



CLINICAL AND
LABORATORY
STANDARDS
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CLMA Body of Knowledge 2013

Updated December 2013

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Related CLSI Documents
(as of June 2013)

Domain 1						
Governance and Organizational Dynamics						
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5	Competency 6	
Demonstrate an ability to function in the entity's governance structure with accountability to the patient, board, CEO, appropriate vice president, and/or other direct report.	Lead the integration of the mission and vision statements into all aspects of the laboratory's culture.	Lead development of the laboratory activities to support strategic planning and its implementation.	Facilitate the establishment, monitoring, and record keeping of the appropriate business organizational structure of the laboratory.	Foster relationships and communication with stakeholders beyond the laboratory.	Promote, develop, track, and report Quality Initiatives to support mission, vision, values, and goals.	
QMS01-A4						
QMS02-A6						
QMS03-A3						
QMS04-A2						
QMS05-A2						
QMS06-A3						
QMS10-A						
QMS11-A						
QMS12-A						<input checked="" type="checkbox"/>
QMS13-A						
QMS14-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
C24-A3						<input checked="" type="checkbox"/>
EP12-A2						<input checked="" type="checkbox"/>
EP23-A™ and EP23-A WB (EP23 workbook)						<input checked="" type="checkbox"/>

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Related CLSI Documents
(as of June 2013)

Domain 2						
Business and Clinical Operations						
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5	Competency 6	
Develop and innovate work processes that deliver customer value while achieving the mission and the strategic plan.	Implement and manage work processes to ensure they meet goals.	Develop work process improvements that reduce variability, minimize errors, and ensure quality.	Employ system thinking that coordinates and integrates work systems within the parent entity.	Develop workplace preparedness plans for disasters and emergencies to ensure continuity of operations.	Establish a process to identify and evaluate innovative or new technologies or practices.	
QMS01-A4						
QMS02-A6						
QMS03-A3						
QMS04-A2						
QMS05-A2	☑					
QMS06-A3		☑				
QMS10-A						
QMS11-A						
QMS12-A	☑					
QMS13-A						
QMS14-A				☑		
GP46-R					☑	



Related CLSI Documents
(as of June 2013)

Domain 3					
Financial Management					
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5	
Develop and implement the budget to achieve institution strategic goals – basic financial statements, including the balance sheet, income statement, and statement of cash flows.	Demonstrate knowledge of current and future reimbursement for clinical services from government agencies, insurers, and managed care.	Establish internal controls for management of collections and optimum reimbursement to maximize the system's return on investment (ROI) for diagnostic services.	Monitor and control the allocation of operational resources by analyzing financial performance and reporting results to stakeholders.	Monitor and control the capital cycle investment decisions in alignment with the strategic planning process.	
QMS01-A4					
QMS02-A6					
QMS03-A3					
QMS04-A2					
QMS05-A2					
QMS06-A3					
QMS10-A					
QMS11-A					
QMS12-A					
QMS13-A					
QMS14-A					
GP11-A	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		



Related CLSI Documents
(as of June 2013)

Domain 4					
Strategic Planning and Marketing					
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5	Competency 6
Develop and implement an effective strategic plan for the laboratory that supports the corporate mission, vision, values, and goals.	Develop and implement a dynamic annual business plan.	Formulate a marketing plan that identifies opportunities and strategic alliances targeting growth initiatives.	Organize an effective promotional campaign that promotes service and education to the outreach market.	Develop and manage an ongoing customer feedback process to ensure market retention and customer satisfaction.	Produce ongoing metrics of organizational effectiveness for strategic and growth targets, and identify opportunities for improvement.
QMS01-A4					
QMS02-A6					
QMS03-A3					
QMS04-A2					
QMS05-A2					
QMS06-A3					
QMS10-A					
QMS11-A				<input checked="" type="checkbox"/>	
QMS12-A					
QMS13-A					
QMS14-A	<input checked="" type="checkbox"/>				<input checked="" type="checkbox"/>

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Related CLSI Documents
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Domain 5						
Human Resource Management						
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5	Competency 6	Competency 7
Develop competitive recruitment and hiring programs that attract talent to the laboratory.	Formulate a competitive compensation and benefit program that attracts and retains qualified personnel.	Develop a workforce plan that meets operational staffing needs.	Establish a staff development program that develops and retains talent while understanding personality, professional, generational, and cultural unique qualities of each individual.	Implement or support parent entity's management of performance expectations of clinical conduct.	Develop an Employee Relations Program that: promotes employee satisfaction, motivates high performers, and proactively identifies and resolves employee problems.	Establish a culture that promotes and supports change.
QMS01-A4						
QMS02-A6						
QMS03-A3			<input checked="" type="checkbox"/>			
QMS04-A2						
QMS05-A2						
QMS06-A3						
QMS10-A						
QMS11-A						
QMS12-A						
QMS13-A						
QMS14-A					<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>



Related CLSI Documents
(as of June 2013)

Domain 6					
Quality Management for Patient Safety					
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5	
Develop, implement, and maintain a QC program for ensuring the quality of examination and test results.	Develop, implement, maintain, and evaluate key indicators of laboratory quality that determine how well preanalytic, analytic, and postanalytic processes are performing against goals and standards.	Develop, implement, and maintain a QMS that leads to meeting regulatory, accreditation, customer requirements, improvement of laboratory services, and contribution to optimal patient safety outcomes.	Understand the financial impact of quality in laboratory operations.	Integrate and promote the innovative aspects of laboratory quality assurance methods within the organization to improve overall quality, patient safety, and customer satisfaction.	
QMS01-A4	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			
QMS02-A6		<input checked="" type="checkbox"/>			
QMS03-A3		<input checked="" type="checkbox"/>			
QMS04-A2		<input checked="" type="checkbox"/>			
QMS05-A2		<input checked="" type="checkbox"/>			
QMS06-A3	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	
QMS10-A		<input checked="" type="checkbox"/>			
QMS11-A		<input checked="" type="checkbox"/>			
QMS12-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			
QMS13-A		<input checked="" type="checkbox"/>			
QMS14-A		<input checked="" type="checkbox"/>			
C24-A3	<input checked="" type="checkbox"/>				



**Related CLSI Documents
(as of June 2013)**

Domain 6 (continued)				
Quality Management for Patient Safety (continued)				
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5
Develop, implement, and maintain a QC program for ensuring the quality of examination and test results.	Develop, implement, maintain, and evaluate key indicators of laboratory quality that determine how well preanalytic, analytic, and postanalytic processes are performing against goals and standards.	Develop, implement, and maintain a QMS that leads to meeting regulatory, accreditation, customer requirements, improvement of laboratory services, and contribution to optimal patient safety outcomes.	Understand the financial impact of quality in laboratory operations.	Integrate and promote the innovative aspects of laboratory quality assurance methods within the organization to improve overall quality, patient safety, and customer satisfaction.
EP12-A2	<input checked="" type="checkbox"/>			
EP23-A™ and EP23-A-WB (EP23 workbook)	<input checked="" type="checkbox"/>			
GP11-A			<input checked="" type="checkbox"/>	
GP27-A2		<input checked="" type="checkbox"/>		
GP29-A2		<input checked="" type="checkbox"/>		
GP31-A		<input checked="" type="checkbox"/>		
The Key to Quality™		<input checked="" type="checkbox"/>		
Laboratory Quality Management System Certificate Program		<input checked="" type="checkbox"/>		

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Domain 7						
Information Management and Technology						
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5	Competency 6	
Demonstrate an ability to maintain operation of current laboratory technology systems, ensuring accurate and consistent flow of information and communication for all stakeholders.	Demonstrate an ability to provide an appropriate computer environment.	Demonstrate an ability to plan, design, and manage the security of laboratory information systems.	Demonstrate an ability to meet various regulatory requirements for information systems.	Demonstrate an ability to determine the need, selection criteria, and implementation of a new information technology system.	Demonstrate an ability to determine the need for inactivation, retiring, disposal, and/or archiving of a technology information system.	
AUTO03-A2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
AUTO08-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
AUTO10-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
AUTO13-A2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LIS01-A2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LIS02-A2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LIS03-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LIS04-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LIS05-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LIS06-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LIS07-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LIS08-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
LIS09-A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

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Domain 8							
Compliance and Risk Management							
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5	Competency 6	Competency 7	Competency 8
US Only Maintain compliance with the CLIA regulations and understand how the regulation is related to institutional accreditation organizations.	US Only Recognize the requirements HIPAA places on privacy and security in the use of patient information in clinical practice.	US Only Identify OSHA, EPA, DOT, and other safety-related federal and state regulations that apply in laboratory operations.	US Only Recognize high-risk compliance areas and create policies and their requirements where needed.	US Only Participate with the compliance department to ensure that all compliance requirements are incorporated to support an effective program.	Identify and control the risks inherent to laboratory operations.	Internalize laws and regulations that govern laboratory operations.	Evaluate all contracts the institution has signed with vendors, reference laboratories, and/or physicians' offices.
QMS01-A4						<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
QMS02-A6							
QMS03-A3							
QMS04-A2							
QMS05-A2							<input checked="" type="checkbox"/>
QMS06-A3							
QMS10-A							
QMS11-A					<input checked="" type="checkbox"/>		
QMS12-A							
QMS13-A							
QMS14-A							
GP05-A3		<input checked="" type="checkbox"/>					
GP17-A3		<input checked="" type="checkbox"/>					
M29-A3		<input checked="" type="checkbox"/>					



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Domain 9					
Medical Decision Support					
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5	
Ensure optimal test utilization in compliance with clinical standards that are aligned with the organizational mission.	Investigate new methodologies, tests, and equipment to ensure the laboratory is offering the highest quality and most cost-effective services.	Seek physician/health care provider's involvement in decision making regarding optimal laboratory services.	Improve service levels based upon results of laboratory performance assessments.	Create a culture that places emphasis on patient-focused activities.	
QMS01-A4					
QMS02-A6					
QMS03-A3					
QMS04-A2					
QMS05-A2					
QMS06-A3			<input checked="" type="checkbox"/>		
QMS10-A					
QMS11-A					
QMS12-A			<input checked="" type="checkbox"/>		
QMS13-A					
QMS14-A					

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Domain 10					
Professional Development					
Competency 1	Competency 2	Competency 3	Competency 4	Competency 5	
Demonstrate professionalism.	Identify professional goals for career development.	Develop personal attributes for a leadership role.	Identify continuing education opportunities to develop areas of weakness and advance personal knowledge base and leadership.	Evaluate the effectiveness of instructional programs and professional growth.	
QMS01-A4					
QMS02-A6					
QMS03-A3					
QMS04-A2					
QMS05-A2					
QMS06-A3					
QMS10-A					
QMS11-A					
QMS12-A					
QMS13-A					
QMS14-A					
The Key to Quality™			<input checked="" type="checkbox"/>		
Laboratory Quality Management System Certificate Program			<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>

Abbreviations: CLIA, Clinical Laboratory Improvement Amendments; DOT, US Department of Transportation; EPA, US Environmental Protection Agency; HIPAA, Health Insurance Portability and Accountability Act; OSHA, Occupational Safety and Health Administration; QC, quality control; QMS, quality management system.

DOCUMENT CODES AND TITLES

Automation and Informatics

AUTO03-A2	Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition
AUTO08-A	Managing and Validating Laboratory Information Systems; Approved Guideline
AUTO10-A	Autoverification of Clinical Laboratory Test Results; Approved Guideline
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
LIS03-A	Standard Guide for Selection of a Clinical Laboratory Information Management System
LIS04-A	Standard Guide for Documentation of Clinical Laboratory Computer Systems
LIS05-A	Standard Specification for Transferring Clinical Observations Between Independent Computer Systems
LIS06-A	Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems
LIS07-A	Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory
LIS08-A	Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems
LIS09-A	Standard Guide for Coordination of Clinical Laboratory Services Within the Electronic Health Record Environment and Networked Architectures

Clinical Chemistry and Toxicology

C24-A3	Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition
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General Laboratory

GP05-A3	Clinical Laboratory Waste Management; Approved Guideline—Third Edition
GP11-A	Basic Cost Accounting for Clinical Services; Approved Guideline
GP17-A3	Clinical Laboratory Safety; Approved Guideline—Third Edition
GP27-A2	Using Proficiency Testing to Improve the Clinical Laboratory; Approved Guideline—Second Edition
GP29-A2	Assessment of Laboratory Tests When Proficiency Testing Is Not Available; Approved Guideline—Second Edition
GP31-A	Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline
GP46-R	Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report

DOCUMENT CODES AND TITLES

Method Evaluation

EP12-A2	User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition
EP23-A™	Laboratory Quality Control Based on Risk Management; Approved Guideline
EP23-A WB	A Practical Guide for Laboratory Quality Control Based on Risk Management; Workbook

Microbiology

M29-A3	Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition
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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
QMS03-A3	Training and Competence Assessment; Approved Guideline—Third Edition
QMS04-A2	Laboratory Design; Approved Guideline—Second Edition
QMS05-A2	Quality Management System: Qualifying, Selecting, and Evaluating a Referral Laboratory; Approved Guideline—Second Edition
QMS06-A3	Quality Management System: Continual Improvement; Approved Guideline—Third Edition
QMS10-A	A Model for Managing Medical Device Alerts (Hazards and Recalls) for Healthcare Organizations; Approved Guideline
QMS11-A	Management of Nonconforming Laboratory Events; Approved Guideline
QMS12-A	Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Approved Guideline
QMS13-A	Quality Management System: Equipment; Approved Guideline
QMS14-A	Quality Management System: Leadership and Management Roles and Responsibilities; Approved Guideline

Other

The Key to Quality™	This bound workbook contains fundamental information for implementing and sustaining a quality management system (QMS) and guidance for developing a QMS infrastructure. It includes ready-to-use electronic templates as well as examples of completed forms and QMS tools to assist users in fulfilling the required elements in each of the 12 CLSI quality system essentials (QSEs).
Laboratory Quality Management System Certificate Program	This is an online, distance learning certificate program that imparts the knowledge and skills necessary for successful implementation and sustainment of a QMS in your laboratory. The program consists of 12 modules, each representing one of the 12 QSEs, as well as introductory and summary modules.



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