WAC 246-225-160 Mammography. (1) The use of a special purpose X-ray machine designed and used solely for mammography is required. Exempted from this requirement shall be X-ray equipment using xerography for evaluation of breast implant integrity.

(2) All mammographic calibration, evaluation, service, and quality control actions shall be documented in writing and maintained at the facility for a three-year period. Records must be easily accessible to operators of these X-ray units.

(3) All tests requiring the use of a breast phantom shall employ a phantom similar to or identical to the one required by the American College of Radiology for its mammography accreditation program.

(4) Machine requirements:

(a) Mammography X-ray machines must be evaluated upon any major component change and on a yearly basis by a qualified medical physicist. Evaluation shall document (but is not limited to) half-value layer (HVL), kVP accuracy, reproducibility, timer accuracy, resolution achieved with film in use at the facility, focal spot size, mA linearity, light versus X-ray field alignment, and patient exposures (glandular tissue dose) following the measurement protocol in NCRP Report No. 85 (using a breast phantom). This requirement shall include initial acceptance testing upon the X-ray system's installation prior to human use.

(b) The half-value layer (HVL) for film/screen mammography shall be between the values of measured kVp/100 and measured kVp/100 + 0.1 millimeters aluminum. The half-value layer for xerography shall be at least 1.2 mm but no greater than 1.6 mm of aluminum as measured at 50 kVP. The HVL shall include the contribution to filtration made by the compression device.

(c) Exposure reproducibility: Manual techniques. See WAC 246-225-090.

(d) Exposure reproducibility: Photo-timed techniques. Mammographic systems in the AEC mode shall be able to maintain constant film density to within an optical density of ± 0.3 of the average optical density over the range of clinically used kVps, using BR-12 or other breast equivalent material phantom thicknesses of 2 centimeters to 6 centimeters. If the facility has established a technique chart that utilizes varying technical factors for different breast thicknesses, those adjustments in technique may be used when complying with this requirement.

(e) Radiographic timers. See WAC 246-225-070.

(f) kVP accuracy: The kVP accuracy published by the X-ray machine manufacturer shall be maintained at the specified level. For determination of actual versus indicated kVP, the manufacturer's recommendations for testing shall be followed.

(g) mA linearity. See WAC 246-225-040(10).

(h) All special purpose X-ray machines designed solely for mammography and installed after January 1, 1992, shall be equipped with a milli-ampere-second (mAs) read-out device, registering after each phototimed exposure. Alternatively, a means of determining mAs after each exposure shall be provided.

(i) Beam limitation:

(i) Mammographic systems shall be provided with means to limit the useful beam such that the X-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor at any designed SID except the edge of the image receptor designed to be adjacent to the chest wall where the X-ray field may not extend beyond such edge by more than two percent of the SID.

(ii) Beam limiting devices consisting of an assortment of fixed, removable cones sufficient to meet the requirement for each combination of image receptor size and SID for which the unit is designed shall have clear and permanent markings to indicate the image receptor size and SID for which it is designed.

(iii) When the beam limiting device and image receptor support device are designed to be used to immobilize the breast during a mammographic procedure and the SID may vary, the SID indication specified in WAC 246-225-060 (4)(c)(i) and (ii) shall be the maximum SID for which the beam limiting device or aperture is designed.

(iv) In the absence of a visually defined X-ray field each image receptor support shall have clear and permanent markings to indicate the maximum image receptor size for which it is designed.

(j) The combination of source-to-image distance, magnification, and focal spot size shall result in a radiographic resolution of at least 12 line pairs per millimeter. This standard applies to the mammographic, single emulsion film being used at the facility.

(k) The X-ray machine shall be equipped with a means of immobilizing and compressing the breast with a force of at least twenty-five pounds but no greater than forty pounds.

(l) Dedicated mammographic X-ray units are exempted from the requirements of WAC 246-225-030 (5)(b)(i) provided that appropriate operator shielding is employed (as defined by NCRP Report 49).

(m) *Transmission limit for image receptor supporting devices used for mammography.* For X-ray systems manufactured after September 5, 1978, which are designed only for mammography, the transmission of the primary beam through any image receptor support provided with the system shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the image receptor supporting device does not exceed 25.8 nanocoulombs per kilogram (0.1 milliroentgen) for each activation of the tube. Exposure shall be measured with the system operated at the minimum SID for which it is designed. Compliance shall be determined at the maximum rated peak tube potential for the system and at the maximum rated product of tube current and exposure time (mAs) for that peak tube potential. Compliance shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters.

(n) Maximum glandular doses. Glandular tissue dose for a craniocaudal view of a 4.5 cm compressed breast using dose calculation methods found in NCRP Report # 85 shall not exceed the following:

Screen-film:

No grid	=	1.5 milliGray (100 millirads)/projection
Grid	=	2.5 milliGray (300 millirads)/projection
Xerox	=	4.0 milliGray (400 millirads)/projection

(5) A quality control program shall be written and implemented for all mammographic facilities. This shall include (but shall not be limited to) tests performed, testing frequency, testing protocol, control limits for each test, corrective actions taken, and equipment maintenance/service. Program requirements include:

(a) Daily tests:

Film processor control charts using a sensitometric/densitometric based measurement system shall be required for each day the mammographic machine is in operation. Single emulsion mammographic film shall be used for this evaluation. The sensitometer shall be one with a 21-step optical attenuator.

Parameters in daily film processor tests shall include:

(i) Speed index (mid-density):

Control limits ± 0.15 optical density

(ii) Contrast index (density difference):

Control limits ± 0.15 optical density

(iii) Base + fog:

Maximum density shall not exceed 0.20 optical density.

(iv) Solution temperatures, using a digital thermometer that reads out in tenths of a degree and that is accurate to within ± 0.5°F.

Control limits ± 1.0 F

(b) Monthly tests:

(i) Chemical replenishment rates.

(ii) Image quality evaluation. The mammographic system shall be capable of providing an image of a 0.75 mm fiber, 0.32 mm speck group, and a 0.75 mm mass from an ACR, or equivalent, phantom on the standard mammographic image receptor system in use at the facility. Mammograms shall not be taken on patients if this minimum is not met. Any fibers, speck groups or masses larger than those specified shall also be imaged.

(c) Quarterly tests:

(i) Film/screen contact for all cassettes, using a 40-mesh copper screen.

(ii) Analyses of reject/repeat films.

(iii) Fixer retention in processed film.

(d) Semi-annual tests:

(i) Darkroom fog.

(ii) Compression device force.

(e) Yearly tests: See WAC 246-225-160 (4)(a).

(f) Cassette screens must be cleaned at least weekly.

(g) Records shall be maintained for quality control test equipment which requires calibration, and such calibrations shall be performed in accordance with recommendations of the manufacturer of the test equipment.

(h) Film processing. See WAC 246-225-150. A film processor that cannot be consistently made to operate within the control limits specified in (a) of this subsection shall not be used to process mammographic films.

(6) Operator competency:

(a) A mammographic machine operator shall be licensed, certified, or registered by the department as either:

(i) A health care practitioner, licensed under Title 18 RCW, if performing mammography is within the person's authorized scope of practice; or

(ii) A diagnostic radiologic technologist certified in accordance with chapter 18.84 RCW; or

(iii) An X-ray technician registered in accordance with chapter 18.84 RCW, with two or more years' experience in performing mammography and satisfactory completion of at least sixteen hours of training in mammographic positioning, mammographic quality assurance, and/or other related areas subject to approval by the department.

(b) A mammographic machine operator shall complete the equivalent of at least eight hours of training every twelve months covering such areas as mammographic positioning, mammographic quality assurance and other related areas subject to approval by the department.

(c) A mammographic machine operator shall meet the requirements of WAC 246-225-020 (2)(b) and 246-225-99920.

(7) Masking devices shall be made available to block extraneous light from the viewer's eye when the illuminated surface of the viewbox is larger than the exposed area on the film.

(8) Additional requirement for mobile mammography services:

The daily film processor performance testing required in subsection (5)(a) of this section shall apply to all film processors used by the mobile service. No processor shall be used unless it meets the control limits specified by subsection (5)(a)(i) through (iv) of this section.

[Statutory Authority: RCW 70.98.050. WSR 94-01-073, § 246-225-160, filed 12/9/93, effective 1/9/94; WSR 92-05-011 (Order 240), § 246-225-160, filed 2/7/92, effective 3/9/92.]