The Joint Commission recently approved a revision to “Waived Testing” (WT) Standard WT.04.01.01, Element of Performance (EP) 4, addressing quality control checks for instrument-based waived testing in the ambulatory care, behavioral health care, home care, hospital, laboratory, long term care, Medicare/Medicaid certification–based long term care, and office-based surgery accreditation programs. Effective immediately, the revised EP 4 no longer requires organizations to perform quality control checks on each day of testing. Organizations are now required to perform quality control checks per manufacturers’ instructions for instrument-based waived testing.

As described in the Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) at 42 CFR 493.15(e)(1), laboratories performing only waived tests are expected to follow manufacturers’ instructions for performing the test (including its quality control). Prior to the revision, Standard WT.04.01.01, EP 4, was more rigorous than CLIA ’88, requiring laboratories to perform quality control checks each day an instrument was used for testing. Customer feedback in multiple accreditation programs indicated that EP 4 was burdensome, and no evidence has been identified to demonstrate that the performance of quality control checks beyond manufacturers’ instructions leads to increased quality and safety. The revised EP 4 aligns Joint Commission requirements with the current CLIA ’88 requirement and decreases undue burden on the field.

The language for the revised EP is provided below. Deletions are noted in strikethrough. These changes will appear in the 2012 Update 2 to the Comprehensive Accreditation Manuals for the applicable accreditation programs, scheduled for publication in fall 2012, as well as in the E-dition® update scheduled for release in October.

For more information, contact Christina Cordero, PhD, MPH, associate project director, Department of Standards and Survey Methods, at ccordero@jointcommission.org.