**APPROVED: Revision for Laboratory Procedure Review**

The Joint Commission recently approved a revision to Quality System Assessment for Nonwaived Testing (QSA) Standard QSA.05.01.01, Element of Performance (EP) 4, addressing how frequently policies and procedures of blood transfusion services are reviewed for the laboratory accreditation program. Effective immediately, the revised requirement allows the blood transfusion service director or technical supervisor to review blood transfusion policies and procedures every two years instead of annually.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA ’88) at 42 CFR §493.1251(d) states: “Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.” While this CLIA requirement is effectively represented at Leadership (LD) Standard LD.04.05.09, EP 2 (“The laboratory director signs and dates new laboratory procedures or changes in laboratory procedures before they are implemented”), CLIA does not require an annual review of unchanged laboratory procedures. Before its revision, Standard QSA.05.01.01, EP 4, was more rigorous than the CLIA standard in that it required the blood transfusion service director or an individual qualified as a technical supervisor in immunohematology to annually review all policies and procedures of the blood transfusion service. Customer feedback indicated that the increasing number of procedures requiring evaluation made Standard QSA.05.01.01, EP 4, burdensome. The revised requirement will decrease undue burden to the field and align with federal CLIA requirements that allow for a biennial review of unchanged procedures.

The box below displays the revised EP; new text is underlined and deletions are shown in strikethrough. These changes will appear in the 2013 Update 2 to the Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing (CAMLAB) and 2014 CAMLAB as well as the fall E-dition® update for laboratories. Questions may be directed to Christina Cordero, PhD, MPH, associate project director, Department of Standards and Survey Methods, at ccordero@jointcommission.org.


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**Official Publication of Joint Commission Requirements**

**Revision to Requirement for Laboratory Procedure Review**

**APPLICABLE TO LABORATORIES**

**Effective immediately**

**Quality System Assessment for Nonwaived Testing (QSA)**

**Standard QSA.05.01.01**

The laboratory has written policies and procedures for the blood transfusion service.

**Element of Performance for QSA.05.01.01**

A 4. © The blood transfusion service director or an individual qualified as a technical supervisor in immunohematology* conducts an annual review of the policies and procedures of the blood transfusion service every two years. The annual review is documented.

**Note:** A designee is not permitted to conduct this review.