1. Mammography Equipment Evaluation (MEE)

Facility Name _____ **MAP ID-Unit#** *(00000-00)* _____ - _____

Mfr & Model _____ **Room ID** _____

Survey Date _____

MQSA Requirements for Equipment [FDA Rule Sec. 900.12 (b)] - only applies to MEE

Feature	FDA Rule	Requirement	Meets? Yes/No/NA
Motion of tube-image receptor assembly	3(i)	The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.	
	3(ii)	This mechanism shall not fail in the event of power interruption.	
Image receptor sizes	4(iii)	Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.	
Light fields	5	For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 ft-candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.	
Magnification	6(i)	Systems used to perform noninterventional problem-solving procedures shall have radiographic magnification capability available for use by the operator.	
	6(ii)	Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.	
Focal spot selection	7(i)	When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.	
	7(ii)	When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.	
	7(iii)	When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.	
Application of compression	8(i)(A)	Each system shall provide an initial power-driven compression activated by hands-free controls operable from both sides of the patient.	
	8(i)(B)	Each system shall provide fine adjustment compression controls operable from both sides of the patient.	
Compression paddle	8(ii)(A)	Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system.	
	8(ii)(B)	Compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.	
	8(ii)(C)	Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.	
	8(ii)(D)	Chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.	
	8(ii)(E)	Chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.	
Technique factor selection and display	9(i)	Manual selection of mAs or at least one of its component parts (mA and/or time) shall be available.	
	9(ii)	The technique factors (kVp and either mA and seconds or mAs) to be used during an exposure shall be indicated before the exposure begins, except when AEC is used, in which case the technique factors that are set prior to the exposure shall be indicated.	
	9(iii)	Following AEC mode use, the system shall indicate the actual kVp and mAs (or mA and time) used during the exposure.	
Lighting**	14	The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.	
Film masking devices**	15	Film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.	
Beam quality assessment	*	Must meet the specifications of FDA's Performance Standards for Ionizing Radiation Emitting Products (Part 1020.30)	
kVp accuracy & reproducibility	*	The mean kVp must not differ from the nominal by more than + 5% of the nominal kVp.	
	*	The coefficient of variation must be ≤0.02.	
Collimation assessment	*	If sum of left plus right edge deviations or anterior plus chest edge deviations exceeds 2% of SID, seek service adjustment.	
	*	If X-ray field exceeds image receptor at any side by more than + 2% of SID or if X-ray field falls within image receptor on the chest wall side, seek service adjustment.	
	*	If chest-wall edge of compression paddle is within the image receptor or projects beyond the chest-wall edge of the image receptor by more than 1% of SID, seek service correction.	
		Overall Pass/Fail	

** ACR adoption for MEEs of pertinent sections in FDA Rule 900.12(e)(5) that apply to annual testing of screen-film only*

*** NA is acceptable if 1) no hard copy interpretations are made, 2) no hard copy comparisons are made or 3) for new units at existing facilities if these were previously evaluated and have not changed*