641—41.2(136C) Definitions. The definitions contained in 21 CFR 900.2, as adopted by reference, apply to the mammography provisions of this chapter. The definitions provided in 641—Chapters 37 and 40 may also apply. Additionally, the definitions set forth below are specific to this chapter.

"Annually" means within 10 to 14 months of previous occurrence.

"Authorization" means the same as defined in 641—Chapter 37.

"Collaborative setting" means a setting in which a qualified radiologist and surgeon are working together in consultation and in performing stereotactically guided breast biopsies with a common goal of the patient's benefit.

"EQUIP" means Enhancing Quality Using the Inspection Program and uses inspection questions related to the image quality regulations of MQSA to emphasize the significance of continuous clinical image quality.

"Full field digital mammography" or *"FFDM"* means radiographic imaging of the breast using a digital image receptor with minimum dimensions of 18×23 cm to allow imaging the average size breast in a single exposure.

"Grids" means a set of thin lead strips spaced close to one another, interspaced by carbon fiber for mammographic grids. The grid is placed between the breast and the screen-film image receptor to reduce scattered radiation reaching the image receptor.

"Iowa-approved" means recognized or accepted by the department as meeting the training and experience requirements established by MQSA and any additional criteria set forth in this chapter. This may include but is not limited to formal approval by the department based on documentation of education, training, certification, and clinical experience.

"Phantom" means an artificial test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

"Procedure" means a stereotactically guided breast biopsy performed on a patient for diagnostic purposes.

"Qualified training physician" means a physician who is qualified under the rules of this chapter to perform stereotactically guided breast biopsies and who has performed at least 24 procedures.

"Radiologic technologist" means the same as defined in 21 CFR 900.2 and also includes the definition of "general radiologic technologist" as set forth in 641—Chapter 38.

"Radiologist continuing experience" means the number of mammograms interpreted by a radiologist in the past 24-month period. For the purpose of counting, a radiologist may count the current mammographic examination and one prior mammographic examination, provided the radiologist was not the interpreter of the prior mammographic examination. A separate tally shall be kept for the prior examinations.

"Reinstatement" means the process of recertification of a facility that has lost or voluntarily given up previous accreditation/certification.

"Review workstation" or *"RWS"* means soft copy display device intended for use in mammography interpretations.

"Screening mammography" means X-ray breast examination of asymptomatic individuals in an attempt to detect breast cancer when it is small, nonpalpable, and confined to the breast.

"Stereotactic training phantom" means a training or practice tool or medium used for stereotactically guided breast biopsy procedures.

"Stereotactically guided breast biopsy" means a breast biopsy procedure performed with the utilization of a dedicated system that emits ionizing radiation and is designed specifically for that procedure.

"Supervising physician" means the physician designated by the facility/owner to:

1. Evaluate the equipment, personnel, procedures, and records annually; and
2. Establish and conduct the quality assurance program.

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