CLSI Documents and ISO Quality Documents

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CLSI Documents and ISO Quality Documents

	CLSI QSE: Organization		
	ISO 15189:2012 Clause(s)	**ISO 17025:2017 Clause(s)**	**ISO 9001:2015 Clause(s)**
Related CLSI Documents	4.1 Organization and management responsibility 4.2 Quality management system 4.15 Management review	8 Management system requirements 8.9 Management reviews	4.4 Quality management system and its processes 5.1 Leadership and commitment 5.2 Policy 5.3 Organizational roles, responsibilities, and authorities 6 Planning 7.1 Resources 9.3 Management review
Quality Management Systems*			
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*		
QMS14-A	*Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline*		
Automation and Informatics			
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*		
Molecular Methods			
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*		
MM20-A	*Quality Management for Molecular Genetic Testing; Approved Guideline*		
Point-of-Care Testing			
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of-Care Testing Program, Third Edition*		
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*		

Abbreviations: ISO, International Organization for Standardization; QSE, quality system essential.

*The Quality Management Systems documents listed on this page are the foundational documents that relate specifically to QSE: Organization.

Related CLSI Documents	CLSI QSE: Customer Focus		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	4.7 Advisory services		5.1.2 Customer focus 9.1.2 Customer satisfaction
Quality Management Systems*			
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*		
Automation and Informatics			
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*		
Immunology and Ligand Assay			
I/LA23-A	*Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guideline*		
Molecular Methods			
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*		
MM20-A	*Quality Management for Molecular Genetic Testing; Approved Guideline*		
Point-of-Care Testing			
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*		

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Related CLSI Documents	CLSI QSE: Facilities and Safety		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.2 Accommodation and environmental conditions	6.3 Facilities and Environmental Conditions	7.1.3 Infrastructure 7.1.4 Environment for the operation of processes
Quality Management Systems*			
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*		
QMS04-Ed3	*Laboratory Design, Third Edition*		
GP05-A3	*Clinical Laboratory Waste Management; Approved Guideline—Third Edition*		
GP17-A3	*Clinical Laboratory Safety; Approved Guideline—Third Edition*		
Automation and Informatics			
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*		
Immunology and Ligand Assay			
I/LA21-A2	*Clinical Evaluation of Immunoassays; Approved Guideline—Second Edition*		
Microbiology			
M29-A4	*Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*		
M36-A	*Clinical Use and Interpretation of Serologic Tests for* Toxoplasma gondii; *Approved Guideline*		
M43-A	*Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas; Approved Guideline*		
M48-A	*Laboratory Detection and Identification of Mycobacteria; Approved Guideline*		
M54-A	*Principles and Procedures for Detection of Fungi in Clinical Specimens—Direct Examination and Culture; Approved Guideline*		
Molecular Methods			
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*		
MM20-A	*Quality Management for Molecular Genetic Testing; Approved Guideline*		
Point-of-Care Testing			
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of Care Testing Program, Third Edition*		
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*		

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*The Quality Management Systems documents listed on this page are the foundational documents that relate specifically to QSE: Facilities and Safety.

Related CLSI Documents	CLSI QSE: Personnel		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.1 Personnel	6.2 Personnel	7.1.2 People
Quality Management Systems*			
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*		
QMS03-Ed4	*Training and Competence Assessment, Fourth Edition*		
Automation and Informatics			
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*		
Molecular Methods			
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*		
MM20-A	*Quality Management for Molecular Genetic Testing; Approved Guideline*		
Point-of-Care Testing			
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of-Care Testing Program, Third Edition*		
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*		
POCT10-A2	*Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition*		
POCT12-A3	*Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition*		
POCT13-Ed3	*Glucose Monitoring in Settings Without Laboratory Support, Third Edition*		

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*The Quality Management Systems documents listed on this page are the foundational documents that relate specifically to QSE: Personnel.

Related CLSI Documents	CLSI QSE: Purchasing and Inventory		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	4.4 Service agreements 4.5 Examination by referral laboratories 4.6 External services and supplies	6.6 Externally provided products and services 7.1 Review of requests, tenders, and contracts	8.4 Control of externally provided processes, products and services
Quality Management Systems*			
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*		
QMS05-A2	*Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory; Approved Guideline—Second Edition*		
Automation and Informatics			
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*		
Immunology and Ligand Assay			
I/LA21-A2	*Clinical Evaluation of Immunoassays; Approved Guideline—Second Edition*		
Molecular Methods			
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*		
Point-of-Care Testing			
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition*		
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*		
POCT09-A	*Selection Criteria for Point-of-Care Testing Devices; Approved Guideline*		

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*The Quality Management Systems documents listed on this page are the foundational documents that relate specifically to QSE: Purchasing and Inventory.

Related CLSI Documents	CLSI QSE: Equipment		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.3 Laboratory equipment, reagents, and consumables	6.4 Equipment	7.1.5 Monitoring and measuring resources
Quality Management Systems*			
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*		
QMS13-A	*Quality Management System: Equipment; Approved Guideline*		
Automation and Informatics			
AUTO01-A	*Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard*		
AUTO02-A2	*Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition*		
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*		
Hematology			
H42-A2	*Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline—Second Edition*		
H43-A2	*Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline—Second Edition*		
H57-A	*Protocol for the Evaluation, Validation, and Implementation of Coagulometers; Approved Guideline*		
Immunology and Ligand Assay			
I/LA21-A2	*Clinical Evaluation of Immunoassays; Approved Guideline—Second Edition*		
I/LA33-A	*Validation of Automated Systems for Immunohematological Testing Before Implementation; Approved Guideline*		
Molecular Methods			
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*		
Newborn Screening			
NBS04-Ed2	*Newborn Screening by Tandem Mass Spectrometry, Second Edition*		

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*The Quality Management Systems documents listed on this page are the foundational documents that relate specifically to QSE: Equipment.

Related CLSI Documents	CLSI QSE: Equipment (Continued)		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.3 Laboratory equipment, reagents, and consumables	6.4 Equipment	7.1.5 Monitoring and measuring resources
Point-of-Care Testing			
POCT02-A	*Implementation Guide of POCT01 for Health Care Providers; Approved Guideline*		
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of-Care Testing Program, Third Edition*		
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*		
POCT09-A	*Selection Criteria for Point-of-Care Testing Devices; Approved Guideline*		
POCT10-A2	*Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition*		
POCT13-Ed3	*Glucose Monitoring in Settings Without Laboratory Support, Third Edition*		

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Related CLSI Documents	CLSI QSE: Process Management		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision

Quality Management Systems*	
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*
Automation and Informatics	
AUTO02-A2	*Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition*
AUTO08-A	*Managing and Validating Laboratory Information Systems; Approved Guideline*
AUTO09-A	*Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Approved Standard*
AUTO10-A	*Autoverification of Clinical Laboratory Test Results; Approved Guideline*
AUTO11-Ed2	*IT Security of* In Vitro *Diagnostic Instruments and Software Systems, Second Edition*
AUTO12-A	*Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard*
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*
LIS01-A2	*Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition*
LIS02-A2	*Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition*
LIS04-A	*Standard Guide for Documentation of Clinical Laboratory Computer Systems*

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*The Quality Management Systems documents listed on this page are the foundational documents that relate specifically to QSE: Process Management.

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision
Clinical Chemistry and Toxicology			
C52-Ed3	*Toxicology and Drug Testing in the Medical Laboratory, Third Edition*		
C56-A	*Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis; Approved Guideline*		
C58-A	*Assessment of Fetal Lung Maturity by the Lamellar Body Count; Approved Guideline*		
General Laboratory			
GP15-A3	*Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline—Third Edition*		
GP16-A3	*Urinalysis; Approved Guideline—Third Edition*		
GP20-A2	*Fine-Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition*		
GP23-Ed2	*Nongynecological Cytology Specimens: Preexamination, Examination, and Postexamination Processes, Second Edition*		
GP33-A	*Accuracy in Patient and Sample Identification; Approved Guideline*		
GP34-A	*Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection; Approved Guideline*		
GP39-A6	*Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard—Sixth Edition*		
GP41-Ed7	*Collection of Diagnostic Venous Blood Specimens, Seventh Edition*		
GP42-A6	*Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Sixth Edition*		
GP44-A4	*Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline—Fourth Edition*		

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CLSI QSE: Process Management (Continued)		
ISO 15189:2012 Clause(s)	**ISO 17025:2017 Clause(s)**	**ISO 9001:2015 Clause(s)**
5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision

Related CLSI Documents	
Hematology	
H02-A5	*Procedures for the Erythrocyte Sedimentation Rate Test; Approved Standard—Fifth Edition*
H07-A3	*Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard—Third Edition*
H15-A3	*Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition*
H20-A2	*Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard—Second Edition*
H21-A5	*Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline—Fifth Edition*
H26-A2	*Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition*
H30-A2	*Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—Second Edition*
H42-A2	*Enumeration of Immunologically Defined Cell Populations by Flow Cytometry; Approved Guideline—Second Edition*
H43-A2	*Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells; Approved Guideline—Second Edition*
H47-A2	*One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline—Second Edition*
H52-A2	*Red Blood Cell Diagnostic Testing Using Flow Cytometry; Approved Guideline—Second Edition*
H54-A	*Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline*
H56-A	*Body Fluid Analysis for Cellular Composition; Approved Guideline*
H57-A	*Protocol for the Evaluation, Validation, and Implementation of Coagulometers; Approved Guideline*

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Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision
Hematology (Continued)			
H58-A	*Platelet Function Testing by Aggregometry; Approved Guideline*		
H59-A	*Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline*		
H60-A	*Laboratory Testing for the Lupus Anticoagulant; Approved Guideline*		
Immunology and Ligand Assay			
I/LA02-A2	*Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens: (1) Indirect Fluorescence Assay for Microscopy and (2) Microtiter Enzyme Immunoassay Methods; Approved Guideline—Second Edition*		
I/LA20-Ed3	*Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities, Third Edition*		
I/LA21-A2	*Clinical Evaluation of Immunoassays; Approved Guideline—Second Edition*		
I/LA23-A	*Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guideline*		
I/LA25-A2	*Maternal Serum Screening; Approved Standard—Second Edition*		
I/LA26-A2	*Performance of Single Cell Immune Response Assays; Approved Guideline—Second Edition*		
I/LA28-A2	*Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays; Approved Guideline—Second Edition*		
I/LA29-A	*Detection of HLA-Specific Alloantibody by Flow Cytometry and Solid Phase Assays; Approved Guideline*		
I/LA30-A	*Immunoassay Interference by Endogenous Antibodies; Approved Guideline*		

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Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision
Immunology and Ligand Assay (Continued)			
I/LA33-A	*Validation of Automated Systems for Immunohematological Testing Before Implementation; Approved Guideline*		
I/LA34-A	*Design and Validation of Immunoassays for Assessment of Human Allergenicity of New Biotherapeutic Drugs; Approved Guideline*		
Method Evaluation			
EP05-A2	*Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition*		
EP06-A	*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*		
EP07-A2	*Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition*		
EP09-A3	*Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*		
EP10-A3-AMD	*Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline—Third Edition*		
EP12-A2	*User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition*		
EP14-Ed3	*Evaluation of Commutability of Processed Samples, Third Edition*		
EP15-Ed3	*User Verification of Precision and Estimation of Bias, Third Edition*		
EP17-A2	*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*		
EP18-A2	*Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition*		
EP19-R	*A Framework for NCCLS Evaluation Protocols; A Report*		
EP21-A	*Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline*		

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Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision
Method Evaluation (Continued)			
EP23-A	*Laboratory Quality Control Based on Risk Management; Approved Guideline*		
EP24-A2	*Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline—Second Edition*		
EP25-A	*Evaluation of Stability of* In Vitro *Diagnostic Reagents; Approved Guideline*		
EP26-A	*User Evaluation of Between-Reagent Lot Variation; Approved Guideline*		
EP27-A	*How to Construct and Interpret an Error Grid for Quantitative Diagnostic Assays; Approved Guideline*		
EP30-A	*Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine; Approved Guideline*		
EP31-A-IR	*Verification of Comparability of Patient Results Within One Health Care System; Approved Guideline (Interim Revision)*		
EP32-R	*Metrological Traceability and Its Implementation; A Report*		
Microbiology			
M02-Ed13	*Performance Standards for Antimicrobial Disk Susceptibility Tests, Thirteenth Edition*		
M07-Ed11	*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, Eleventh Edition*		
M11-Ed9	*Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria, 9th Edition*		
M15-A	*Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline*		
M22-A3	*Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition*		

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Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision
Microbiology (Continued)			
M23-Ed5	*Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters, Fifth Edition*		
M24-Ed3	*Susceptibility Testing of Mycobacteria,* Nocardia *spp., and Other Aerobic Actinomycetes, 3rd Edition*		
M26-A	*Methods for Determining Bactericidal Activity of Antimicrobial Agents; Approved Guideline*		
M27-A4	*Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts, Fourth Edition*		
M28-A2	*Procedures for the Recovery and Identification of Parasites From the Intestinal Tract; Approved Guideline—Second Edition*		
M29-A4	*Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition*		
M34-A	*Western Blot Assay for Antibodies to* Borrelia burgdorferi; *Approved Guideline*		
M35-A2	*Abbreviated Identification of Bacteria and Yeast; Approved Guideline—Second Edition*		
M36-A	*Clinical Use and Interpretation of Serologic Tests for* Toxoplasma gondii; *Approved Guideline*		
M38-Ed3	*Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi, Third Edition*		
M39-A4	*Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data; Approved Guideline—Fourth Edition*		
M40-Ed2	*Quality Control of Microbiological Transport Systems, Second Edition*		
M41-A	*Viral Culture; Approved Guideline*		
M43-A	*Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas; Approved Guideline*		
M44-Ed3	*Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts, 3rd Edition*		

Abbreviations: ISO, International Organization for Standardization; QSE, quality system essential.

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision
Microbiology (Continued)			
M45-Ed3	*Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline—Second Edition*		
M47-A	*Principles and Procedures for Blood Cultures; Approved Guideline*		
M48-Ed2	*Laboratory Detection and Identification of Mycobacteria, 2nd Edition*		
M50-A	*Quality Control for Commercial Microbial Identification Systems; Approved Guideline*		
M51-A	*Method for Antifungal Disk Diffusion Susceptibility Testing of Nondermatophyte Filamentous Fungi; Approved Guideline*		
M53-A	*Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection; Approved Guideline*		
M54-A	*Principles and Procedures for Detection of Fungi in Clinical Specimens—Direct Examination and Culture; Approved Guideline*		
M60-Ed1	*Performance Standards for Antifungal Susceptibility Testing of Yeasts, First Edition*		
M62-Ed1	*Performance Standards for Susceptibility Testing of Mycobacteria,* Nocardia *spp., and Other Aerobic Actinomycetes, 1st Edition*		
M100-Ed29	*Performance Standards for Antimicrobial Susceptibility Testing, Twenty-Ninth Edition*		
Molecular Methods			
MM01-A3	*Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline—Third Edition*		
MM03-Ed3	*Molecular Diagnostic Methods for Infectious Diseases, Third Edition*		
MM05-A2	*Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline—Second Edition*		
MM06-A2	*Quantitative Molecular Methods for Infectious Diseases; Approved Guideline—Second Edition*		

Abbreviations: ISO, International Organization for Standardization; QSE, quality system essential.

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision

Molecular Methods (Continued)	
MM07-A2	*Fluorescence* In Situ *Hybridization Methods for Clinical Laboratories; Approved Guideline—Second Edition*
MM09-A2	*Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline—Second Edition*
MM10-A	*Genotyping for Infectious Diseases: Identification and Characterization; Approved Guideline*
MM11-A	*Molecular Methods for Bacterial Strain Typing; Approved Guideline*
MM12-A	*Diagnostic Nucleic Acid Microarrays; Approved Guideline*
MM13-A	*Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline*
MM14-A2	*Design of Molecular Proficiency Testing/External Quality Assessment; Approved Guideline—Second Edition*
MM17-Ed2	*Validation and Verification of Multiplex Nucleic Acid Assays, Second Edition*
MM18-Ed2	*Interpretive Criteria for Identification of Bacteria and Fungi by Targeted DNA Sequencing, Second Edition*
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*
MM20-A	*Quality Management for Molecular Genetic Testing; Approved Guideline*
MM22-A	*Microarrays for Diagnosis and Monitoring of Infectious Diseases; Approved Guideline*

Abbreviations: ISO, International Organization for Standardization; QSE, quality system essential.

CLSI QSE: Process Management (Continued)		
ISO 15189:2012 Clause(s)	**ISO 17025:2017 Clause(s)**	**ISO 9001:2015 Clause(s)**
5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision

Related CLSI Documents	
Newborn Screening	
NBS01-A6	*Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Sixth Edition*
NBS02-A2	*Newborn Screening Follow-up; Approved Guideline—Second Edition*
NBS03-A	*Newborn Screening for Preterm, Low Birth Weight, and Sick Newborns; Approved Guideline*
NBS04-Ed2	*Newborn Screening by Tandem Mass Spectrometry, Second Edition*
NBS05-A	*Newborn Screening for Cystic Fibrosis; Approved Guideline*
NBS06-A	*Newborn Blood Spot Screening for Severe Combined Immunodeficiency by Measurement of T-cell Receptor Excision Circles; Approved Guideline*
Point-of-Care Testing	
POCT02-A	*Implementation Guide of POCT01 for Health Care Providers; Approved Guideline*
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of-Care Testing Program, Third Edition*
POCT05-A	*Performance Metrics for Continuous Interstitial Glucose Monitoring; Approved Guideline*
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*
POCT08-A	*Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline*
POCT09-A	*Selection Criteria for Point-of-Care Testing Devices; Approved Guideline*
POCT10-A2	*Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition*

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Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.4 Pre-examination processes 5.5 Examination processes 5.6 Ensuring quality of examination results 5.7 Post-examination processes 5.8 Reporting results 5.9 Releasing results	7 Process requirements 7.2.2 Validation of Methods Annex A Metrological Traceability 7.3 Sampling 7.4 Handling of test or calibration items 7.7 Ensuring the validity of results 7.8 Reporting of results	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and Development of Products and Services 8.5 Production and service provision
Point-of-Care Testing (Continued)			
POCT12-A3	*Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition*		
POCT13-Ed3	*Glucose Monitoring in Settings Without Laboratory Support, Third Edition*		
POCT14-A	*Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline*		
Veterinary Medicine			
VET01-Ed5	*Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals, Fifth Edition*		
VET02-A3	*Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters for Veterinary Antimicrobial Agents; Approved Guideline—Third Edition*		
VET03-A	*Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline*		
VET04-A	*Methods for Broth Dilution Susceptibility Testing of Bacteria Isolated From Aquatic Animals; Approved Guideline*		
VET03/VET04-Ed2	*Performance Standards for Antimicrobial Susceptibility Testing of Bacteria Isolated From Aquatic Animals, Second Edition*		
VET05-R	*Generation, Presentation, and Application of Antimicrobial Susceptibility Test Data for Bacteria of Animal Origin; A Report*		

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CLSI QSE: Documents and Records			
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
Related CLSI Documents	4.3 Document control 4.13 Control of records	7.5 Technical records 7.11 Control of data and information management 8.3. Control of management system documents (Option A) 8.4 Control of records (Option A)	7.5 Documented information
Quality Management Systems*			
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*		
QMS02-A6	*Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition*		
Automation and Informatics			
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*		
Immunology and Ligand Assay			
I/LA21-A2	*Clinical Evaluation of Immunoassays; Approved Guideline—Second Edition*		
I/LA33-A	*Validation of Automated Systems for Immunohematological Testing Before Implementation; Approved Guideline*		
Microbiology			
M07-Ed11	*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, Eleventh Edition*		
Molecular Methods			
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*		
MM20-A	*Quality Management for Molecular Genetic Testing; Approved Guideline*		
Point-of-Care Testing			
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*		
POCT10-A2	*Physician and Nonphysician Provider-Performed Microscopy Testing; Approved Guideline—Second Edition*		
POCT12-A3	*Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Third Edition*		
POCT13-Ed3	*Glucose Monitoring in Settings Without Laboratory Support, Third Edition*		

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*The Quality Management Systems documents listed on this page are the foundational documents that relate specifically to QSE: Documents and Records.

Related CLSI Documents	CLSI QSE: Information Management		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.10 Laboratory information management	7.11 Control of data and information management	7.5 Documented information
Quality Management Systems*			
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*		
Automation and Informatics			
AUTO03-A2	*Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition*		
AUTO04-A	*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard*		
AUTO05-A	*Laboratory Automation: Electromechanical Interfaces; Approved Standard*		
AUTO07-A	*Laboratory Automation: Data Content for Specimen Identification; Approved Standard*		
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*		
LIS01-A2	*Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition*		
LIS02-A2	*Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard—Second Edition*		
Immunology and Ligand Assay			
I/LA21-A2	*Clinical Evaluation of Immunoassays; Approved Guideline—Second Edition*		
Molecular Methods			
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*		
MM20-A	*Quality Management for Molecular Genetic Testing; Approved Guideline*		
Point-of-Care Testing			
POCT01-A2	*Point-of-Care Connectivity; Approved Standard—Second Edition*		
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*		

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*The Quality Management Systems documents listed on this page are the foundational documents that relate specifically to QSE: Information Management.

Related CLSI Documents	CLSI QSE: Nonconforming Event Management		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	4.8 Resolution of complaints 4.9 Identification and control of nonconformities 4.10 Corrective action	7.9 Complaints 7.10 Nonconforming work 8.7 Corrective actions (Option A)	8.7 Control of nonconforming outputs

Quality Management Systems*	
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*
QMS11-Ed2	*Nonconforming Event Management, Second Edition*
Automation and Informatics	
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*
Method Evaluation	
EP18-A2	*Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition*
Molecular Methods	
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*
MM20-A	*Quality Management for Molecular Genetic Testing; Approved Guideline*
Point-of-Care Testing	
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*

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*The Quality Management Systems documents listed on this page are the foundational documents that relate specifically to QSE: Nonconforming Even Management.

	CLSI QSE: Assessments		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
Related CLSI Documents	4.11 Preventive action 4.14 Evaluation and audits	8.5 Actions to address risks and opportunities (Option A) 8.8 Internal audits (Option A)	5.1.1 General 9.1 Monitoring, measurement, analysis and evaluation 9.1.3 Analysis and evaluation8.4 Analysis of data
Quality Management Systems*			
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*		
QMS15-A	*Assessments: Laboratory Internal Audit Program; Approved Guideline*		
QMS24-Ed3	*Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality, 3rd Edition*		
Hematology			
H57-A	*Protocol for the Evaluation, Validation, and Implementation of Coagulometers; Approved Guideline*		
Immunology and Ligand Assay			
I/LA21-A2	*Clinical Evaluation of Immunoassays; Approved Guideline—Second Edition*		
I/LA25-A2	*Maternal Serum Screening; Approved Standard—Second Edition*		
Method Evaluation			
EP10-A3-AMD	*Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline—Third Edition*		
EP18-A2	*Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition*		
Molecular Methods			
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*		
MM20-A	*Quality Management for Molecular Genetic Testing; Approved Guideline*		
Point-of-Care Testing			
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*		
POCT09-A	*Selection Criteria for Point-of-Care Testing Devices; Approved Guideline*		

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*The Quality Management Systems and General Laboratory documents listed on this page are the foundational documents that relate specifically to QSE: Assessments.

Related CLSI Documents	CLSI QSE: Continual Improvement		
	ISO 15189:2012 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	4.12 Continual improvement	8.6 Improvement (Option A)	10 Improvement
Quality Management Systems*			
QMS01-A4	*Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition*		
QMS12-A	*Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline*		
QMS06-A3	*Quality Management System: Continual Improvement; Approved Guideline—Third Edition*		
Automation and Informatics			
AUTO13-A2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition*		
Hematology			
H26-A2	*Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition*		
Immunology and Ligand Assay			
I/LA21-A2	*Clinical Evaluation of Immunoassays; Approved Guideline—Second Edition*		
I/LA25-A2	*Maternal Serum Screening; Approved Standard—Second Edition*		
Method Evaluation			
EP18-A2	*Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition*		
Molecular Methods			
MM19-A	*Establishing Molecular Testing in Clinical Laboratory Environments; Approved Guideline*		
MM20-A	*Quality Management for Molecular Genetic Testing; Approved Guideline*		
Point-of-Care Testing			
POCT07-A	*Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline*		

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*The Quality Management Systems documents listed on this page are the foundational documents that relate specifically to QSE: Continual Improvement.

ISO Document Titles	
ISO 15189:2012	*Medical laboratories -- Requirements for quality and competence*
ISO 17025:2017	*General requirements for the competence of testing and calibration laboratories*
ISO 9001:2015	*Quality management systems -- Requirements*

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