



Breast Tomosynthesis Training Requirements and Site Readiness

FDA Required Breast Tomosynthesis Training

On any new mammography technology, such as breast tomosynthesis, the Mammography Quality Standards Act (MQSA) (<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114148.htm>) requires that all health care professionals obtain eight hours of training prior to using new mammography technology on patients.

If you are a Radiologist already trained in Full Field Digital Mammography (FFDM)

Eight hours of training in the interpretation of breast tomosynthesis will be offered through Hologic non-CME courses. In addition, you may find non-Hologic CME courses to meet this requirement, such as through World Class CME or another provider.



For suggested radiologist training opportunities, please visit:

www.worldclasscme.com

www.hologic.com/tomotraining

If you are a Radiologist not yet trained in FFDM

Radiologists not yet trained in FFDM will need to complete the additional required eight hours of training in digital mammography, and then proceed to completing the breast tomosynthesis training outlined above, for a total of sixteen training hours.

If you are a Technologist already trained in FFDM

A Hologic applications scheduling coordinator will contact your site once tomosynthesis installation is planned to determine training needs and to schedule training dates at your location. Please note that this training cannot be performed until the MQSA (<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm>) FFDM certification extension is received for tomosynthesis.

If you are a Technologist not yet trained in FFDM

The FDA requires technologists with screen-film only experience to complete eight hours of digital mammography training, as well as an additional eight hours of breast tomosynthesis training (sixteen hours of total training time).

A Hologic applications scheduling coordinator will contact your site regarding FFDM and tomosynthesis applications once tomosynthesis installation is planned to determine training needs and to schedule training dates. Please note that tomosynthesis training for technologists cannot be performed until technologists have received their 8 hours of MQSA (<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm243765.htm>) FFDM training.



Questions on technologist breast tomosynthesis training? Contact Hologic.

Tel: 888.679.0689

E-mail: appschedule@hologic.com

If you are a Medical Physicist already trained in FFDM

Eight hours of training in breast tomosynthesis will be offered through Hologic. In addition, you may find training courses to meet this requirement through another qualified provider. Three hours of this training may be completed online or in a live setting.

During installation, Hologic will provide five hours of Quality Control training by a qualified field service engineer.

If you are a Medical Physicist not yet trained in FFDM

Medical Physicists not yet trained in FFDM will need to complete the additional required eight hours of training in digital mammography, and then proceed to completing the breast tomosynthesis training outlined above, for a total of sixteen training hours.



For suggested online training opportunities, please visit: www.hologic.com/tomotraining

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Breast Tomosynthesis Site Readiness

If your site is already MQSA certified in FFDM

Tomosynthesis units will be accredited under facility's existing FFDM certification through the MQSA's FFDM Certification Extension Program. To become breast tomosynthesis certified your site must apply to the MQSA for a 3D extension certification. Once an application is sent for breast tomosynthesis approval, it will take approximately 14 days for the MQSA to process and approve/deny the request. At this time only the MQSA will need to approve breast tomosynthesis imaging at your site. Neither the state nor ACR is involved in the approval process to date.

MQSA Certification Extension Program
 Division of Mammography Quality and Radiation Programs
 FDA/CDRH/OCER
 10903 New Hampshire Avenue
 W066-4621
 Silver Spring, MD 20903-0002
 Phone: 301-796-5710
 Fax: 301-847-8502
 Contact: Denise Robinson, denise.robinson@fda.hhs.gov
 Website: (<http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/FacilityCertificationandInspection/ucm114148.htm>)

If your site is not yet MQSA certified in digital mammography

If your site has not yet been FFDM accredited, you will need to apply to the ACR or State for FFDM certification. Once that is received, you may contact the MSQA for the FFDM certification extension program for tomosynthesis at 301-796-5710. Please contact Denise Robinson at the MQSA, denise.robinson@fda.hhs.gov with questions.

For details on your Hologic supported training, please refer to your Hologic tomosynthesis sales quotation.

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