

The ACR forwarded the following questions to the FDA MQSA for review and response regarding the [2023 Amended MQSA Final Regulations](#) that become effective September 10, 2024. If you have a specific question related to meeting the regulatory requirements or the FDA's response to the questions posted below, we encourage you to directly contact the FDA, through the MQSA Facility Hotline, at telephone number 1-800-838-7715 or email [MQSAHotline@versatechinc.com](mailto:MQSAHotline@versatechinc.com).

Q. I am writing to ask for your assistance in connecting me with someone who may be able to clarify the definitions for the new ACR BI-RADS categories that will be implemented in September 2024 as part of the FDA-MQSA mandate. I would greatly appreciate your help with this matter.

- ACR BI-RADS 0 - Incomplete
- Now 2 separate categories :
- needing additional imaging OR prior mammograms
- Needs 2 separate letters
- Needs to be tracked separately in QC

A. **FDA Response:** Please note that the MQSA requirement that every report must include an overall assessment of findings refers to the assessment statements listed in the regulations, not the ACR BI-RADS categories (nor their alphanumeric codes). Physicians are permitted to add a BI-RADS code if desired, but such a code alone does not satisfy the MQSA assessment requirement.

The assessment statement "Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison" does not appear in either the existing MQSA regulations, which are currently in effect, or the amended regulations which will be in effect as of September 10, 2024. Under the existing regulations, there is a single Incomplete assessment statement, "Incomplete: Need additional imaging evaluation" (see 21 CFR § 900.12(c)(1)(v)). However, the use of the combined assessment statement "Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison" was approved on August 29, 2003, as part of MQSA Alternative Standard #11, "Modifications in the Assessment Categories Used in Medical Reports."

Under the amended regulations, there will be two Incomplete assessment statements, "Incomplete: Need additional imaging evaluation" and "Incomplete: Need prior mammograms for comparison." These statements reflect FDA's recognition that some mammograms require comparison for interpretation, while some mammograms require additional imaging to reach a final interpretation. Additionally, the two Incomplete assessment categories have different reporting requirements. When the assessment category "Incomplete: Need prior mammograms for comparison" is used, a follow-up report to the mammographic examination with an assessment category identified in 21 CFR 900.12(c)(1)(iv)(A) through (E) ["Negative," "Benign," "Probably Benign," "Suspicious," or "Highly Suggestive of Malignancy,"] must be issued within 30 calendar days of the initial report whether or not comparison views can be obtained, whereas the assessment category "Incomplete: Need additional imaging evaluation" does not require a follow-up report to the mammographic examination be issued within a specified time frame.

If additional imaging was recommended and the results of the follow-up examination are available within 30 calendar days of the initial examination, the facility has the option of combining the results into one lay summary (rather than providing two lay summaries). If one combined lay summary is provided, it must state specifically that it refers to both the initial and the follow-up examinations. If the results of the follow-up examination are not available within 30 calendar days of the initial examination, the facility must provide two lay summaries, one for the initial examination and one for the follow-up. Each must be provided within 30 calendar days of the examination it covers.

Please note, the Division of Mammography Quality Standards (DMQS) is actively reviewing all the approved alternative standards to determine compliance with the amended regulations. Therefore, DMQS encourages facilities to use the two separate Incomplete assessment categories when the rules become effective on September 10, 2024.

- Q. There is one new regulation that seems incomplete, the updated BIRADS for Benign with 3 new assessment categories. I can't find what the new updated assessment categories for benign actually are. Can you help?
- A. **FDA Response:** There is no change to the Benign assessment statement, which remains just the word "Benign." The three new assessment statements are "Post-Procedure Mammogram for Marker Placement" (identical to approved alternative standard #12), "Known Biopsy-Proven Malignancy" (identical to approved alternative standard #11), and "Incomplete: Need Prior Mammograms for Comparison."

Under the amended regulations, the explanatory language for the negative and benign assessment categories was updated. For each assessment category, the required assessment statement is only the word or phrase in quotation marks. As in the existing regulations, each assessment statement, identified in quotation marks, is followed by explanatory language, which is not in quotation marks. This explanatory language not in quotation marks is intended to provide an explanation of the assessment category in order to promote its consistent use, but it is not part of the assessment statement, and is not required to be included in the report to the referring healthcare provider nor in the lay summary to the patient.

The explanatory language for the negative assessment was updated to "Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be documented and addressed)." The explanatory language for the benign assessment category was updated to "Also a normal result, with benign findings present, but no evidence of malignancy (If the interpreting physician is aware of clinical findings or symptoms, despite the benign assessment, these shall be documented and addressed)."

- Q. How does a facility know what breast density report requirements to follow; state or federal? Does the facility need to include two breast density statements in the report?
- A. **FDA Response:** The FDA will require that the specific Federal density assessments and notification statements be included verbatim in every report to the referring healthcare provider and every lay summary to the patient, respectively. In some States, facilities may be required to issue both the State and Federal notifications to patients, to satisfy the respective State and Federal requirements. We recommend that facilities check with its State to ensure

compliance with its requirements. The final rule does not prohibit facilities from providing patients with additional information, including information that may be required by any applicable State breast density reporting requirements. However, any additional information given to patients should be separate and distinct from the required Federal breast density notification statements, which must be used verbatim and must not be altered.

- Q. In the amended regulations, page 15135, first column third paragraph: Display that has not met premarket authorization requirements for use in interpreting mammograms will be in violation of the MQSA quality standards regulation. However, premarket authorization is required by the FDA for displays intended for use in mammographic interpretation, so this nuance should not impact which displays can be used for mammographic interpretation, correct?
- A. **FDA Response:** All devices used in mammography must have met the applicable FDA premarket authorization requirements for medical devices of that type with that intended use. This applies to devices used in the acquisition, processing, or display of digital mammographic images. A display device used in the interpretation of digital mammographic images generally needs to have 510(k) clearance prior to being used in a mammographic facility. Not all equipment needs clearance or approval; for example, some devices, such as medical image storage devices (e.g., PACS), may be exempted from premarket notification requirements.

The FDA classifies a device based on its intended use (IU), indications for use (IFU), and the level of risk that the device poses to the patient and/or the user. Before a medical device, such as a mammography unit or a display monitor, can be marketed in the United States, it must meet any applicable FDA premarket authorization requirements. If a device is cleared or approved by the FDA for use in mammography, this will be stated in the IFU.

Also note that facilities are responsible for ensuring that any equipment they use in the acquisition, processing, interpretation, retention, and retrieval of mammographic images be compatible, in order to facilitate mammography practice and to allow compliance with the record retention, transfer, and release provisions in § 900.12(c)(4) of the final rule.

- Q. Where do I find a list of approved RWS that facilities may continue to use after the implementation of the final regulations?
- A. **FDA Response:** If it is unclear whether a facility's display device is intended for mammography, it is recommended that the facility request a copy of the 510(k) Summary with the Indications for Use (IFU) statement from the manufacturer of the mammography unit and/or display device to ensure it is intended for use in mammography. Facilities may also look up their display device's 510(k) status at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>.
- Q. If the FDA approval letter of an RWS states that the equipment is specifically approved for Full Field Digital Mammography or Digital Mammography, can this be used for DBT mammography as well?
- A. **FDA Response:** Generally, yes. However, it is recommended that the facility contact the manufacturer for its intended use.