CLSI Documents and ISO Quality Documents

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CLSI Documents and ISO Quality Documents

This crosswalk shows how CLSI quality system essentials (QSE) correspond with clauses in ISO quality documents. The ISO quality documents are listed along with the related CLSI documents under each QSE.

To see the full titles of all CLSI document codes included in this crosswalk or to purchase those documents, visit **clsi.org/accreditation.**

CLSI Documents and ISO Quality Documents

	CLSI QSE: Organization		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
Related CLSI Documents	4 General requirements 5 Structural and governance requirements 8 Management system requirements 8.9 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-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*		
QMS14-Ed1	*Quality Management System: Leadership and Management Roles and Responsibilities, 1st Edition*		
QMS20-Ed2	*The Cost of Quality in Medical Laboratories, 2nd Edition*		
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*		
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*		
Automation and Informatics			
AUTO13-Ed2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring, 2nd Edition*		
Preexamination			
GP45-Ed1	*Studies to Evaluate Patient Outcomes, 1st Edition*		
Molecular Methods			
MM19-Ed1	*Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*		
MM20-Ed1	*Quality Management for Molecular Genetic Testing, 1st Edition*		
Point-of-Care Testing			
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition*		
POCT07-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*		

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 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.3.3 Advisory activities		5.1.2 Customer focus 9.1.2 Customer satisfaction
Quality Management Systems*			
QMS01-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*		
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*		

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: Customer Focus.

Related CLSI Documents	CLSI QSE: Facilities and Safety		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	6.3 Facilities and environmental conditions 6.3.1 General 6.3.3 Storage facilities 6.3.4 Personnel facilities 6.3.5 Sample collection facilities 6.3.2 Facility controls	6.3 Facilities and Environmental Conditions	7.1.3 Infrastructure 7.1.4 Environment for the operation of processes
Quality Management Systems*			
QMS01-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*		
QMS04-Ed3	*Laboratory Design, 3rd Edition*		
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*		
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*		
GP05-Ed3	*Clinical Laboratory Waste Management, 3rd Edition*		
GP17-Ed3	*Clinical Laboratory Safety, 3rd Edition*		
Automation and Informatics			
AUTO13-Ed2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring, 2nd Edition*		
Hematology, Immunology, and Ligand Assay			
I/LA23-Ed1	*Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays, 1st Edition*		
Preexamination			
GP36-Ed1	*Planning for Laboratory Operations During a Disaster, 1st Edition*		
GP45-Ed1	*Studies to Evaluate Patient Outcomes, 1st Edition*		
Microbiology			
M29-Ed4	*Protection of Laboratory Workers From Occupationally Acquired Infections, 4th Edition*		
M36-Ed1	*Clinical Use and Interpretation of Serologic Tests for* Toxoplasma gondii, *1st Edition*		
M48-Ed2	*Laboratory Detection and Identification of Mycobacteria, 2nd Edition*		
M54-Ed2	*Principles and Procedures for Detection of Fungi in Clinical Specimens—Direct Examination and Culture, 2nd Edition*		

CLSI QSE: Facilities and Safety (Continued)			
Related CLSI Documents	**ISO 15189:2022 Clause(s)**	**ISO 17025:2017 Clause(s)**	**ISO 9001:2015 Clause(s)**
	6.3 Facilities and environmental conditions 6.3.1 General 6.3.3 Storage facilities 6.3.4 Personnel facilities 6.3.5 Sample collection facilities 6.3.2 Facility controls	6.3 Facilities and Environmental Conditions	7.1.3 Infrastructure 7.1.4 Environment for the operation of processes
Molecular Methods			
MM13-Ed2	*Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods, 2nd Edition*		
MM19-Ed1	*Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*		
MM20-Ed1	*Quality Management for Molecular Genetic Testing, 1st Edition*		
Clinical Chemistry and Toxicology			
C34-Ed4	*Sweat Testing: Specimen Collection and Quantitative Chloride Analysis, 4th Edition*		
Point-of-Care Testing			
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of Care Testing Program, 3rd Edition*		
POCT07-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*		

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

Related CLSI Documents	CLSI QSE: Personnel		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	6.2 Personnel	6.2 Personnel	7.1.2 People
Quality Management Systems*			
QMS01-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*		
QMS03-Ed4	*Training and Competence Assessment, 4th Edition*		
QMS16-Ed1	*Laboratory Personnel Management, 1st Edition*		
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*		
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*		
Automation and Informatics			
AUTO13-Ed2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring, 2nd Edition*		
Hematology, Immunology, and Ligand Assay			
I/LA23-Ed1	*Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays, 1st Edition*		
Preexamination			
GP45-Ed1	*Studies to Evaluate Patient Outcomes, 1st Edition*		
Molecular Methods			
MM19-Ed1	*Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*		
MM20-Ed1	*Quality Management for Molecular Genetic Testing, 1st Edition*		
Clinical Chemistry and Toxicology			
C34-Ed4	*Sweat Testing: Specimen Collection and Quantitative Chloride Analysis, 4th Edition*		
Point-of-Care Testing			
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition*		
POCT07-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*		
POCT10-Ed2	*Physician and Nonphysician Provider-Performed Microscopy Testing, 2nd Edition*		
POCT12-Ed2	*Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities, 3rd Edition*		
POCT13c-Ed3	*Glucose Monitoring in Settings Without Laboratory Support, 3rd Edition*		

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: Personnel.

Related CLSI Documents	CLSI QSE: Purchasing and Inventory		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	6.7 Service agreements 6.8.2 Referral laboratories and consultants 6.8 Externally provided products and services 6.8.3 Review and approval of externally provided products and services	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-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*
QMS05-Ed3	*Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory, 3rd Edition*
QMS21-Ed1	*Purchasing and Inventory Management, 1st Edition*
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*

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: Purchasing and Inventory.

Related CLSI Documents	CLSI QSE: Equipment		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	6.4 Equipment 6.5 Equipment calibration and metrological traceability 6.6 Reagents and consumables	6.4 Equipment	7.1.5 Monitoring and measuring resources
Quality Management Systems*			
QMS01-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*		
QMS13-Ed1	*Quality Management System: Equipment, 1st Edition*		
QMS23-Ed2	*General Laboratory Equipment Performance Qualification, Use, and Maintenance, 2nd Edition*		
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*		
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*		
Automation and Informatics			
AUTO01-Ed1	*Laboratory Automation: Specimen Container/Specimen Carrier, 1st Edition*		
AUTO02-Ed2	*Laboratory Automation: Bar Codes for Specimen Container Identification, 2nd Edition*		
AUTO13-Ed2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring, 2nd Edition*		
Hematology, Immunology, and Ligand Assay			
H42-Ed2	*Enumeration of Immunologically Defined Cell Populations by Flow Cytometry, 2nd Edition*		
H58-Ed1	*Platelet Function Testing by Aggregometry, 1st Edition*		
I/LA23-Ed1	*Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays, 1st Edition*		
Molecular Methods			
MM19-Ed1	*Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*		
Newborn Screening			
NBS01-Ed7	*Blood Collection on Filter Paper for Newborn Screening Programs, 7th Edition*		
NBS04-Ed2	*Newborn Screening by Tandem Mass Spectrometry, 2nd Edition*		
NBS07-Ed1	*Newborn Blood Spot Screening for Pompe Disease by Lysosomal Acid α-Glucosidase Activity Assays, 1st Edition*		

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: Equipment.

Related CLSI Documents	CLSI QSE: Equipment (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	6.4 Equipment 6.5 Equipment calibration and metrological traceability 6.6 Reagents and consumables	6.4 Equipment	7.1.5 Monitoring and measuring resources
Method Evaluation			
EP19-Ed3	*A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods, 3rd Edition*		
EP36-Ed1	*Harmonization of Symbology and Equations, 1st Edition*		
Clinical Chemistry and Toxicology			
C24-Ed4	*Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, 4th Edition*		
C34-Ed4	*Sweat Testing: Specimen Collection and Quantitative Chloride Analysis, 4th Edition*		
C50-Ed1	*Mass Spectrometry in the Clinical Laboratory: General Principles and Guidance, 1st Edition*		
Point-of-Care Testing			
POCT02-Ed1	*Implementation Guide of POCT01 for Health Care Providers, 1st Edition*		
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition*		
POCT07-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*		
POCT09-Ed1	*Selection Criteria for Point-of-Care Testing Devices, 1st Edition*		
POCT10-Ed2	*Physician and Nonphysician Provider-Performed Microscopy Testing, 2nd Edition*		
POCT13c-Ed3	*Glucose Monitoring in Settings Without Laboratory Support, 3rd Edition*		
POCT14-Ed2	*Point-of-Care Coagulation Testing and Anticoagulation Monitoring, 2nd Edition*		

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: Equipment.

Related CLSI Documents	CLSI QSE: Process Management		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*		
QMS18-Ed2	*Process Management, 2nd Edition*		
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*		
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*		
Automation and Informatics			
AUTO02-Ed2	*Laboratory Automation: Bar Codes for Specimen Container Identification, 2nd Edition*		
AUTO04-Ed1	*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements, 1st Edition*		
AUTO08-Ed1	*Managing and Validating Laboratory Information Systems, 1st Edition*		
AUTO09-Ed1	*Remote Access to Clinical Laboratory Diagnostic Devices via the Internet, 1st Edition*		
AUTO10-Ed1	*Autoverification of Clinical Laboratory Test Results, 1st Edition*		
AUTO11-Ed2	*IT Security of* In Vitro *Diagnostic Instruments and Software Systems, 2nd Edition*		
AUTO12-Ed1	*Specimen Labels: Content and Location, Fonts, and Label Orientation, 1st Edition*		
AUTO13-Ed2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring, 2nd Edition*		
AUTO15-Ed1	*Autoverification of Medical Laboratory Results for Specific Disciplines, 1st Edition*		
AUTO16-Ed1	*Next-Generation* In Vitro *Diagnostic Instrument Interface, 1st Edition*		
AUTO17-Ed1	*Semantic Interoperability for* In Vitro *Diagnostic Systems, 1st Edition*		

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: Process Management.

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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
Automation and Informatics (Continued)			
LIS01-Ed2	*Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems, 2nd Edition*		
LIS02-Ed2	*Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems, 2nd Edition*		
Clinical Chemistry and Toxicology			
C24-Ed4	*Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions, 4th Edition*		
C29-Ed2	*Standardization of Sodium and Potassium Ion-Selective Electrode Systems to the Flame Photometric Reference Method, 2nd Edition*		
C31-Ed2	*Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling, 2nd Edition*		
C34-Ed4	*Sweat Testing: Specimen Collection and Quantitative Chloride Analysis, 4th Edition*		
C37-Ed1	*Preparation and Validation of Commutable Frozen Human Serum Pools as 2ndary Reference Materials for Cholesterol Measurement Procedures, 1st Edition*		
C38-Ed1	*Control of Preanalytical Variation in Trace Element Determinations, 1st Edition*		
C39-Ed1	*A Designated Comparison Method for the Measurement of Ionized Calcium in Serum, 1st Edition*		
C42-Ed1	*Erythrocyte Protoporphyrin Testing, 1st Edition*		
C43-Ed2	*Gas Chromatography/Mass Spectrometry Confirmation of Drugs, 2nd Edition*		
C45-Ed1	*Measurement of Free Thyroid Hormones, 1st Edition*		
C46-Ed2	*Blood Gas and pH Analysis and Related Measurements, 2nd Edition*		
C48-Ed1	*Application of Biochemical Markers of Bone Turnover in the Assessment and Monitoring of Bone Diseases, 1st Edition*		
C49-Ed2	*Analysis of Body Fluids in Clinical Chemistry, 2nd Edition*		

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

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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 (Continued)			
C52-Ed3	*Toxicology and Drug Testing in the Medical Laboratory, 3rd Edition*		
C56-Ed1	*Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis, 1st Edition*		
C57-Ed1	*Mass Spectrometry for Androgen and Estrogen Measurements in Serum, 1st Edition*		
C58-Ed1	*Assessment of Fetal Lung Maturity by the Lamellar Body Count, 1st Edition*		
C61-Ed1	*Determination of Serum Iron, Total Iron-Binding Capacity and Percent Transferrin Saturation, 1st Edition*		
C63-Ed1	*Laboratory Support for Pain Management Programs, 1st Edition*		
C64-Ed1	*Quantitative Measurement of Proteins and Peptides by Mass Spectrometry, 1st Edition*		
Preexamination			
GP15-Ed3	*Cervicovaginal Cytology Based on the Papanicolaou Technique, 3rd Edition*		
GP16-Ed3	*Urinalysis, 3rd Edition*		
GP23-Ed2	*Nongynecological Cytology Specimens: Preexamination, Examination, and Postexamination Processes, 2nd Edition*		
GP33-Ed2	*Accuracy in Patient and Sample Identification, 2nd Edition*		
GP34-Ed1	*Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection, 1st Edition*		
GP39-Ed6	*Tubes and Additives for Venous and Capillary Blood Specimen Collection, 6th Edition*		
GP40-Ed4-AMD	*Preparation and Testing of Reagent Water in the Clinical Laboratory, 4th Edition*		
GP41-Ed7	*Collection of Diagnostic Venous Blood Specimens, 7th Edition*		

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Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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
Preexaminiation (Continued)			
GP42-Ed7	*Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens, 7th Edition*		
GP45-Ed1	*Studies to Evaluate Patient Outcomes, 1st Edition*		
GP47-Ed1	*Management of Critical- and Significant-Risk Results, 1st Edition*		
GP48-Ed1	*Essential Elements of a Phlebotomy Training Program, 1st Edition*		
GP49-Ed1	*Developing and Managing a Medical Laboratory (Test) Utilization Management Program, 1st Edition*		
Hematology, Immunology, and Ligand Assay			
H02-Ed5	*Procedures for the Erythrocyte Sedimentation Rate Test, 5th Edition*		
H07-Ed3	*Procedure for Determining Packed Cell Volume by the Microhematocrit Method, 3rd Edition*		
H26-Ed2	*Validation, Verification, and Quality Assurance of Automated Hematology Analyzers, 2nd Edition*		
H30-Ed2	*Procedure for the Determination of Fibrinogen in Plasma, 2nd Edition*		
H42-Ed2	*Enumeration of Immunologically Defined Cell Populations by Flow Cytometry, 2nd Edition*		
H43-Ed2	*Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells, 2nd Edition*		
H47-Ed3	*One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test, 3rd Edition*		
H48-Ed2	*Determination of Coagulation Factor Activities Using the One-Stage Clotting Assay, 2nd Edition*		
H52-Ed2	*Red Blood Cell Diagnostic Testing Using Flow Cytometry, 2nd Edition*		
H54-Ed1	*Procedures for Validation of INR and Local Calibration of PT/INR Systems, 1st Edition*		

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

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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, Immunology, and Ligand Assay (Continued)			
H56-Ed1	*Body Fluid Analysis for Cellular Composition, 1st Edition*		
H57-Ed1	*Protocol for the Evaluation, Validation, and Implementation of Coagulometers, 1st Edition*		
H58-Ed1	*Platelet Function Testing by Aggregometry, 1st Edition*		
H59-Ed1	*Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease, 1st Edition*		
H60-Ed1	*Laboratory Testing for the Lupus Anticoagulant, 1st Edition*		
H62-Ed1	*Determination of Coagulation Factor Activities Using the One-Stage Clotting Assay, 2nd Edition*		
I/LA02-Ed2	*Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens: (1) Indirect Fluorescence Assay for Microscopy and (2) Microtiter Enzyme Immunoassay Methods, 2nd Edition*		
I/LA20-Ed3	*Analytical Performance Characteristics, Quality Assurance, and Clinical Utility of Immunological Assays for Human Immunoglobulin E Antibodies of Defined Allergen Specificities, 3rd Edition*		
I/LA21-Ed2	*Clinical Evaluation of Immunoassays, 2nd Edition*		
I/LA23-Ed1	*Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays, 1st Edition*		
I/LA25-Ed2	*Maternal Serum Screening, 2nd Edition*		
I/LA26-Ed2	*Performance of Single Cell Immune Response Assays, 2nd Edition*		
I/LA28-Ed2	*Quality Assurance for Design Control and Implementation of Immunohistochemistry Assays, 2nd Edition*		
I/LA30-Ed1	*Immunoassay Interference by Endogenous Antibodies, 1st Edition*		

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

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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, Immunology, and Ligand Assay (Continued)			
I/LA33-Ed1	*Validation of Automated Systems for Immunohematological Testing Before Implementation, 1st Edition*		
I/LA34-Ed1	*Design and Validation of Immunoassays for Assessment of Human Allergenicity of New Biotherapeutic Drugs, 1st Edition*		
Method Evaluation			
EP05-Ed3	*Evaluation of Precision Performance of Quantitative Measurement Method, 3rd Edition*		
EP06-Ed2	*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach, 2nd Edition*		
EP07-Ed3	*Interference Testing in Clinical Chemistry, 3rd Edition*		
EP09c-Ed3	*Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd Edition*		
EP10-Ed3-AMD	*Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures, 3rd Edition*		
EP12-Ed3	*User Protocol for Evaluation of Qualitative Test Performance, 3rd Edition*		
EP14-Ed4	*Evaluation of Commutability of Processed Samples, 4th Edition*		
EP15-Ed3	*User Verification of Precision and Estimation of Bias, 3rd Edition*		
EP17-Ed2	*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition*		
EP18-Ed2	*Risk Management Techniques to Identify and Control Laboratory Error Sources, 2nd Edition*		
EP19-Ed3	*A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods, 3rd Edition*		
EP21-Ed2	*Estimation of Total Analytical Error for Clinical Laboratory Methods, 2nd Edition*		
EP23-Ed1	*Laboratory Quality Control Based on Risk Management, 1st edition*		

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

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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)			
EP24-Ed2	*Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves, 2nd Edition*		
EP25-Ed2	*Evaluation of Stability of* In Vitro *Diagnostic Reagents, 1st Edition*		
EP26-Ed2	*User Evaluation of Between-Reagent Lot Variation, 2nd Edition*		
EP27-Ed2	*How to Construct and Interpret an Error Grid for Quantitative Diagnostic Assays, 2nd Edition*		
EP28c-Ed3	*Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory, 3rd Edition*		
EP29-Ed1	*Expression of Measurement Uncertainty in Laboratory Medicine, 1st Edition*		
EP30-Ed1	*Characterization and Qualification of Commutable Reference Materials for Laboratory Medicine, 1st Edition*		
EP31-A-IR-Ed1	*Verification of Comparability of Patient Results Within One Health Care System, (Interim Revision) 1st Edition*		
EP32-R-Ed1	*Metrological Traceability and Its Implementation; A Report, 1st Edition*		
EP33-Ed2	*Use of Delta Checks in the Medical Laboratory, 2nd Edition*		
EP34-Ed1	*Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking, 1st Edition*		
EP35-Ed1	*Assessment of Equivalence or Suitability of Specimen Types for Medical Laboratory Measurement Procedures, 1st Edition*		
EP36-Ed1	*Harmonization of Symbology and Equations, 1st Edition*		
EP37-Ed1	*Supplemental Tables for Interference Testing in Clinical Chemistry, 1st Edition*		
EP39-Ed1	*A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests, 1st Edition*		

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

	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
Related CLSI Documents	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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			
M02-Ed13	*Performance Standards for Antimicrobial Disk Susceptibility Tests, 13th Edition*		
M07-Ed11	*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, 11th Edition*		
M11-Ed9	*Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria, 9th Edition*		
M15-Ed1	*Laboratory Diagnosis of Blood-borne Parasitic Diseases, 1st Edition*		
M22-Ed3	*Quality Control for Commercially Prepared Microbiological Culture Media, 3rd Edition*		
M23-Ed6	*Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters, 6th Edition*		
M23S-Ed1	*Procedure for Optimizing Disk Contents (Potencies) for Disk Diffusion Testing of Antimicrobial Agents Using Harmonized CLSI and EUCAST Criteria, 1st Edition*		
M24-Ed3	*Susceptibility Testing of Mycobacteria,* Nocardia *spp., and Other Aerobic Actinomycetes, 3rd Edition*		
M26-Ed1	*Methods for Determining Bactericidal Activity of Antimicrobial Agents, 1st Edition*		
M27-Ed4	*Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts, 4th Edition*		
M27M44S-Ed3	*Performance Standards for Antifungal Susceptibility Testing of Yeasts, 3rd Edition*		
M28-Ed2	*Procedures for the Recovery and Identification of Parasites From the Intestinal Tract, 2nd Edition*		
M34-Ed1	*Western Blot Assay for Antibodies to* Borrelia burgdorferi, *1st Edition*		
M35-Ed2	*Abbreviated Identification of Bacteria and Yeast, 2nd Edition*		
M36-Ed1	*Clinical Use and Interpretation of Serologic Tests for* Toxoplasma gondii, *1st Edition*		
M38-Ed3	*Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi, 3rd Edition*		

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

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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)			
M38M51S-Ed3	*Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi, 3rd Edition*		
M39-Ed5	*Analysis and Presentation of Cumulative Antimicrobial Susceptibility Test Data, 5th Edition*		
M40-Ed2	*Quality Control of Microbiological Transport Systems, 2nd Edition*		
M41-Ed1	*Viral Culture, 1st Edition*		
M43-Ed1	*Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas, 1st Edition*		
M44-Ed3	*Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts, 3rd Edition*		
M45-Ed3	*Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria, 3rd Edition*		
M47-Ed2	*Principles and Procedures for Blood Cultures, 2nd Edition*		
M48-Ed2	*Laboratory Detection and Identification of Mycobacteria, 2nd Edition*		
M50-Ed1	*Quality Control for Commercial Microbial Identification Systems, 1st Edition*		
M51-Ed1	*Method for Antifungal Disk Diffusion Susceptibility Testing of Nondermatophyte Filamentous Fungi, 1st Edition*		
M52-Ed1	*Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems, 1st Edition*		
M54-Ed2	*Principles and Procedures for Detection of Fungi in Clinical Specimens—Direct Examination and Culture, 2nd Edition*		
M56-Ed1	*Principles and Procedures for Detection of Anaerobes in Clinical Specimens, 1st Edition*		
M57-Ed1	*Principles and Procedures for the Development of Epidemiological Cutoff Values for Antifungal Susceptibility Testing, 1st Edition*		
M57S-Ed4	*Epidemiological Cutoff Values for Antifungal Susceptibility Testing, 4th Edition*		

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

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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)			
M58-Ed1	*Methods for the Identification of Cultured Microorganisms Using Matrix-Assisted Laser Desorption/Ionization Time-of-Flight Mass Spectrometry, 1st Edition*		
M62-Ed1	*Performance Standards for Susceptibility Testing of Mycobacteria,* Nocardia *spp., and Other Aerobic Actinomycetes, 1st Edition*		
M100-Ed33	*Performance Standards for Antimicrobial Susceptibility Testing, 33rd Edition*		
Molecular Methods			
MM01-Ed4	*Molecular Methods for Clinical Genetics and Oncology Testing, 4th Edition*		
MM03-Ed3	*Molecular Diagnostic Methods for Infectious Diseases, 3rd Edition*		
MM05-Ed2	*Nucleic Acid Amplification Assays for Molecular Hematopathology, 2nd Edition*		
MM06-Ed2	*Quantitative Molecular Methods for Infectious Diseases, 2nd Edition*		
MM07-Ed2	*Fluorescence* In Situ *Hybridization Methods for Clinical Laboratories, 2nd Edition*		
MM09-Ed3	*Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine, 3rd Edition*		
MM11-Ed1	*Molecular Methods for Bacterial Strain Typing, 1st Edition*		
MM12-Ed1	*Diagnostic Nucleic Acid Microarrays, 1st Edition*		
MM13-Ed2	*Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods, 2nd Edition*		
MM14-Ed2	*Design of Molecular Proficiency Testing/External Quality Assessment, 2nd Edition*		
MM17-Ed2	*Validation and Verification of Multiplex Nucleic Acid Assays, 2nd Edition*		

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

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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)			
MM18-Ed2	*Interpretive Criteria for Identification of Bacteria and Fungi by Targeted DNA Sequencing, 2nd Edition*		
MM19-Ed1	*Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*		
MM20-Ed1	*Quality Management for Molecular Genetic Testing, 1st Edition*		
MM21-Ed1	*Genomic Copy Number Microarrays for Constitutional Genetic and Oncology Applications, 1st Edition*		
MM22-Ed1	*Microarrays for Diagnosis and Monitoring of Infectious Diseases, 1st Edition*		
MM23-Ed1	*Molecular Diagnostic Methods for Solid Tumors (Nonhematological Neoplasms), 1st Edition*		
MM24-Ed1	*Molecular Methods for Genotyping and Strain Typing of Infectious Organisms, 1st Edition*		
Newborn Screening			
NBS01-Ed7	*Blood Collection on Filter Paper for Newborn Screening Programs, 7th Edition*		
NBS03-Ed2	*Newborn Screening for Preterm, Low Birth Weight, and Sick Newborns, 2nd Edition*		
NBS04-Ed2	*Newborn Screening by Tandem Mass Spectrometry, 2nd Edition*		
NBS05-Ed2	*Newborn Screening for Cystic Fibrosis, 2nd Edition*		
NBS07-Ed1	*Newborn Blood Spot Screening for Pompe Disease by Lysosomal Acid α-Glucosidase Activity Assays, 1st Edition*		
NBS08-Ed1	*Newborn Screening for Hemoglobinopathies, 1st Edition*		
NBS09-Ed1	*Newborn Screening for X-Linked Adrenoleukodystrophy, 1st Edition*		

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

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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			
POCT02-Ed1	*Implementation Guide of POCT01 for Health Care Providers, 1st Edition*		
POCT04-Ed3	*Essential Tools for Implementation and Management of a Point-of-Care Testing Program, 3rd Edition*		
POCT05-Ed2	*Performance Metrics for Continuous Interstitial Glucose Monitoring, 2nd Edition*		
POCT06-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*		
POCT07-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*		
POCT08-Ed1	*Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers, 1st Edition*		
POCT09-Ed1	*Selection Criteria for Point-of-Care Testing Devices, 1st Edition*		
POCT10-Ed2	*Physician and Nonphysician Provider-Performed Microscopy Testing, 2nd Edition*		
POCT12-Ed3	*Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities, 3rd Edition*		
POCT13c-Ed3	*Glucose Monitoring in Settings Without Laboratory Support, 3rd Edition*		
POCT14-Ed2	*Point-of-Care Monitoring of Anticoagulation Therapy, 2nd Edition*		

Related CLSI Documents	CLSI QSE: Process Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.2 Pre-examination processes 7.3 Examination processes 7.4 Post-examination processess	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
Veterinary Medicine			
VET01-Ed5	*Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals, 5th Edition*		
VET01S-Ed6	*Performance Standards for Antimicrobial Disk and Dilution Susceptibility Tests for Bacteria Isolated From Animals, 6th Edition*		
VET02-Ed4	*Development of* In Vitro *Susceptibility Testing Criteria and Quality Control Parameters for Veterinary Antimicrobial Agents, 4th Edition*		
VET03-Ed2	*Methods for Antimicrobial Disk Susceptibility Testing of Bacteria Isolated From Aquatic Animals, 2nd Edition*		
VET04S-Ed3	*Performance Standards for Antimicrobial Susceptibility Testing of Bacteria Isolated From Aquatic Animals, 3rd Edition*		
VET05-R-Ed1	*Generation, Presentation, and Application of Antimicrobial Susceptibility Test Data for Bacteria of Animal Origin; A Report, 1st Edition*		
VET06-Ed1	*Methods for Antimicrobial Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria Isolated From Animals, 1st Edition*		
VET09-Ed1	*Understanding Susceptibility Test Data as a Component of Antimicrobial Stewardship in Veterinary Settings, 1st Edition*		

Related CLSI Documents	CLSI QSE: Documents and Records (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
		7.5 Technical records 7.11 Control of data and information management	
	8.3 Control of management system documents	8.3. Control of management system documents (Option A)	
	8.4 Control of records	8.4 Control of records (Option A)	7.5 Documented information

Quality Management Systems*	
QMS01-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*
QMS02-Ed6	*Quality Management System: Development and Management of Laboratory Documents, 6th Edition*
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*
QMS26-Ed1	*Managing Laboratory Records, 1st Edition*
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*
Automation and Informatics	
AUTO13-Ed2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring, 2nd Edition*
Hematology, Immunology, and Ligand Assay	
I/LA21-Ed2	*Clinical Evaluation of Immunoassays, 2nd Edition*
Microbiology	
M07-Ed11	*Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, 11th Edition*
Molecular Methods	
MM13-Ed2	*Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods, 2nd Edition*
MM19-Ed1	*Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*
MM20-Ed1	*Quality Management for Molecular Genetic Testing, 1st Edition*
Point-of-Care Testing	
POCT07-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*
POCT10-Ed2	*Physician and Nonphysician Provider-Performed Microscopy Testing, 2nd Edition*

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: Documents and Records.

Related CLSI Documents	CLSI QSE: Documents and Records (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
		7.5 Technical records 7.11 Control of data and information management	
	8.3 Control of management system documents	8.3. Control of management system documents (Option A)	
	8.4 Control of records	8.4 Control of records (Option A)	7.5 Documented information

Point-of-Care Testing (Continued)	
POCT12-Ed3	*Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities, 3rd Edition*
POCT13c-Ed3	*Glucose Monitoring in Settings Without Laboratory Support, 3rd Edition*
Method Evaluation	
EP19-Ed3	*A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods, 3rd Edition*
EP36-Ed1	*Harmonization of Symbology and Equations, 1st Edition*
Preexamination	
GP45-Ed1	*Studies to Evaluate Patient Outcomes, 1st Edition*
Clinical Chemistry and Toxicology	
C34-Ed4	*Sweat Testing: Specimen Collection and Quantitative Chloride Analysis, 4th Edition*
C52-Ed3	*Toxicology and Drug Testing in the Medical Laboratory, 3rd Edition*

Related CLSI Documents	CLSI QSE: Information Management		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.6 Control of data and information management 7.8 Continuity and emergency preparedness planning	7.11 Control of data and information management	7.5 Documented information
Quality Management Systems*			
QMS01-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*		
QMS22-Ed1	*Management of Paper-based and Electronic Laboratory Information, 1st Edition*		
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*		
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*		
Automation and Informatics			
AUTO03-Ed2	*Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems, 2nd Edition*		
AUTO04-Ed1	*Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements, 1st Edition*		
AUTO05-Ed1	*Laboratory Automation: Electromechanical Interfaces, 1st Edition*		
AUTO07-Ed1	*Laboratory Automation: Data Content for Specimen Identification, 1st Edition*		
AUTO13-Ed2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitorin, 2nd Edition*		
AUTO16-Ed1	*Next-Generation* In Vitro *Diagnostic Instrument Interface, 1st Edition*		
LIS01-Ed2	*Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems, 2nd Edition*		
LIS02-Ed2	*Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems, 2nd Edition*		
Hematology, Immunology, and Ligand Assay			
I/LA23-Ed1	*Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays, 1st Edition*		
Molecular Methods			
MM19-Ed1	*Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*		
MM20-Ed1	*Quality Management for Molecular Genetic Testing, 1st Edition*		

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: Information Management.

Related CLSI Documents	CLSI QSE: Information Management (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	7.6 Control of data and information management 7.8 Continuity and emergency preparedness planning	7.11 Control of data and information management	7.5 Documented information
Point-of-Care Testing			
POCT01-Ed2	*Point-of-Care Connectivity, 2nd Edition*		
POCT07-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*		
Clinical Chemistry and Toxicology			
C52-Ed3	*Toxicology and Drug Testing in the Medical Laboratory, 3rd Edition*		
Preexamination			
GP45-Ed1	*Studies to Evaluate Patient Outcomes, 1st Edition*		

CLSI QSE: Nonconforming Event Management		
ISO 15189:2022 Clause(s)	**ISO 17025:2017 Clause(s)**	**ISO 9001:2015 Clause(s)**
7.7 Complaints 7.5 Nonconforming work 8.7 Nonconformities and corrective action 8.7.1 Actions when nonconformity occurs 8.7.2 Corrective action effectiveness 8.7.3 Records of nonconformities	7.9 Complaints 7.10 Nonconforming work 8.7 Corrective actions (Option A)	8.7 Control of nonconforming outputs

Related CLSI Documents	
Quality Management Systems*	
QMS01-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*
QMS11-Ed2	*Nonconforming Event Management, 2nd Edition*
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*
Automation and Informatics	
AUTO13-Ed2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitorin, 2nd Edition*
Method Evaluation	
EP18-Ed2	*Risk Management Techniques to Identify and Control Laboratory Error Sources, 2nd Edition*
Molecular Methods	
MM19-Ed1	*Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*
MM20-Ed1	*Quality Management for Molecular Genetic Testing, 1st Edition*
Point-of-Care Testing	
POCT07-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*
POCT14-Ed2	*Point-of-Care Coagulation Testing and Anticoagulation Monitoring, 2nd Edition*

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: Nonconforming Even Management.

CLSI QSE: Assessments		
ISO 15189:2022 Clause(s)	**ISO 17025:2017 Clause(s)**	**ISO 9001:2015 Clause(s)**
5.6 Risk management 7.2.3 Requests for providing laboratory examinations 8.5 Actions to address risks and opportunities for improvement 8.6.2 Laboratory user and personnel feedback 8.8 Evaluations 8.8.1 General 8.8.2 Quality indicators 8.8.3 Internal 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

Related CLSI Documents	
Quality Management Systems*	
QMS01-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*
QMS12-Ed2	*Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality, 2nd Edition*
QMS15-Ed2	*Assessments: Laboratory Internal Audit Program, 2nd Edition*
QMS17-Ed1	*External Assessments, Audits, and Inspections of the Laboratory, 1st Edition*
QMS24-Ed3	*Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality, 3rd Edition*
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*
Hematology, Immunology, and Ligand Assay	
H58-Ed1	*Platelet Function Testing by Aggregometry, 1st Edition*
I/LA23-Ed1	*Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays, 1st Edition*
I/LA25-Ed2	*Maternal Serum Screening, 2nd Edition*
Method Evaluation	
EP10-Ed3-AMD	*Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures, 3rd Edition*
EP18-Ed2	*Risk Management Techniques to Identify and Control Laboratory Error Sources, 2nd Edition*
EP19-Ed3	*A Framework for Using CLSI Documents to Evaluate Medical Laboratory Test Methods, 3rd Edition*

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

*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: Assessments (Continued)		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	5.6 Risk management 7.2.3 Requests for providing laboratory examinations 8.5 Actions to address risks and opportunities for improvement 8.6.2 Laboratory user and personnel feedback 8.8 Evaluations 8.8.1 General 8.8.2 Quality indicators 8.8.3 Internal 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
Method Evaluation (Continued)			
EP39-Ed1	*A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests, 1st Edition*		
Molecular Methods			
MM05-Ed2	*Nucleic Acid Amplification Assays for Molecular Hematopathology, 2nd Edition*		
MM19-Ed1	*Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*		
MM20-Ed1	*Quality Management for Molecular Genetic Testing, 1st Edition*		
Point-of-Care Testing			
POCT07-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*		
POCT09-Ed1	*Selection Criteria for Point-of-Care Testing Devices, 1st Edition*		
POCT14-Ed2	*Point-of-Care Coagulation Testing and Anticoagulation Monitoring, 2nd Edition*		
Clinical Chemistry and Toxicology (Continued)			
C64-Ed1	*Quantitative Measurement of Proteins and Peptides by Mass Spectrometry, 1st Edition*		
Microbiology			
M47-Ed2	*Principles and Procedures for Blood Cultures, 2nd Edition*		
Preexamination			
GP45-Ed1	*Studies to Evaluate Patient Outcomes, 1st Edition*		

Related CLSI Documents	CLSI QSE: Continual Improvement		
	ISO 15189:2022 Clause(s)	ISO 17025:2017 Clause(s)	ISO 9001:2015 Clause(s)
	8.6 Improvement 8.6.1 Continual improvement 8.6.2 Laboratory patients, user and personnel feedback	8.6 Improvement (Option A)	10 Improvement
Quality Management Systems*			
QMS01-Ed5	*Quality Management System: A Model for Laboratory Services, 5th Edition*		
QMS06-Ed3	*Quality Management System: Continual Improvement,3rd Edition*		
QMS25-Ed1	*Handbook for Developing a Laboratory Quality Manual, 1st Edition*		
QSRLDT	*Quality System Regulations for Laboratory Developed Tests: A Practical Guide for the Laboratory*		
Automation and Informatics			
AUTO13-Ed2	*Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring,2nd Edition*		
Hematology, Immunology, and Ligand Assay			
H30-Ed2	*Procedure for the Determination of Fibrinogen in Plasma, 2nd Edition*		
I/LA23-Ed1	*Assessing the Quality of Immunoassay Systems: Radioimmunoassays and Enzyme, Fluorescence, and Luminescence Immunoassays, 1st Edition*		
I/LA25-Ed2	*Maternal Serum Screening, 2nd Edition*		
Method Evaluation			
EP18-Ed2	*Risk Management Techniques to Identify and Control Laboratory Error Sources, 2nd Edition*		
Preexamination			
GP45-Ed1	*Studies to Evaluate Patient Outcomes, 1st Edition*		
Clinical Chemistry and Toxicology (Continued)			
C34-Ed4	*Sweat Testing: Specimen Collection and Quantitative Chloride Analysis, 4th Edition*		
Microbiology			
M47-Ed2	*Principles and Procedures for Blood Cultures, 2nd Edition*		

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: Continual Improvement.

CLSI QSE: Continual Improvement		
ISO 15189:2022 Clause(s)	**ISO 17025:2017 Clause(s)**	**ISO 9001:2015 Clause(s)**
8.6 Improvement 8.6.1 Continual improvement 8.6.2 Laboratory patients, user and personnel feedback	8.6 Improvement (Option A)	10 Improvement

Related CLSI Documents	
Molecular Methods	
MM19-Ed1	*Establishing Molecular Testing in Clinical Laboratory Environments, 1st Edition*
MM20-Ed1	*Quality Management for Molecular Genetic Testing, 1st Edition*
Point-of-Care Testing	
POCT07-Ed1	*Quality Management: Approaches to Reducing Errors at the Point of Care, 1st Edition*

ISO Document Titles	
ISO 15189:2022	*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*

Updated September 2023

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