

4732.1120 THERAPEUTIC EQUIPMENT PERFORMANCE TESTS AND LIMITS FOR MEASUREMENT EQUIPMENT.

Subpart 1. Required tests.

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 892, or 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 compliance with a nationally recognized standard, such as Code of Federal Regulations, title 21, section 892, or manufacturer's specifications and to ensure compliance with this chapter prior to using the equipment again.

Subp. 2. Local standard (Loc. Std.) instrument.

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. AAPM - accredited dosimetry calibration laboratory calibration	Intercomparison every 12 months At intervals not to exceed 24 months traceable to NIST Standard	Documented and correction applied or noted in report of measurement when appropriate
B. Linearity	At intervals not to exceed 48 months	0.5 percent
C. Venting	At intervals not to exceed 48 months	Documented and correction applied
D. Extracameral signal	Initial use	0.5 percent
E. Leakage	Each use	0.1 percent
F. Recombination	Initial use	Documented and correction applied
G. Collecting potential	Each use	Documented and correction applied

Subp. 3. Other field instruments.

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Local standard comparison	At intervals not to exceed 24 months	1 percent
B. Linearity	At intervals not to exceed 24 months	Documented and correction applied
C. Venting	At intervals not to exceed 24 months	Documented and correction applied
D. Extracameral signal	At intervals not to exceed 24 months	Documented and correction applied
E. Leakage	Each use	1 percent
F. Recombination	Initial use	Documented and correction applied
G. Collecting potential	Each use	Documented and correction applied

Subp. 4. **Relative dosimetry equipment.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Thermoluminescent Dosimeter		
(1) Calibration	Each batch or box	Documented and correction applied
(2) Linearity	Initial use	Documented and correction applied
B. Film		
(1) Dose and response	Each batch or box	Documented and correction applied
(2) Densitometer linearity	At intervals not to exceed 12 months	Documented and correction applied
C. Air ionization chamber system		

(1) Linearity	At intervals not to exceed 12 months	Documented and correction applied
(2) Extracameral signal	Initial use	1 percent
D. Diode system		
(1) Energy dependence	Initial use	Documented and correction applied
(2) Extracameral signal	Initial use	Documented and correction applied
(3) Linearity	Initial use	Documented and correction applied

Subp. 5. **Radiation survey instruments.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Calibration	At intervals not to exceed 12 months	Documented and correction applied
B. Linearity	At intervals not to exceed 12 months	Documented and correction applied
C. Constancy	Each use	5 percent

Subp. 6. **Positioning equipment lasers.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Accuracy	Daily before patient use	2 mm
B. Hysteresis	Each use	2 mm

Subp. 7. **Phantoms and attenuators.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Thickness	Initial use	Documented and correction applied

B. Density	Initial use	Documented and correction applied
C. Phantom stacked density	Initial use	Documented and correction applied
D. Detector fit	Initial use	Documented and correction applied

Subp. 8. **Accessory equipment.**

TEST TYPE	MINIMUM TEST INTERVAL	TOLERANCE
A. Thermometer calibration	Initial use	0.1 degree/C
B. Barometer (aneroid)		
(1) Calibration Hg	Initial use	1 mm Hg
(2) Intercomparison	At intervals not to exceed 12 months	1 mm Hg

Statutory Authority: *MS s 144.12*

History: *32 SR 777*

Published Electronically: *December 10, 2007*