The American College of Radiology
Digital Breast Tomosynthesis (DBT) Initial Training: Frequently Asked Questions
(Updated: 5/14/15)

Introduction

Q. I understand that the Food and Drug Administration’s MQSA regulations require mammography personnel to obtain 8 hours of initial training before working with new mammographic modalities, i.e. modalities in which they have not been trained before. I just discovered as of March 2015, FDA considers each Digital Breast Tomosynthesis (DBT) manufacturer’s system to be a “separate mammographic modality”, thus requiring personnel to have 8 hours of initial new-modality training on each manufacturer’s DBT system before they independently interpret/survey or operate. Is this correct?

A. Yes. See the FDA website at http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm413117.htm. The following FAQs are based on discussions the ACR had with the FDA’s Division of Mammography Quality Standards (DMQS) to obtain clarification of these requirements.

Q. How does the FDA’s MQSA definition of a new mammographic modality apply to DBT?

A. The MQSA defines a mammographic modality as “a technology….for radiography of the breast.” Due to the technological differences between DBT systems, and differences in their FDA-approved Indications for Use (IFU), the FDA’s Division of Mammography Quality Standards (DMQS) currently considers each manufacturer’s DBT system to be a separate mammographic modality under this MQSA definition. Under MQSA, personnel need to receive 8 hours of initial new-modality training prior to independently using any mammographic modality. For clarification of eligible training, please see the questions below.

Initial Training

Q. Do personnel with 8 hours of DBT training specific to one manufacturer’s system meet the requirements for the initial 8 hours of DBT training for another manufacturer’s system?

A. No. However, the FDA’s Division of Mammography Quality Standards (DMQS) recognizes that there are many features which are common to different DBT systems, so

- Personnel who have already received 8 hours of general training in DBT need documentation of training in the features of the particular DBT system they will use that were not covered in generalized DBT training.
- Personnel who have received 8 hours of training on any one DBT unit also need documentation of training on the unique features of another DBT system prior to independently using that other system.

Q. How much training on the “unique features of the particular DBT system” is required?

A. Currently, the FDA’s Division of Mammography Quality Standards (DMQS) has not specified the # of hours of training needed on the “unique features of the particular DBT system.”
Q. Must the training be provided by the manufacturer?

A. No. Under MQSA, the new-modality training, including the training on the unique features (technological differences and Indications for Use) of a particular DBT system, does not need to be provided by the manufacturer. Each of the currently approved manufacturers (see the FDA Digital Accreditation webpage for currently approved DBT manufacturers), offers formal training on its own system; however, third-party training courses as well as informal training can also provide new mammographic modality training under MQSA. Residents and fellows may receive the training during their residency or fellowship. The individual providing the training must be a qualified instructor, defined as “an individual whose training and experience adequately prepare him or her to carry out specified training assignments.” For example, peer training by a qualified peer who has previously met the training requirement is permitted. The FDA’s Division of Mammography Quality Standards (DMQS) will accept signed attestation, using DMQS’s recommended form or a form with similar elements, to document that personnel received training in the new unique features of a particular manufacturer's DBT system.

Q. What is the status of training received prior to this clarification?

A. Such training counts toward the 8 hours of new-modality training for any approved DBT system, but personnel also need to document that they received training in the unique features of whichever DBT system they will use. For documentation of training in the unique features of a particular manufacturer’s DBT system, the FDA’s Division of Mammography Quality Standards (DMQS) will accept:

- A course certificate or letter that clearly indicates that the training included the unique features of a particular system, or
- A signed attestation, using DMQS’s recommended form or a form with similar elements, to document training in the unique features.

If the 8 hours of new modality training in DBT were obtained between February 18, 2011, and August 26, 2014, when Hologic was the only DBT system approved for marketing in the US, DMQS will accept that such training included the unique features of the Hologic system, even if that is not stated explicitly on the training certificate.

Q. What documentation will MQSA inspectors look for in order to determine that a facility is in compliance with new mammographic modality training?

A. Personnel need to have acceptable documentation of a total of 8 hours of training in a new mammographic modality, i.e. one in which they have not been trained before, prior to using the modality independently. With regard to DBT, the modality is the specific manufacturer’s DBT system. The training in the unique features of the particular DBT system the personnel will use may be included in the 8 hours of new-modality training, or this training in the unique features may be obtained separately. Thus, personnel may receive:

- 8 hours of training in general DBT topics, plus training in the unique features of the specific DBT system they will use; or
- 8 hours of training in one specific DBT system they will use; or
- 8 hours of training in one DBT system, plus training in the unique features of another DBT system prior to independent use of that other system

Signed attestation is acceptable for documentation of the training in the unique features of a particular DBT system. Also, if 8 hours of new-modality training in DBT were obtained prior to August 26, 2014, when Hologic was the only DBT system approved for marketing in the United States, inspectors will
accept that the training included the unique features of the Hologic system, even if that is not stated explicitly on the training certificate.

Q. A 3rd party education provider held a DBT course in January 2014, before the General Electric (GE) DBT system was approved by the FDA. The identical course was repeated in September 2014, after GE DBT approval. If 8 hours of new-modality training in DBT were obtained prior to August 26, 2014, when Hologic was the only DBT system approved for marketing in the United States, we understand that inspectors will accept that the training included the unique features of the Hologic system, even if that is not stated explicitly on the training certificate. This means the January 2014 course will be acceptable for Hologic training.

Will the September 2014 course be acceptable for Hologic training since it is the same course repeated? If so, how should this training be documented?

A. Yes. Complete and sign an attestation using DMQS’s recommended form or a form with similar elements, to document training in the unique features of the Hologic system.

Q. I am qualified to interpret DBT with only one DBT system. We are employing a new radiologist who has had some general CME on DBT. The FDA guidance says that I can provide peer training to my radiologist colleague. How do I know which unique features of our system I should teach him or her?

A. The unique features of a specific DBT system will typically include its particular technological features of image acquisition, processing, and/or display, and its unique FDA-approved Indications for Use, such as the particular combination of views approved for screening mammography using that DBT system. You should emphasize to your physician colleague those unique features that fall into the interpreting physician’s area of responsibility.

Similarly, a medical physicist or a radiologic technologist providing peer training to a colleague should emphasize those unique features that fall into the colleague’s respective area of responsibility.

Q. Do the above requirements apply to recently graduated radiology residents, fellows, radiologists providing locums services, consulting medical physicists and mammography technologists providing per diem services?

A. Yes.

Mammography Equipment Evaluations

Q. Our GE DBT mammography equipment evaluation (MEE) was performed prior to the March 18, 2015 DMQS clarification issued inspectors. Must a MEE be done again after manufacturer-specific training is completed?

A. The FDA’s Division of Mammography Quality Standards (DMQS) has informed the ACR that MQSA-certified facilities which have already had their certificate extended to include the GE DBT system and whose MEE was performed prior to the March 18, 2015 DMQS clarification can continue using the equipment if they make arrangements to obtain training in the unique features of GE DBT as soon as possible.
More Information

Q. How is the ACR dealing with these requirements and their significant impact on the mammography community?

A. ACR has been in active discussion with the FDA’s Division of Mammography Quality Standards (DMQS), expressing our members’ significant concerns, as well as exploring ways to address these concerns. DMQS acknowledges that there are features which are common to more than one DBT system, such that personnel do not need to receive training twice on the common features in order to qualify to use two different DBT systems. ACR is also considering applying for an Alternative Standard for personnel training requirements under MQSA. This will take time to develop and submit for DMQS approval. We will update these FAQs as we obtain more information.

Q. I have additional questions on these requirements. Who should I contact?

A. Contact the FDA Mammography Facility Hotline at 1-800-838-7715 or MQSAhotline@hcmsllc.com.