indicators of interpretive performance. It stands to reason that the more data collected and analyzed, the more comprehensive an understanding one may derive about underlying interpretive performance. Analysis of performance based on a single metric is of little value. For example, what useful information can one deduce from the recall rate alone? One can deduce simply that a given percentage of screened women are recommended for additional imaging evaluation, but nothing about how frequently biopsy is recommended, the likelihood of cancer when biopsy is recommended, the frequency of cancer detection, or whether detected cancers are clinically occult or early in stage (hence favorable in prognosis). A similar, very limited amount of information may be derived from any other single performance metric or pair of metrics. Instead, the data collected in and derived from the basic clinically relevant audit, as described in Table 2 (see page 23) should

provide sufficient insight into the interpretive performance of a breast imaging practice and its individual radiologists. The more complete audit described in Tables 9 and 10 (see pages 35 and 36) should provide an even more comprehensive understanding of performance.

7. ***When doing medical audits, are the pathology-proven high-risk lesions described in the BI-RADS® Atlas (lobular carcinoma in situ, atypical ductal hyperplasia, atypical lobular hyperplasia, peripheral duct papillomas, phyllodes tumor) considered "truth positive" in categorizing examinations as TP or FP?***

   No, these are considered ***negative*** pathology results. Note that some cases of pleomorphic lobular carcinoma in situ (LCIS) may be treated as breast cancer. However, to maintain consistency in auditing, a uniform definition of cancer is required (no exceptions permitted), so this definition does not include the diagnosis of pleomorphic LCIS. ***Nor, by the way, does the definition of cancer include malignant phyllodes tumor, breast sarcoma, metastasis, lymphoma, leukemia, etc. These are malignancies that occur within the breast but are not breast cancer***.

8. ***A patient has a diagnostic examination assessed as suspicious (BI-RADS® category 4) with a management recommendation for tissue diagnosis. Within the next month, she then has a core biopsy showing atypical ductal hyperplasia (ADH), followed 1 week later by an excisional biopsy showing ductal carcinoma in situ and invasive ductal carcinoma. Should the diagnostic examination be classified as both FP (for the ADH) and TP (for the cancer)?***

   In this scenario, the diagnostic examination was interpreted as positive (BI-RADS® category 4 with a management recommendation for tissue diagnosis). Because there is a tissue diagnosis of cancer within the next year, the examination is classified as TP. Note that the examination would still be classified as TP even if there were many biopsies within the next year and only one of them yielded a cancer diagnosis.

B. Mammography

1. ***Isn't it internally inconsistent to consider BI-RADS® category 3 assessments positive at screening but negative at diagnostic imaging?***

   No, this actually is internally consistent. The binary management decision at screening involves recommending action before the next routine screening (positive) versus recommending no action until the next routine screening (negative), whereas the management decision pertinent to diagnostic imaging involves recommending tissue diagnosis (positive) versus anything other than tissue diagnosis (negative). Also remember that, as stated previously, BI-RADS® category 3 assessments are not recommended for use at screening.

2. ***Does MQSA require auditing of BI-RADS® category 0 assessments?***

   No, FDA regulations[1] specify that mammography facilities "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 a final assessment of suspicious (BI-RADS® category 4) or highly suggestive of malignancy (BI-RADS® category 5) to be positive, not category 0 assessments. However, the ACR asserts that a meaningful audit of screening examinations requires that a management recommendation for additional imaging evaluation (BI-RADS® category 0) also be considered positive, and that facilities should collect and review outcome data on category 0 screening examinations.

3. ***We always do a postprocedure mammography examination after an imaging-guided biopsy. We bill for the mammography examination 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 BI-RADS® Atlas, the software vendor for our breast imaging reporting system has not provided this option in their medical audit software. Consequently, we cannot include these examinations in our annual breast imaging audit. Do you have any suggestions for how we can include these examinations?***

   These mammography examinations are performed to assess for successful treatment (proper marker-clip placement) rather than for the presence or absence of malignancy. Therefore, it is not appropriate to include these examinations in the breast imaging audit.

4. ***We have several mobile mammography units, each accredited and certified as a separate facility. FDA regulations require that each facility has a separate mammography medical outcomes audit. May we combine the mammography medical outcomes audits for these facilities and units?***

   Yes, the FDA has approved an alternative standard (http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/Guidance/PolicyGuidanceHelpSystem/ucm135407.htm) allowing mobile unit operators to combine mammography medical outcomes audits under certain conditions. In situations where multiple mobile mammography facilities are under the same ownership, they may be treated collectively as a single facility for the purposes of meeting FDA audit requirements, if all of the following conditions are met.

   Each facility must consist of a single mobile mammography unit.

   - The same entity or group administers the operation of all of the included mobile facilities.
   - The same lead interpreting physician has the responsibility for assuring that all of the included mobile facilities meet FDA requirements.
   - The same group of radiologists interprets all of the images from all of the included mobile facilities.
   - All of the included mobile facilities provide services to the same patient population.

5. ***The following discussion also appears previously as item #12*** (see page 43) ***in Section IV, "Examples of How to Classify Examinations as True-Positive, True-Negative, False-Positive, and False-Negative." It is duplicated here because the topic is specific to mammography, and because questions are frequently asked about how to audit in this clinical scenario.***

   A woman has a mammography screening examination at a facility in which the examination is interpreted before the woman leaves the premises, so that additional imaging can be performed immediately if needed. A noncalcified asymmetry is seen in one breast, only on the craniocaudal view. The interpreting radiologist obtains a second craniocaudal view to clarify the significance of this asymmetry. The examination is then interpreted as negative because the asymmetry (judged to represent a summation artifact) is not visible on the repeat craniocaudal view. No breast cancer is found within 1 year of examination. How should this scenario be classified?

   This single examination in effect represents a positive screening examination (BI-RADS® category 0), for which the woman was recalled for additional diagnostic imaging that resulted in a negative (BI-RADS® category 1) assessment. Thus the screening component of this examination should be classified as false-positive (FP) and the diagnostic component of the examination

should be classified as true-negative (TN). Note that whenever a screening examination is interpreted before a woman leaves the premises, and the examination is converted to a diagnostic examination to clarify a mammographic finding identified on standard screening views, this single examination should be considered to have a positive screening interpretation (BI-RADS® category 0) and also a positive or negative diagnostic interpretation depending on the final assessment that is rendered.

C. Ultrasound (See US page 124.)

1. In most practices, a completed screening breast US examination contains the same images as a full diagnostic US examination. Why are screening breast US examinations audited using an approach similar to that for mammography rather than breast MRI, for which a screening examination is considered to be equivalent to a full diagnostic examination?

As explained in the Introduction to the Follow-up and Outcome Monitoring section, auditing must be based on objective and reproducible rules. Furthermore, auditing for all breast imaging modalities should utilize the same rules to facilitate cross-modality comparisons, except when the unique aspects of a given modality justify a different approach. Auditing procedures for mammography have been established for many years and clinically representative benchmarks using these auditing procedures have been published, so that an individual mammography facility (or individual interpreting physician) may reliably compare observed outcomes with these benchmarks. Only now, with publication of the fifth edition of BI-RADS®, are auditing procedures being established for breast US and breast MRI examinations. And now is the appropriate time to establish these procedures because the use of US and MRI for both screening and diagnostic breast imaging has become widespread. It is not only reasonable but also highly desirable to base the auditing of US and MRI examinations on the procedures used for mammography, whenever practical. In defining positive screening examinations, mammography auditing utilizes the objective and reproducible rule of whether one or more additional images is recorded to further characterize a finding depicted on standard screening images, in so doing, taking into account the scenario of online interpretation. This rule also may be applied to US auditing because, contrary to what is stated in the question, additional (nonstandard) images are recorded to further characterize findings on some but not all screening breast US examinations. Indeed, each breast imaging facility should indicate in its policy and procedure manual what standard images should be recorded for normal (BI-RADS® category 1 or 2) screening examinations. Furthermore, the screening breast US report should indicate whether standard or standard plus additional (diagnostic) images were recorded. This will allow for objective and reproducible auditing, especially if screening breast US reports are created using a computerized reporting system, which would prospectively capture data on whether additional images were recorded, hence permitting auditing of additional-image examinations as screening-positive and diagnostic-positive/negative depending on the final assessment rendered. The mammography auditing rule defining positive screening examinations (whether one or more additional images is recorded to further characterize a finding depicted on standard screening images) does not apply to screening breast MRI examinations because there usually is no difference in the standard images recorded for a screening and diagnostic breast MRI examination; hence, a screening examination is simultaneously a full diagnostic examination. As a result of this difference, the outcome parameters of recall rate and PPV_1 do not apply to the auditing of screening breast MRI examinations, as they do to both screening mammography and screening breast US.

2. I do not understand why BI-RADS® assessment category 3 is not recommended at screening for mammography but there is no mention of this for US. Why this difference in recommendations?

BI-RADS® assessment category 3 is not recommended at screening for mammography because a full diagnostic breast imaging workup should be completed before rendering a category 3 assessment. In most breast imaging practices, mammography screening examinations are interpreted in batches (after women have left the breast imaging center), so there is no opportunity to complete the diagnostic workup before interpreting the screening examination. However, for almost all breast imaging practices, US screening currently is interpreted online, while the woman remains in the breast imaging center. If an abnormal finding is identified at screening (whether on one or more images recorded by the breast sonographer or as seen during real-time scanning by the interpreting physician), additional nonstandard images (perpendicular images of the finding without and with caliper measurements) will be recorded that supplement the screening examination with a simultaneous diagnostic examination. Hence, there would be no purpose in recommending against category 3 assessments at US screening because the diagnostic imaging workup would be completed simultaneously. Note that this same explanation is why there is no recommendation against using BI-RADS® assessment categories 4 or 5 at US screening. Such cases also would involve the recording of both screening and diagnostic images. Remember that for US screening examinations given a final assessment of category 3, 4, or 5, the screening component of the examination would be audited as positive while the diagnostic component of the examination would be audited as negative (if category 3) or positive (if category 4 or 5).

3. If handheld screening US is performed either by a physician or a technologist, does every potential abnormality identified at sonography need to be documented before an assessment is made?

Identification of findings ("every potential abnormality") at handheld US examination is accomplished in real time by the operator, whether this is a technologist or the interpreting physician. Then, selected images are recorded. The interpreting physician then renders an assessment in the screening US report. At times, abnormalities are being identified and documented by a nonphysician, but it is the physician's ultimate responsibility to interpret the examination and render an assessment in the screening US report. The situation is straightforward if the screening examination is performed by the interpreting physician, because he or she completes interpretation in real time. Rarely, the interpreting physician may also call in a colleague for a second opinion. Thus, in the vast majority of cases, additional images need not be recorded since the characteristically benign findings may be safely dismissed after real-time scanning while those findings requiring further analysis and management can be appropriately documented. The situation is more complex if a technologist scans the breasts, depending upon the policy established in the breast imaging facility. In some facilities, the established policy is that the interpreting physician routinely rescans the patient if the technologist identifies a potential abnormality. Using this approach, the interpreting physician then decides at real-time scanning how to interpret the examination, appropriate images are recorded, and an assessment is rendered in the screening US report. In other facilities, the established policy is that the technologist records images of every potential abnormality she identifies, and then the interpreting physician decides whether these images are sufficient for rendering an assessment, hence whether rescanning is needed. The decision of whether or not to rescan, made by the interpreting physician, depends on how skilled the technologist is at detecting and recording potential abnormalities, how many images are recorded of each potential abnormality (this also is part of the established policy), how benign or suspicious each finding appears on the recorded image(s), and a variety of other factors.

The approaches described above will provide good patient care. Basic to these policies is usage of the full potential of US, which is its real time capability. Utilization of this capability may be assigned to a highly trained sonographer who is the agent of the interpreting physician in regards to detection and recording of potential findings.

4. I have been asked to do a screening ultrasound examination of both breasts. I have only handheld scanning equipment. How should I perform the examination?

There is no standard examination procedure for bilateral handheld whole-breast US, but in some research studies, such as ACRIN 6666,[15] real-time, handheld sonography was performed by the interpreting physician, on a quadrant-by-quadrant basis without image capture. Transverse or antiradial scanning of a quadrant (sweeping from posterior to anterior) was most efficient, then longitudinal or radial scanning of that quadrant, concluding with scanning just posterior to the nipple. Representative images were captured: one of each quadrant in the radial plane at the same distance posterior to the nipple, 4 cm on average, with appropriate annotation of each image (for example, R breast, 10 o'clock, 4 cm FN), and last, recording of the retroareolar image. These were the images recorded when no findings were identified, and constituted the images for a negative (category 1) screening US examination. Note that ACRIN 6666 was a research study, for which there was interest in capturing fully documented (diagnostic) images of many findings that were assessed as benign at real time scanning and which probably contributed to the the median examination time of 19 minutes.[15] At service screening (screening in usual clinical practice), it will be much more time efficient to limit the frequency of recording fully documented images of benign-assessed findings, since these will be assessed as characteristically benign at real-time scanning and no further action is required prior to the next scheduled screening exam. For each characteristically benign finding that is described in the US report, consider recording only one representative image (instead of a the standard negative image of that quadrant). Also note that it is not necessary to describe all characteristically benign findings in a screening US report. Indeed, in usual clinical practice (service screening), most interpreting physicians do not describe all characteristically benign findings at screening mammography. If a significant finding (one that will require either surveillance imaging or biopsy prior to the next scheduled screening exam) is identified during handheld scanning, return to it and record appropriate views, following the same procedure as for a diagnostic examination. This, in effect, converts the screening examination into a (recalled) diagnostic examination.

5. The following discussion also appears previously as item #13 in Section IV, "Examples of How to Classify Examinations as True-Positive, True-Negative, False-Positive, and False-Negative." It is duplicated here because the topic is specific to breast US and because questions are frequently asked about how to audit in this clinical scenario.

A woman has a breast US screening examination using a handheld transducer, so that additional imaging can be performed immediately if needed. A focal area of posterior acoustic shadowing is visible on one of the standard images recorded as part of the screening examination. The interpreting physician decides to further scan the patient to clarify the significance of this finding, and records one or more images to demonstrate that the focal area of shadowing is not reproducible. The completed examination is then interpreted as negative because the initially depicted finding is judged to be an artifact rather than a true abnormality. No breast cancer is found within 1 year of examination. How should this scenario be classified?

This single examination in effect represents a positive screening examination (BI-RADS® category 0), for which the woman was recalled for additional diagnostic imaging that resulted in a negative

(BI-RADS® category 1) assessment. Thus, the screening component of this examination should be classified as false-positive (FP), and the diagnostic component of the examination should be classified as true-negative (TN). Note that whenever a screening examination is interpreted before a woman leaves the premises, and the examination is converted to a diagnostic examination to clarify a sonographic finding identified on standard screening views (by the recording of additional images), this single examination should be considered to have a positive screening interpretation (BI-RADS® category 0) and also a positive or negative diagnostic interpretation depending on the final assessment that is rendered. Also note if the interpreting physician in the provided scenario had determined at repeat scanning that the initially depicted finding was an artifact without documenting this by recording one or more additional images, the completed screening examination would have contained only standard images, been assessed as negative (BI-RADS® category 1), and therefore been audited as true-negative (TN). However, also note that the approach of not recording additional images upon rescanning may subject the interpreting physician to malpractice exposure if breast cancer subsequently is diagnosed at the site of the depicted finding, although this exposure might be somewhat mitigated by adding a sentence to the screening report indicating that the depicted finding is considered to be an artifact because it could not reproduced at subsequent rescanning (no additional images recorded).

6. ***The following discussion also appears previously as item #14 in Section IV, "Examples of How to Classify Examinations as True-Positive, True-Negative, False-Positive, and False-Negative." It is duplicated here because the topic is specific to breast US, and because questions are frequently asked about how to audit in this clinical scenario.***

   A woman has a breast US screening examination using a handheld transducer, so that additional imaging can be performed immediately if needed. A mass that appears to be a simple cyst is visible on one of the standard images recorded as part of the screening examination. The interpreting physician decides to further scan the patient to clarify the significance of this finding, and records one or more images to demonstrate that the mass indeed is a simple cyst. The cyst is described in the screening report and the completed examination is assessed as benign. No breast cancer is found within 1 year of examination. How should this scenario be classified?

   This single examination in effect represents a positive screening examination (BI-RADS® category 0), for which the woman was recalled for additional diagnostic imaging that resulted in a benign (BI-RADS® category 2) assessment. Thus, the screening component of this examination should be classified as false-positive (FP), and the diagnostic component of the examination should be classified as true-negative (TN). Note that whenever a screening examination is interpreted before a woman leaves the premises and the examination is converted to a diagnostic examination to clarify a sonographic finding identified on standard screening views (by the recording of additional images), this single examination should be considered to have a positive screening interpretation (BI-RADS® category 0) and a positive or negative diagnostic interpretation, depending on the final assessment that is rendered. Also note that in the provided scenario, if the interpreting physician in the provided scenario had determined at repeat scanning that the initially depicted finding was characteristically benign without documenting this by recording one or more additional images, the completed screening examination would have contained only standard images, been assessed as benign (BI-RADS® category 2), and therefore been audited as true-negative (TN). However, also note that the approach of not recording additional images upon rescanning may subject the interpreting physician to malpractice exposure if breast cancer subsequently is diagnosed at the site of the depicted finding, although this exposure might be mitigated by adding a sentence to the screening report indicating that the

depicted finding is considered to be characteristically benign at subsequent rescanning (no additional images recorded).

7. ***The following discussion also appears previously as item #15 in Section IV, "Examples of How to Classify Examinations as True-Positive, True-Negative, False-Positive, and False-Negative." It is duplicated here because the topic is specific to breast US and because questions are frequently asked about how to audit in this clinical scenario.***

   A woman has a breast US screening examination using a hand-held transducer, so that additional imaging can be performed immediately if needed. A mass that is characteristic of a simple cyst is visible on one of the standard images recorded by the breast sonographer as part of the screening examination. The interpreting physician decides to further scan the patient to verify the presence of a simple cyst, verifies at real-time scanning that the mass indeed is a simple cyst, but does not record any additional images. The cyst is described in the screening report and the completed examination is assessed as benign. No breast cancer is found within 1 year of examination. How should this scenario be classified?

   Because no additional (diagnostic) images were recorded, the examination is audited purely as a screening examination that resulted in a benign (BI-RADS® category 2) assessment, classified as true-negative (TN). Note that whenever a screening US examination is interpreted before a woman leaves the premises, but the examination is not converted to a diagnostic examination by recording additional images (even though rescanning is performed to clarify a sonographic finding identified on a standard screening view), the examination is audited purely as a screening examination. Also note that the approach of not recording additional images upon rescanning may subject the interpreting physician to malpractice exposure if breast cancer subsequently is diagnosed at the site of the depicted finding, but in the case of a finding correctly assessed as benign (BI-RADS® category 2), the likelihood of malignancy is essentially zero. Furthermore, note that in routine clinical practice, the presence of one or more characteristically benign findings does not require full documentation by diagnostic imaging, because 1) the likelihood of malignancy is essentially zero, and 2) the fully documented appearance of the finding(s) will not be needed for future comparison, because a) if the finding(s) again appear characteristically benign at a subsequent examination, interval change in size would be irrelevant, and b) if the finding(s) do not appear characteristically benign, biopsy would be recommended. Finally, note that even though characteristically benign finding(s) are depicted on standard screening view(s) in an asymptomatic woman, the interpreting physician may reasonably decide not to describe the finding(s) in the breast imaging report, instead rendering a negative (BI-RADS® category 1) assessment.

D. MRI

1. ***I do not understand why BI-RADS® assessment category 3 is not recommended at screening for mammography but accepted for MRI. Also, I see that a category 3 assessment should be considered positive, regardless of the modality. Why the differences in recommendations for use and why the similarity in how to audit category 3 assessments?***

   The first part of the answer is that MRI screening is unique in that the images recorded for a screening examination are usually identical to those recorded for a diagnostic examination, so that a breast MRI screening examination is simultaneously a full diagnostic examination (hence, a category 3 assessment is acceptable because, in effect, a full diagnostic examination also has been obtained). The second part of the answer is that a category 3 assessment at screening is

considered positive at auditing, independent of screening modality, because the management recommendation (short-interval follow-up) is something other than routine screening in 1 year.

2. ***Why is it that the outcome parameters of recall rate and PPV_1 do not apply to breast MRI screening, although they do apply to both mammography and breast US screening?***

   For auditing purposes, the definition of a positive screening examination is different for breast MRI than it is for both mammography and breast US. This is because mammography and breast US auditing utilize the objective and reproducible rule of whether one or more additional (diagnostic) images is recorded to further characterize a finding depicted on standard screening images. However, breast MRI is unique in that the images recorded for a screening examination are usually identical to those recorded for a diagnostic examination, so that a breast MRI screening examination is simultaneously a full diagnostic examination. The outcome parameters recall rate and PPV_1 relate only to purely screening examinations. Recall rate is meaningless for screening MRI because all patients simultaneously undergo what is effectively a diagnostic examination. Concerning PPV_1, were it to be calculated for breast MRI screening, it would be essentially the same as PPV_2.