4732.1100 INSTALLATION CALIBRATION TESTS AND EQUIPMENT PERFORMANCE TESTS FOR A QUALITY ASSURANCE PROGRAM.

Subpart 1. **Tests required.**

A. Installation calibration tests must be conducted prior to any patient use. Any adjustments must be made to bring the equipment up to a nationally recognized standard such as Code of Federal Regulations, title 21, section 1020, or the manufacturer's specifications, and to ensure compliance with this chapter prior to first use.

B. Equipment performance tests must be conducted over all clinical ranges, when applicable. For equipment performance tests, any adjustments must be made to bring equipment to a nationally recognized standard or manufacturer's specifications; and to ensure compliance with this chapter prior to using the equipment again.

Subp. 2. **Frequency of tests.** The tests in this part are to be made at the time of installation and at the specified intervals thereafter.

Subp. 3. **Image receptors.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Screen-film contact	At intervals not to exceed 24 months	No significant areas of poor contact as measured by no less than: (1) 8 wires/inch mesh; or (2) 7 holes/inch for regular film; (3) 40 wires/inch mesh or greater for mammography film
B. Screen-film-cassette speed match	At intervals not to exceed 24 months	Densities within ± 0.10 O.D. for all cassettes of the same speed used for imaging
C. CR imaging plates	At intervals not to exceed three months or upon observation of image artifacts	Follow manufacturer's recommendations

Subp. 4. **Processing.**

	TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	Darkroom fog	At intervals not to exceed six months	< 0.08 O.D. increase in density (measured at approximately 1.00 O.D.) after 2 minutes using film exposed on-site at the time of test. For mammography the O.D. increase must be < 0.05
B.	Sensitometry and densitometry	Before processing first film of the day	Density difference ± 0.15 O.D. and base + fog + .05 O.D. using film exposed on-site at time of test. Veterinary facilities are not required to perform this test
C.	Temperature check	At the time of sensitometry	Follow manufacturer's recommendations

Subp. 5. **All diagnostic radiographic tubes; required when applicable.**

	TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A.	SID indicator accuracy	At intervals not to exceed 24 months	± 2% of indicated value
B.	X-ray and light field alignment	At intervals not to exceed 24 months	± 2% of SID any one direction, ± 3% of SID, both directions (total)
C.	X-ray and image receptor alignment	At intervals not to exceed 24 months	± 2% of SID
D.	Collimator dial accuracy	At intervals not to exceed 24 months	± 2% of SID
E.	Reproducibility	At intervals not to exceed 24 months	Coefficient of variation < 5%
F.	mR/mAs	At intervals not to exceed 24 months	± 10% of baseline

G. Linearity	At intervals not to exceed 24 months	± 10% over clinical range
H. Linearity - for mAs only units manufactured after May 3, 1994	At intervals not to exceed 24 months	Average ratios of exposure to the indicated mAs obtained in any two consecutive mAs settings must not differ by more than 0.10 times their sum, or at two settings differing by no more than a factor of two where the mAs selector provides continuous selection
I. Timer accuracy	At intervals not to exceed 24 months	Single Phase: ± 10% of setting. Three phase, high frequency, and constant potential: use ± 5% of selected time when measured > 100 milliseconds. At times shorter than 100 milliseconds, use manufacturers' specifications
J. Half-value layer	At intervals not to exceed 24 months	Must meet requirements in part 4732.0810
K. kVp accuracy	At intervals not to exceed 24 months	± 5% of indicated kVp
L. Phototimer reproducibility, if present	At intervals not to exceed 24 months	± 5% of average exposure
M. AEC (phototimer)	At intervals not to exceed 24 months	± 10% of manufacturer's state increments
N. Illuminance of collimator	At intervals not to exceed 24 months	> 15 footcandles
O. Film density vs. thickness change on AEC	At intervals not to exceed 24 months	± 0.30 O.D. of the averaged exposures over the range specified by the manufacturer

P. Film density vs. kVp change on AEC	At intervals not to exceed 24 months	± 0.30 O.D. of the averaged exposures when measured at > 1.2 O.D. and over the range as specified by the manufacturer
Q. Spot film reproducibility (fluoroscopy units with manual mode)	At intervals not to exceed 24 months	± 5% of average exposure
R. Phototimer back-up timer cut off	At time of installation	Terminates exposure at < 600 mAs
S. AEC density at normal or "0"	At intervals not to exceed 24 months	> 1.0 O.D.

Subp. 6. **For facilities with fluoroscopes and C-arm fluoroscopes, except radiation therapy simulators, manufactured before May 19, 1995.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and every tube change	< 5 R (1.3 mC/kg) per minute for manual; < 10 R (2.6 mC/kg) per minute for automatic exposure rate control systems
B. High level control maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and every tube change	< 20 R (5.0 mC/kg^{-1}) per minute
C. Fluoroscopic image size	At intervals not to exceed 12 months and every tube change	Error between fluorographic beam size and observed image size must be no more than ± 3% of SID for all modes and at any tower height

D. Actual spot-film size vs. indicated	At intervals not to exceed 12 months	Error between actual fluorographic beam size at image receptor and indicated image size must be no more than ± 3% of SID for all modes and at any tower height
E. Spot-film reproducibility	At intervals not to exceed 12 months	± 5% of average exposure
F. Phototimer reproducibility, if present	At intervals not to exceed 12 months	± 5% of average exposure
G. Fluoroscopic high contrast resolution and distortion	At intervals not to exceed 12 months	Six inch (15 centimeter) intensifier: center 30 and edge 24 (wires per inch) copper mesh; nine inch (23 centimeter) intensifier
H. Half-value layer	At intervals not to exceed 12 months and after every tube change	± 5% for equipment manufactured before 1973. For equipment manufactured after 1973, follow manufacturer's specified limits

Subp. 7. **For facilities with fluoroscopes and C-arm fluoroscopes, except radiation therapy simulators, manufactured on or after May 19, 1995.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and at every tube change	> 5 R/min must have automatic exposure rate control; > 10 R/min must have high level control; if not high level control maximum is < 10 R/min
B. High level control maximum output at tabletop or equivalent minimum SSD	At intervals not to exceed 12 months and at every tube change	< 20 R/min

C. All other tests as indicated in subpart 5	At intervals not to exceed 24 months	See criteria in subpart 5

Subp. 8. **For facilities with tomography systems other than computed tomography.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Section level	At intervals not to exceed 12 months	± 5 millimeters
B. Level incrementation	At intervals not to exceed 12 months	± 2 millimeters
C. Section thickness (slice width)	At intervals not to exceed 12 months	Follow manufacturer's specifications
D. All other tests in part 4732.1000 if applicable	At intervals not to exceed 24 months	See criteria in subpart 4
E. Spatial plane resolution	At intervals not to exceed 12 months	40 mesh screen or better

Subp. 9. **For facilities with computed tomography scanners.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Accuracy of scout localization view	At intervals not to exceed 12 months	± 1 millimeters
B. Accuracy of distance measurements	At intervals not to exceed 12 months	± 1 millimeters
C. CT dose index	At intervals not to exceed 12 months	± 20% from manufacturer's recommendations
D. CT number dependence on slice thickness	At intervals not to exceed 12 months	Mean ± 3 CT numbers averaged over 100 pixels

E. CT number calibration and noise	Daily	Water: 0 ± 5 CT numbers; Noise: ± 3 standard deviations of the mean of the baseline noise variance measurements
F. CT number uniformity and artifacts	Monthly for mobile units. At intervals not to exceed 12 months for fixed base units.	Variation ± 5 CT numbers between the mean values of measurements made at center and edge of phantom that is at least 20 cm. In diameter among a mean of 100 pixels. Artifacts: no noticeable artifacts
G. Hard copy output and visual display	Daily	Luminance and contrast not significantly different
H. Table indexing	At intervals not to exceed six months	± 0.5 millimeter for each increment
I. Table backlash	At intervals not to exceed six months	± one millimeter

Subp. 10. **For facilities with cinefluorographic and special procedure systems.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Cinefluorographic exposure rates	At intervals not to exceed 12 months	Approximately 10 to 20 μR (2.6 to 5.0 nC/kg) per frame at intensifier for nine inch (23 cm) mode; approximately 20 to 30 μR (5 to 8 nC/kg) per frame at intensifier for six inch (15 cm) mode
B. All tests in subparts 4, 5, and 6, if applicable	At intervals not to exceed 24 months	See criteria in subparts 4, 5, and 6

C. Film changer screen-film contact	At intervals not to exceed 24 months	No significant areas of poor contact as measured by no less than: (1) 8 wire per inch mesh; or (2) 7 holes per inch
D. High contrast resolution for cinefluorographic and digital systems	At intervals not to exceed 12 months	No significant difference between static and dynamic conditions
E. Optical density of films over duration of filming run	At intervals not to exceed 12 months	< ± 0.2 O.D. difference

Subp. 11. **For facilities with dental intraoral systems.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Film processing	Before the first film of the day	Between 0.75 and 1.05 O.D. on the test tool or follow test tool manufacturer's recommendations
B. Fog test	At intervals not to exceed six months	Unable to visualize coin edges
C. Filtration (HVL)	At intervals not to exceed 24 months	Meet requirements in part 4732.0800
D. Radiation exposure at the end of cone	At intervals not to exceed 24 months	Meet requirements in part 4732.0825
E. Timer reproducibility	At intervals not to exceed 24 months	± 10% of indicated timer setting
F. kVp accuracy	At intervals not to exceed 24 months	± 5% of indicated kVp for equipment manufactured before 1973. For equipment manufactured after 1973, follow manufacturer's specified limits

G. Exposure output reproducibility	At intervals not to exceed 24 months	Coefficient of variation < 5%
H. Dental mA linearity	At intervals not to exceed 24 months	± 10% over the clinical range

Subp. 12. **For facilities with dental extraoral systems including panoramic systems.**

TEST TYPE	MINIMUM TEST INTERVAL	MINIMUM PERFORMANCE CRITERIA
A. Film processing	Before the first film of the day	Use processing as specified in subpart 3. A step wedge may be used. ± one step from standard allowed
B. Fog test	At intervals not to exceed six months	Use criteria in subpart 3, item A, for automatic processing; subpart 4, item A, for manual processing
C. Same test types and minimum performance criteria as in diagnostic radiographic tubes in subpart 4	At intervals not to exceed 24 months	See criteria in subpart 4

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