



CLINICAL LABORATORY MANAGEMENT ASSOCIATION



**BODY of KNOWLEDGE**  
*for*  
Medical Laboratory Management

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# **Body of Knowledge (BOK)**

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*November 2010 Edition*

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# An Introduction to the CLMA Body of Knowledge for Medical Laboratory Management

The Body of Knowledge (BOK) of a profession identifies its scope of practice by describing the various knowledge, skills, and attitudes necessary for one to perform. A BOK gives credibility to a profession and legitimizes its value.

## Clinical Laboratory Management Association (CLMA) Membership

The majority of CLMA's membership is comprised of professionals that manage medical laboratories. These laboratories may be in hospitals, independent facilities, physician offices, academic medical centers, and other entities such as a school's infirmary. There is a vast amount of knowledge and expertise that must go into successfully managing a medical laboratory, no matter where it is located.

To create the BOK, CLMA brought together a cross-section of members and subject matter experts who collaborated to identify, define, and develop the domains, competencies, and tasks. As additional competencies and tasks are established, they will be added to the appropriate domain.

### Goal of BOK

**These levels of growth and practice are outlined below:**

- Level I: Emerging laboratory management competency
- Level II: Developed laboratory management competency
- Level III: Advanced laboratory management competency

### BOK Definitions

- Domain:** A practice area in the *Body of Knowledge for Medical Laboratory Management* that describes a major area of management responsibility.
- Competency:** Each domain identifies various skills, written in the form of an objective, that are necessary to demonstrate requisite performance.
- Tasks:** Each competency lists activities that demonstrate the practice of the domain. Tasks are identified by complexity of performance/experience as Level I, Level II, or Level III.

*Tasks in the same discipline are grouped together under a single competency. Related competencies are combined to form a domain. A domain is a broad description of a management discipline.*

## BOK Domain Areas

The 10 BOK domain areas are:

- 1  **Governance and Organizational Dynamics**
- 2  **Business and Clinical Operations**
- 3  **Financial Management**
- 4  **Strategic Planning and Marketing**
- 5  **Human Resource Management**
- 6  **Quality Management for Patient Safety**
- 7  **Information Management and Technology**
- 8  **Compliance and Risk Management**
- 9  **Medical Decision Support**
- 10  **Professional Development**

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**Note:** Certain topics and tasks overlap different domains; as such, additional information on a number of topics may be found in more than one domain. In addition, competencies may not have all three levels defined, in order to reflect the current scope of practice. The CLMA BOK is a “living” document and is expected to evolve over the coming years.



## Domain 1

### Governance and Organizational Dynamics

**Definition:** *Governance and Organizational Dynamics embodies the leadership skills required for an organization to have a shared structure for systems and processes that assure quality, accountability and proper management integrating the corporate mission statement while meeting the strategic direction of the institution.*

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#### **Competency 1**

**Demonstrate an ability to function in the institution's governance structure with accountability to the patient, board, CEO, appropriate vice president, and/or other direct report.**

##### **Level I**

- Describe corporate/institutional structure
- Recognize the role of committee structure in supporting institutional goals
- Explain the application of administrative policies
- Track statistical data to support productivity and financials
- Trend information for predicted outcomes

##### **Level II**

- Participate in corporate management meetings
- Complete committee assignments to support institutional goals
- Suggest changes to administrative policies
- Prepare financial justifications for expenditures
- Prepare reports of trending data and present to relevant committee

##### **Level III**

- Participate in a lead role during management meetings
- Chair a committee leading change through constructive dialogue
- Champion the needs of the department within the institutional resources
- Develop, review, revise, and implement new administrative policies as appropriate

## **Competency 2**

**Lead the integration of the corporate mission and vision statements into all aspects of the institution's culture.**

### **Level I**

- Convey the mission, vision, and values of the institution
- Effectively communicate to staff
- Foster a culture of trust and respect

### **Level II**

- Establish department mission and vision to mirror the institution
- Advocate and uphold ethical standards, behaviors, and decision making
- Understand the institutional culture, patterns of behavior, politics, power, and group interactions

### **Level III**

- Demonstrate support of the institution's mission, vision, and values through specific interdepartmental activities
- Manage the intricate interrelationships of the institution, staff, and stakeholders

## **Competency 3**

**Lead development of the department activities to support the strategic plan and its implementation.**

### **Level I**

- Perform trend analysis for potential test additions
- Solicit staff suggestions
- Identify cost containment strategies

### **Level II**

- Research revenue-enhancement activities
- Perform in-depth cost analysis per procedure
- Solicit physician input
- Implement information technology solutions

### **Level III**

- Perform comprehensive revenue stream analysis
- Conduct comprehensive productivity analysis using standardized tools
- Implement comprehensive cost-containment activities with lean principles
- Evaluate community needs through assessment of market trends
- Conduct SWOT analysis (*strengths, weaknesses, opportunities, threats*)
- Prepare and present a business plan

## **Domain 1**

### **Governance and Organizational Dynamics**

#### **Competency 4**

**Facilitate the establishment, monitoring, and record keeping of the appropriate legal structure of the department within the institution.**

##### **Level I**

- Describe appropriate national and state regulations
- Inform staff of regulatory compliance requirements
- Ensure adherence to all regulatory requirements
- Order survey samples to meet all regulatory requirements

##### **Level II**

- Implement regulatory compliance requirements
- Ensure appropriate staff are hired to perform procedures
- Write policies and procedures to meet all requirements
- Provide appropriate instruction for staff
- Ensure all survey sample deadlines are met
- Participate in remedial action regarding survey needs
- Participate in regulatory compliance surveys

##### **Level III**

- Review survey sample results and recommend actions to be taken
- Complete all licensure and compliance applications in a timely manner
- Complete annual statistical report for licensure
- Participate in regulatory compliance audits
- Develop departmental staff training for compliance risk areas
- Prepare after-action reports as needed
- Seek legal counsel when needed

#### **Competency 5**

**Implement or support institution's management of performance expectations of clinical conduct.**

##### **Level I**

- Document professional/performance standards
- Communicate performance expectations clearly to staff
- Conduct timely performance reviews, maintaining consistent expectations regarding performance
- Perform timely remedial actions, when necessary

### **Level II**

- Recommend changes in professional/performance standards
- Review job descriptions, making adjustments as needed
- Standardize professional expectations with the institution
- Instruct staff regarding performance expectations
- Assist in the analysis of staff compensation in partnership with Human Resources

### **Level III**

- Establish professional standards of conduct and expectations
- Write policy for professional standards violations
- Communicate the standards of conduct clearly and frequently
- Support institution leadership regarding performance issues and disruptive behavior
- Advocate for staff members for compensation reviews, when necessary
- Assess appropriate mix of professional and staff positions
- Recommend creation of new positions, i.e., LIS manager, when appropriate

*Refer to the Human Resources Domain 5 for additional information on this topic.*

## **Competency 6**

### **Foster the development of knowledgeable leaders within the institution cross-departmentally.**

#### **Level I**

- Communicate effectively with other departments
- Demonstrate consistency and professional integrity
- Utilize all resources within the department
- Consider sources outside the department

#### **Level II**

- Seek input from stakeholders on service-level quality
- Participate in inter-departmental meetings
- Utilize employee, patient, and physician satisfaction surveys to evaluate the need for change

#### **Level III**

- Ensure communications between laboratory staff and other departments
- Facilitate conflict resolution, as needed
- Ensure staff involvement in decisions
- Act as a change agent for the institution
- Collaborate with administration to foster team culture
- Identify internal managers with potential for advancement

# **Domain 1**

## **Governance and Organizational Dynamics**

### **Competency 7**

**Promote, develop, track, and report Quality Initiatives to support the institution goals, mission, vision, and values.**

#### **Level I**

- Appraise quality control methods and procedures
- Track and interpret quality monitors for action if warranted
- Prepare summary reports

#### **Level II**

- Seek input from leadership experts, when necessary
- Utilize quality information to identify and promote opportunities for improvement
- Develop plans for change and champion such initiatives

#### **Level III**

Not applicable at this time

*Refer to Quality Management for Patient Safety Domain 6 for additional information on this topic.*



# Business and Clinical Operations

**Definition:** *Business and Clinical Operations require effective management skills in the development and delivery of business and medical laboratory operations best practices to ensure the highest quality of patient care, personnel safety, and effective business and operational management of the laboratory.*

## Competency 1

**Develop and innovate work processes that deliver patient and customer value, and meet the institution's mission and strategic plan.**

### Level I

- Demonstrate knowledge of agencies and organizations that regulate and accredit services to ensure that processes meet or exceed compliance requirements

### Level II

- Evaluate new technology as it aligns with patient care and clinical needs, operational efficiency, and competitive advantage
- Incorporate cycle time, productivity, and cost control into the design of processes
- Develop a staffing model to support the work processes and optimize resource utilization

### Level III

- Demonstrate strategic planning skills to forecast future service demands and allocation of resources

## Competency 2

**Implement and manage work processes to ensure they meet requirements.**

### Level I

- Complete specific project goals and objectives through project management techniques

### Level II

- Set performance measures, monitor and evaluate trends, and benchmark against industry standards

## **Domain 2**

### **Business and Clinical Operations**

- Determine criteria for selecting suppliers, procedures for ordering supplies, and developing an inventory control system

#### **Level III**

- Assess financial data and customer feedback when setting priorities and evaluating alternatives

### **Competency 3**

**Develop work process improvements that reduce variability, minimize errors, and ensure quality.**

#### **Level I**

- Utilize process improvement tools, such as the Plan-Do-Check-Act methodology, Six Sigma methodology, Lean, or ISO quality systems

#### **Level II**

- Establish a process improvement program to identify deviations from designed work processes
- Alter and adjust processes in response to changes in the environment or technology

#### **Level III**

- Apply statistical applications in analysis of data, outcomes algorithms, and utilization

*Refer to Quality Management for Patient Safety Domain Area 6 and Medical Decision Support Domain Area 9 for additional information on this topic.*

### **Competency 4**

**Employ system thinking that coordinates and integrates work systems within the institution.**

#### **Level I**

- Develop effective communication strategies and linkages within the laboratory and other institutional units

#### **Level II**

- Integrate department strategic plans with the institution's vision, mission, goals, and objectives

#### **Level III**

- Coordinate patient care across processes, functions, institutional units, and other healthcare services, providing a continuum of care

## **Competency 5**

**Develop workplace preparedness plans for disasters or emergencies and continuity of operations.**

### **Level I**

- Prepare a hazard vulnerability analysis for community-related disasters, pandemics, and institution-specific incidents (fire, building damage, loss of power/water)

### **Level II**

- Develop a detailed plan to address each of the vulnerabilities, the response, mitigation, and preparedness strategies based on the analysis
- Implement a training plan for staff and develop drills to evaluate the plan's effectiveness

### **Level III**

- Evaluate preparedness plans for disasters or emergencies and ensure operational compliance



## Domain 3

# Financial Management

**Definition:** Financial Management is the competency in healthcare finance, requiring sound financial management practices at all levels of experience, as well as an understanding of budgeting for personnel, including:

- Financial accounting, including basic accounting functions of data entry, transaction analysis, and the preparation and interpretation of financial statements for internal managers and external stakeholders
- Managerial accounting, with a focus on internal uses of accounting information for decision making
- Financial management, including assets management with an emphasis on cash flow analysis

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## Competency 1

**Develop and implement the institution's budget to achieve institution strategic goals. Understand basic financial statements, including the balance sheet, income statement (statement of revenue and expenses), and statement of cash flows.**

### Level I

- Execute operating and personnel budgets to control and coordinate activities for management of the clinical areas

### Level II

- Utilize cost accounting principles in the management of the clinical areas

### Level III

- Develop, analyze, and utilize monthly financial reports in the management of the clinical areas

## Competency 2

**Demonstrate knowledge of current and future reimbursement for clinical services from government agencies, insurers, and managed care.**

### Level I

- Demonstrate a business orientation that recognizes opportunities for new business development and the economic impact of the clinical areas to system
- Understand the true costs associated with producing a test result and reimbursement for laboratory procedures

- Distinguish the structure and dynamics of healthcare markets

**Level II**

- Demonstrate knowledge of reimbursement systems, including coding and payment models, and their relationship to clinical areas

**Level III**

- Assess managed care systems and demonstrate ability to develop and negotiate managed care contracts
- Have a working knowledge of Current Procedural Terminology (CPT) codes and system in place to review all tests annually for proper CPT coding, thereby maximizing reimbursement for the laboratory
- Negotiate contracts by selecting those with terms most favorable economically and clinically

**Competency 3**

**Establish internal controls for management of collections and optimum reimbursements to maximize the system's return on investment (ROI) for diagnostic services.**

**Level I**

- Utilize controls and workflow to minimize the risk of financial loss and ensure institutional integrity

**Level II**

- Establish a system of controls to minimize the risk of financial loss and ensure institutional integrity

**Level III**

- Evaluate institutional costs of operations and market conditions in order to maximize financial reimbursement, including:
  1. Analyze the cost of providing services, including review of fixed costs (FC) and variable costs (VC)
  2. Utilize this information to determine contribution margins, break-even points, and profitability of programs

**Competency 4**

**Monitor and control the allocation of resources within healthcare institutions by analyzing financial performance and reporting results to stakeholders.**

**Level I**

- Perform financial analysis by employing: tools and processes, modeling, forecasting, and benchmarking cost/benefit analysis

## **Domain 3**

### **Financial Management**

#### **Level II**

- Prepare periodic financial statements

#### **Level III**

- Develop and implement business plans in response to results of financial analysis

## **Competency 5**

**Monitor and control the capital cycle investment decisions in alignment with the institution's strategic planning process.**

#### **Level I**

- Assess the capital needs of the department, including equipment and program development

#### **Level II**

- Negotiate contracts with vendors with an understanding of different methods for capital funding (i.e., lease vs. reagent rental vs. outright purchase)

#### **Level III**

- Evaluate equipment and program development needs using economic and accounting evaluation techniques to assess ROI in the following areas:
  1. Net present value (NPV)
  2. Internal rate of return (IRR)
  3. Accounting rate of return (ARR)
  4. Payback
- Create workflows to assist with achieving operating results that create sufficient excess for capital investment



## Strategic Planning and Marketing

**Definition:** Strategic planning is the powerful message of “who are we, what do we do, where are we going, and how are we going to get there.” Marketing is the implementation of this message with specific tools, timetables, and measurements to assist in achieving the institution’s mission with customers.

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### **Competency 1**

**Develop and implement an effective strategic plan for the institution that supports the corporate vision, mission, and values.**

#### **Level I**

- Identify with the mission, vision, and values of the institution and understand the focus and application of these to the business
- Involve staff in applying the strategic plan to their department structure and goals
- Communicate to departmental staff the monitors identified to support the strategic plan

#### **Level II**

- Participate in the review and update of the institution strategic plan
- Involve staff in establishing department mission and goals to support the strategic plan
- Review and redirect department goals and objectives to achieve strategic initiatives
- Perform a departmental SWOT (*strengths, weaknesses, opportunities, threats*) analysis to be used in setting goals and objectives

#### **Level III**

- Lead the senior management team in planning and implementing strategic initiatives and long-range plans to fulfill the institution’s mission, vision, and values
- Identify potential roadblocks and de-railers to strategic plans with appropriate response strategies
- Communicate and actively promote the mission, vision, values, strategic plan, and goals throughout the institution

## **Domain 4**

### **Strategic Planning and Marketing**

#### **Competency 2**

**Develop and implement a dynamic annual business plan.**

##### **Level I**

- Integrate daily operational structure of the department to meet the objectives of the metrics within the business plan
- Detect and report variances of the business plan to senior leadership
- Promote departmental objectives and evaluate achievement of staff targets to the business plan
- Identify and evaluate costs and revenue
- Understand profitability and ROI analysis

##### **Level II**

- Identify key criteria/metrics to measure performance and achieve goals of the annual business plan with performance indicators
- Target specific productivity goals and innovative ideas to achieve growth metrics identified in the business plan
- Implement operational logistics to support business plan foundation
- Perform benchmarking against other facilities

##### **Level III**

- Identify specific department goals to achieve ROI initiatives and ensure long-term growth for the institution
- Describe strengths and weaknesses of the institution and institute a timeline to further improve the operations and growth of the business
- Assess and redirect operational initiatives as needed to achieve business goals

#### **Competency 3**

**Formulate a marketing plan that identifies opportunities and strategic alliances targeting growth for the institution.**

##### **Level I**

- Develop key contacts and relationships with all departments within the institution to achieve synergies and teamwork towards growth targets
- Educate all staff members on the metrics of the marketing plan to ensure ongoing accountability and measurement towards growth target
- Review and reinforce quality standards and appropriate responses to any customer service incidents with the marketing team
- Define your service/product

##### **Level II**

- Promote packaging of services among all departments to achieve seamless customer service for both internal and external customers
- Develop packaging and sales brochures with a positive visual effect

## **Domain 4** **Strategic Planning and Marketing**

- Investigate and engage other laboratory partners in local/regional areas to network and develop strategic partnerships
- Actively educate all staff members on effective tools and resources for quality customer service processes
- Plan logistical support needed to achieve growth targets through efficient, innovative operational and capital budget processes

### **Level III**

- Identify specific service and quality initiatives that will demonstrate the institution's niche within the community
- Measure existing and potential market share to facilitate targeting of specific service and growth targets for the institution
- Perform market assessment and logistics development
- Institute service, price, and growth potential metrics and communicate essential support service areas to achieve targeted goals
- Develop workflow assessments and changes to meet targeted goals

## **Competency 4**

**Organize an effective promotional campaign that promotes service and education to the outreach market.**

### **Level I**

- Identify specific department services that support the advertising campaign
- Educate all staff members on excellence in customer service techniques
- Collaborate with related ancillary services, such as radiology, to develop unique service packages
- Identify and implement efficient processes for phlebotomists, couriers, and customer service representatives focused on the voice of the customer
- Coordinate the messaging of the public relations campaign to internal customers
- Develop a call center as a one-stop resource for the customer
- Implement an internal "tool kit" for seamless conversion of new clients

### **Level II**

- Leverage resources within the department to assist in education and support of the marketing campaign
- Exemplify the integrity and consistent quality outcomes of the department services to sustain the campaign message
- Promote scripting within all service areas to ensure that a consistent message is being communicated to internal and external customers

### **Level III**

- Construct an advertising campaign utilizing community resources to enable an effective communication strategy on institution quality and service promotions

## **Domain 4**

### **Strategic Planning and Marketing**

- Coordinate consistent messaging throughout the market territory to promote confidence, knowledge, and trust with institutional service and support
- Target value-added services to distinguish the institution from the competition
- Partner with managed care and insurance institutions to educate clinicians on effective use of laboratory medicine for improved patient outcomes

## **Competency 5**

**Develop and manage an ongoing customer feedback process to ensure market retention and customer satisfaction.**

### **Level I**

- Develop ongoing monitors to track specific department functions that impact customer service
- Communicate ongoing real-time status reports to staff on customer surveys
- Educate staff members on customer service techniques and options to enhance the customer experience, including related staff outside of your department (billing office, registration, etc.)
- Develop patient and clinician survey tools to assess the voice of the customer and utilize feedback to improve service and improved tracking metrics

### **Level II**

- Identify and implement programs to address customer complaints and create opportunities for improvement in client service and education
- Promote internal recognition programs to highlight staff members who exemplify exceptional customer service techniques
- Utilize performance improvement processes to turn errors and challenges into opportunities

### **Level III**

- Identify market trends and construct education and service levels within the institution to meet/exceed customer needs
- Collaborate with public relations and customer service institutions to benchmark best practices with client retention and promotion
- Create a culture of consistent service and quality improvement

## **Competency 6**

**Produce ongoing metrics of organizational effectiveness toward strategic and growth targets, and identify opportunities for improvement.**

### **Level I**

- Apply institutional targets to department goals and objectives
- Assemble department metrics to relate to institutional strategies
- Evaluate and communicate effectiveness of department to institutional targets
- Review referral test listing to evaluate test repatriation possibilities

### **Level II**

- Review baseline performance and prescribe opportunities to enhance volume and quality of services efficiently
- Diversify services to add additional growth opportunities within the strategic and business plans
- Demonstrate all integral business operations to meet legal and compliance criteria

### **Level III**

- Identify community service needs and formulate targets within the institution to meet/exceed service levels
- Strategize and prioritize specific performance improvement metrics across all aspects of the institution
- Demonstrate and communicate the competitive advantage based on institutional targets



## Domain 5

# Human Resource Management

**Definition:** Human Resource Management is the strategic acquisition, development, and management of personnel and the design of organizational structures required for successful laboratory operations.

### Competency 1

**Develop competitive recruitment and hiring programs that attract talent to the institution.**

#### Level I

- Establish a comprehensive orientation program to prepare new employees for integration into the workforce and institutional culture

#### Level II

- Develop a fair and legal interview process that optimizes the selection of applicants with required job skills and institutional job fit

#### Level III

- Assess local or national job market and identify recruitment resources appropriate for laboratory staffing needs

### Competency 2

**Formulate a competitive compensation and benefit program that attracts and retains qualified personnel.**

#### Level I

- Develop a personnel budget within the institution's budget guidelines that supports reward and recognition programs to ensure employee satisfaction

#### Level II

- Evaluate the competitive local or national compensation packages including hourly pay, shift differentials, bonuses, benefits, and paid time off

#### Level III

- Establish compensation policies that are compliant with federal and state labor laws

## **Competency 3**

**Develop a workforce plan that meets operational staffing needs.**

### **Level I**

- Identify the skill levels of staff needed to perform job responsibilities
- Develop job descriptions that identify job duties, knowledge, and skill required
- Provide monthly continuing education modules to keep competency in all appropriate areas

### **Level II**

- Utilize productivity assessment techniques to develop plans for staffing optimization for required work hours

### **Level III**

- Identify national peer data resources available for external productivity comparisons

## **Competency 4**

**Establish a staff development program that develops and retains talent.**

### **Level I**

- Establish training and competency assessment programs and policies that accurately develop and assess technical skills, and meet regulatory standards
- Convey the importance of individual development planning and goal setting for systematic improvement of skills
- Develop an employee appraisal system that provides regular and consistent feedback to staff on assessment of behaviors and technical skills required for performance of job duties
- Maintain documentation of all training and competency assessments

### **Level II**

- Create a career development program that identifies and promotes both leadership and technical skill development and that supports employee appraisal development planning

### **Level III**

- Examine the importance of succession planning and identification of leadership potential within an institution
- Develop a program for succession planning that includes tuition reimbursement as an incentive to further educational development

## **Domain 5**

### **Human Resource Management**

#### **Competency 5**

**Develop an Employee Relations Program that promotes employee satisfaction, motivates high performers, and proactively identifies and resolves employee problems.**

##### **Level I**

- Demonstrate understanding of employee satisfaction and how to motivate high performers
- Create employee teams to work on the actual development and implementation of engagement/impact plans

##### **Level II**

- Establish effective communication programs that promote staff input into appropriate operational activities and provide timely and accurate information to the staff
- Implement communication methods to ensure shift-to-shift transitions run smoothly

##### **Level III**

- Develop fair personnel policies that are compliant with state and national regulation
- Establish an employee performance improvement process that provides a fair and “just” culture for identifying and resolving performance problems



### Quality Management for Patient Safety

**Definition:** *Quality Management for Patient Safety exemplifies the skills required for successfully developing a laboratory's management and operations infrastructure using the fundamental components of a quality management system.*

#### Competency 1

**Develop, implement, and maintain a Quality Control (QC) program for ensuring the quality of testing and examination results.**

##### Level I

- Identify basic QC requirements
- Write the QC policy in accordance with government and accreditation requirements
- Establish the QC specifications for analytical processes
- Resolve QC outliers
- Implement corrective actions to prevent future QC outliers

##### Level II

- Train laboratory staff in QC principles and practices
- Implement the QC program
- Measure and monitor the analytical process according to established specifications

##### Level III

- Assess the analytical process; monitor compliance with QC specifications
- Ensure documented review of QC data and appropriate follow-up actions are taken, as needed
- Share recommendations with the laboratory director for methods to articulate QC practices of the laboratory to any all laboratory stakeholders, i.e., referring physicians, clients, healthcare workers, etc.

## **Domain 6**

### **Quality Management for Patient Safety**

#### **Competency 2**

**Develop, implement, maintain, and evaluate key indicators of laboratory quality that determine how well pre-analytic, analytic, and post-analytic processes are performing against goals and standards.**

##### **Level I**

- Articulate the laboratory's written Quality Assessment (QA) plan
- Identify pre-analytic, analytic, and post-analytic QA indicators
- Assist with data collection and tabulation

##### **Level II**

- Establish goals for the QA indicators
- Develop data collection processes
- Implement the indicators
- Interpret indicator data and assign follow-up measures
- Demonstrate use of tools to present indicator information

##### **Level III**

- Collaborate with laboratory director in establishing and monitoring QA program
- Direct/lead the laboratory's quality committee
- Reference problematic processes to the laboratory's continual process improvement effort
- Conduct ongoing review of key indicators, and revise laboratory QI program as necessary

#### **Competency 3**

**Develop, implement, and maintain a Quality Management System (QMS) that leads to meeting regulatory, accreditation, and customer requirements, improvement of laboratory services, and contribution to patient safety.**

##### **Level I**

- Articulate quality management standards and requirements of applicable accrediting agencies
- Write policies, processes, and procedures for describing the institution, including organizational charts and management responsibilities
- Convey essentials of the QMS to key stakeholders, including laboratory staff, laboratory director, institutional administrators, etc.

### **Level II**

- Communicate and implement policies, processes, and procedures for managing:
  1. Customer service
  2. Laboratory facility and employee safety
  3. Laboratory personnel
  4. Laboratory equipment
  5. Efficient purchasing and inventory activities
  6. Pre-analytic, analytic, and post-analytic laboratory processes and procedures
  7. Control of information, documents, and records
  8. Nonconformance and follow-up
  9. Participation in external assessments and performance of internal assessments
  10. Continual improvement
- Implement the QMS policies, processes, and procedures

### **Level III**

- Integrate QC, QA, continual improvement, and other quality activities into a systematic approach to quality management
- Assess the effectiveness of the QMS
- Collaborate with the laboratory director, making recommendations as indicated

## **Competency 4**

### **Understand the financial impact of quality in laboratory operations.**

#### **Level I**

- Identify the costs of evaluating and maintaining quality in the laboratory
- Identify the types and respective costs of internal and external failures experienced by the laboratory

#### **Level II**

- Develop the means to estimate and compare the laboratory's positive and negative quality costs
- Implement a quality cost review program

#### **Level III**

- Create an action plan when failure costs are identified that:
  1. Affect regulatory compliance
  2. Diminish customer service, or patient outcomes
  3. Have a significant negative impact on the operating budget
- Communicate failure cost of quality to the institution's senior management

## **Domain 6**

### **Quality Management for Patient Safety**

#### **Competency 5**

**Integrate laboratory into institutional Quality Improvement (QI) program to improve quality, patient safety, and customer satisfaction.**

##### **Level I**

- Understand laboratory integration into institutional QI program
- Describe and implement the laboratory components of the corrective action process
- Describe and implement the preventive action process for the laboratory and institution

##### **Level II**

- Identify opportunities for improving laboratory services that cross departmental boundaries
- Design plans to improve intra-departmental (i.e., within the laboratory) processes

##### **Level III**

- Design and implement plans to improve institutional components of laboratory improvement programs
- Develop and implement a plan to communicate laboratory quality management outcomes to the institutional stakeholders and customers (i.e., market the laboratory's quality)



### Information Management and Technology

**Definition:** *Information Management and Technology is the implementation, assessment, and management of the operation of laboratory information system(s) to meet corporate strategic plans and clinical needs within the parameters of best practice. It may also include laboratory management collaboration, stakeholder input, partial oversight, or direct management by the laboratory.*

#### **Competency 1**

**Demonstrate an ability to maintain operation of current laboratory technology systems, ensuring accurate and consistent flow of information and communication for all stakeholders.**

##### **Level I**

- Describe corporate and laboratory staffing structure and accountability for individual laboratory systems
- Identify all current laboratory computer information system structures within the manager's area of responsibility
- Describe computer and technology terminology related to the laboratory
- Establish uses and maintain laboratory and corporate information technology systems for routine operation, which may include Laboratory Information System (LIS) area module(s), word processing, file storage, etc.
- Establish a consistent, professional communication system for stakeholders to communicate about themselves (including clinical, non-clinical staff, other healthcare providers, institutions, and patients)
- Demonstrate how to document and report to the most responsible person: exceptional orders, cancellations, errors, corrections, unusual specimens, and atypical occurrences
- Provide functions/reports required by regulatory agencies
- Practice application of Administrative Policies related to information systems, including privacy requirements
- Provide training of maintenance processes and procedures to ensure adequate staffing for backup and support

##### **Level II**

- Evaluate and ensure that changes or modifications do not negatively affect other stakeholders
- Define if an upgrade is necessary and what is provided, including:
  1. Plan a schedule for the upgrade
  2. Test/validate to ensure integrity of data
  3. Document and communicate changes

## **Domain 7**

### **Information Management and Technology**

4. Retrain staff if necessary
5. Move the upgrade to the live environment
6. Monitor and adjust/correct if necessary

#### **Level III**

- Alter, further develop, or adjust operations to maximize information technology in response to changes in the environment, customer needs, or technology.

### **Competency 2**

**Demonstrate an ability to provide an appropriate computer environment.**

#### **Level I**

- Provide clean, well-maintained locations for computers that meet vendor specifications
- Protect computer devices from interference from electromagnetic sources (e.g., MRI equipment)
- Locate computer wires or cables in a protected area
- Use instrument cabling that meets standards for instrument and LIS interfacing
- Provide physical security to computer systems and data storage devices

#### **Level II**

Not applicable at this time

#### **Level III**

Not applicable at this time

### **Competency 3**

**Demonstrate an ability to plan, design, and manage laboratory information systems security.**

#### **Level I**

- Establish procedures for system integrity to include backup of data and system files, contingency and disaster plans for software or hardware recall, physical protection and power protection, database integrity checks, dictionary consistency checks, and the related documentation of procedures and event outcomes
- Plan for appropriate redundancy in hardware or software to enable critical processes to operate if a system fault occurs
- Establish and implement security audit procedures for all technology systems
- Develop policies to address employees' personal use of the institution's technology

- Establish procedures to ensure technology security, access control, and confidentiality of information according to institutional and regulatory requirements

**Level II**

Not applicable at this time

**Level III**

Not applicable at this time

**Competency 4**

**Demonstrate an ability to meet various regulatory requirements for information systems.**

**Level I**

- Understand and maintain regulatory compliance for technology systems of the laboratory area

**Level II**

- Evaluate regulatory updates to ensure regulatory compliance for laboratory information systems
- Collaborate with other areas to meet regulatory compliance for corporate-wide systems

**Level III**

- Participate as an information technology peer assessor for regulatory accreditation and/or inspection visits
- Participate on regulatory association committees or feedback surveys for recommendations on regulatory requirement updates for information technology

**Competency 5**

**Demonstrate an ability to determine the need, selection criteria, and implementation of a new information technology system.**

**Level I**

- Track trends and statistical data for the system needs assessment
- Identify stakeholders and understand stakeholder needs

**Level II**

- Remain current with technology development news and education, and attend user group meetings
- Evaluate trends and internal and external factors that may identify the need for new information technology systems

## **Domain 7**

### **Information Management and Technology**

- Validate, verify, and ensure training for and implementation of new information technology systems

#### **Level III**

- Determine and understand the risks, challenges, and barriers for laboratory-related systems and communicate the findings to Senior Administration, including the understanding of:
  1. The life cycle of current systems
  2. Security and access
  3. File storage and maintenance
  4. System utilities (program loading, crash recovery, disk copying and backup, usage monitoring, and problem diagnosis)
  5. Input and output accuracy and usability (printout formats, displays, manual data entry screens, laboratory test definitions, and codes)
- Determine purpose and priorities of a new laboratory information system based on the corporate strategic plan and risk assessment
- Identify laboratory information system feature and functionality requirements of clinician and institution stakeholders
- Appraise, recommend, and implement requirements for a successful choice of technology
- Participate in selection process with staff, stakeholders, and vendors
- Recommend or approve the purchase of laboratory technology information systems
- Develop laboratory change management strategies, test and implement the system, and evaluate the outcome
- Develop expertise in the adaptation and user enhancement of the new system
- Adjust and improve processes through staff, vendor, and stakeholder input
- Develop contingency plans for lack of vendor support
- Determine the feasibility of an alpha/beta testing arrangement with vendors for the design and development of key modules to gain a marked improvement with the current system or an advantage over competitors
- Initiate or participate in corporate meetings to discuss, plan, and implement corporate-wide information technology systems
- Plan and perform post-implementation audit to validate benefits realization and achieved return-on-investment
- Prepare to take a role in external and/or regional information technology planning and implement initiatives

## **Competency 6**

**Demonstrate an ability to determine the need for the inactivation, retiring, disposal, or archiving of a technology information system.**

#### **Level I**

- Track and trend statistical data for the current system use
- Identify stakeholders and understand stakeholder needs and/or requirements, including regulatory requirements

**Level II**

- Demonstrate currency with technology development
- Evaluate trends and internal and external factors that may identify the need for the disposal or archiving of the current information system
- Approve, decline, or modify inactivation, disposal, or archiving of current information system
- Develop or change management process, contingency plans, and appropriate documentation for regulatory requirements
- Schedule audits for retrieval of archived information from inactivated or archived systems

**Level III**

- Evaluate outcome and adjust and improve processes through staff and stakeholder input
- Initiate or participate in corporate meetings to discuss, plan, and implement corporate-wide inactivation of information technology systems
- Establish exit strategy and identify ownership, access to records, and length of time records to be maintained if institution ceases to conduct business



## Domain 8

### Compliance and Risk Management

**Definition:** *Compliance and Risk Management is the management of governance and operations while remaining within the definitions of the institution's established legal structure in order to maintain compliance with Federal, State, local, and contractual mandates.*

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#### Competency 1

**Clinical Laboratory Improvement Amendments (CLIA), Accreditation – Maintain compliance with CLIA regulations and understand how the regulations are related to College of American Pathologists (CAP), American Association of Blood Banks (AABB), The Joint Commission (TJC, formerly JCAHO), and other institutional accreditation processes.**

##### Level I

- Describe CLIA-related regulations and accreditation requirements
- Create policies and procedures that comply with CLIA-related regulations and accreditation requirements
- Participate in the inspection preparation processes

##### Level II

- Instruct new laboratory staff how the application of CLIA-related regulations is accomplished
- Review and apply policies and procedures addressing CLIA-related accreditation issues
- Participate in accreditation inspections

##### Level III

- Serve as an inspector for peer accreditation inspections
- Approve policies and procedures addressing CLIA-related accreditation issues

## **Competency 2**

**Health Insurance Portability and Accountability Act (HIPAA) – Recognize the requirements HIPAA places on privacy and security in the use of patient information in clinical practice.**

### **Level I**

- Recognize HIPAA requirements for the collection, storage, and retrieval of patient health information in relation to privacy and security of Protected Health Information (PHI)

### **Level II**

- Ensure adequate safeguards are in place to prevent the delivery and/or transmission of patient information to incorrect healthcare providers, addresses, patients, electronic domains, or fax numbers.

### **Level III**

- Instruct laboratory staff regarding the application of HIPAA regulations and how to recognize HIPAA violations
- Develop mechanisms to coordinate with the hospital compliance or privacy office, documenting improper PHI disclosures
- Oversee the business associate agreement process to ensure that business associate agreements are in place for all necessary vendors, including reference laboratories
- Ensure Institutional Review Board (IRB) approval is obtained from all involved institutions if clinical research is performed

## **Competency 3**

**Identify the Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), and Department of Transportation (DOT) regulations that commonly apply in laboratory operations.**

### **Level I**

- Review the OSHA and DOT regulations that apply to a laboratory operation, including: chemical hygiene, blood-borne pathogens, and hazard communication regulations
- Review the EPA and DOT rules that apply to hazardous specimen/material packing and transportation
- Review the Nuclear Regulatory Commission (NRC) regulations, if radioactive isotopes are used, and ensure compliance
- Ensure all required training is up-to-date and documented
- Ensure that all employees follow safe laboratory practice
- Instruct appropriate laboratory staff in specimen packaging rules on a regular basis

## **Domain 8**

### **Compliance and Risk Management**

#### **Level II**

- Manage the laboratory in a compliant and safe atmosphere
- Document compliance with laboratory policies that address OSHA, EPA, and DOT requirements
- Participate with institution's safety department to ensure all new employees receive adequate training upon hire and at the required intervals

#### **Level III**

- Supervise or perform self-inspections
- Develop a training program for staff regarding specimen packaging rules for infectious materials

### **Competency 4**

**Recognize high-risk compliance areas and create policies where needed.**

#### **Level I**

- Describe the Centers for Medicare and Medicaid Services (CMS) Billing Regulations that apply to medical laboratory billing for Medicare, Medicaid, and other payers
- Ensure that all pricing and discounting arrangements comply with Office of Inspector General (OIG) guidelines
- Identify laws and regulations that restrict sales and marketing practices in healthcare

#### **Level II**

- Create policies to comply with all OIG guidelines regarding acceptable and not acceptable sales and marketing and contracting practices
- Ensure that employees responsible for Current Procedural Terminology (CPT) code assignments are trained regarding each laboratory procedure
- Apply modifier usage of common laboratory billing modifiers, including the application of Correct Coding Initiative (CCI) and Outpatient Code Editor (OCE) coding edits, as well as End Stage Renal Disease (ESRD) billing requirements
- Ensure that employees responsible for International Classification of Diseases-9 (ICD9) code translation are trained and certified according to the level of coding.

#### **Level III**

- Prepare for transition to International Classification of Diseases-10 (ICD10) coding that is scheduled to begin in 2011, with full implementation scheduled for October 1, 2013
- Review and update laboratory Charge Description Master (CDM) for additions and changes on a regular basis

## **Competency 5**

**Participate with the institution's compliance department to ensure that all compliance requirements are incorporated to support an effective program.**

### **Level I**

- Review institution's Corporate Compliance Plan or activities
- Support monitoring and auditing programs
- Participate in internal monitoring needs
- Review medical necessity requirements including National Coverage Determination (NCD), Local Coverage Determinations (LCD), and Medically Unlikely Edits (MUE)

### **Level II**

- Ensure that all employees have the opportunity and participate in laboratory specific compliance training
- Enforce all compliance policies and, when necessary, institute employee discipline
- Discuss Medical Necessity requirements with clients (physicians/ healthcare providers)

### **Level III**

- Create a Laboratory Compliance Plan as directed by the OIG, using the OIG Model Compliance Plan for Laboratories as a template
- Provide training to staff regarding Laboratory Compliance
- Monitor and audit the Laboratory Compliance Plan
- Write and distribute annual letter to physicians and other healthcare providers describing the laboratory's compliance efforts

## **Competency 6**

**Identify and control the risks inherent to laboratory operations.**

### **Level I**

- Identify potential areas of risk in the laboratory, including: patient safety, liability, and employee safety
- Ensure that the institution uses a well-documented event reporting system that includes oversight and review of reportable events

### **Level II**

- Create processes to address identified areas of risk
- Document processes to maintain institutional memory to provide for future reference and reduce risk
- Participate with the institution's risk management office to document reportable events

## **Domain 8**

### **Compliance and Risk Management**

- Develop a process for identifying the basic or causal factors in a root cause analysis system
- Participate in process improvement activities that addresses areas of risk

#### **Level III**

- Apply Failure Mode and Effect Analysis (FMEA) as a root cause analysis tool

## **Competency 7**

**Internalize laws and regulations that govern laboratory operations.**

#### **Level I**

- Participate in professional organizations that follow legislative and regulatory initiatives
- Review and assess the impact of new regulations on laboratory operations and profitability

#### **Level II**

- Implement processes to comply with new regulations and instruct laboratory staff regarding these regulations
- Subscribe to professional newsletters to increase awareness of government activity that can affect the institution

#### **Level III**

- Proactively advocate on proposed laws or regulations when needed
- Submit comments to Congress and the Centers for Medicare and Medicaid Services (CMS) when necessary

## **Competency 8**

**Evaluate all contracts the institution has signed with vendors, reference laboratories, or physicians' offices.**

#### **Level I**

- Recognize the existence of contracts with external parties

#### **Level II**

- Identify potential opportunities to contract with external parties

#### **Level III**

- Accept responsibility to comply with the contractual language
- Develop a process to monitor contract compliance
- Review new and existing contracts and comply with all contractual agreements
- Participate in contract negotiations when appropriate



## Medical Decision Support

**Definition:** *Medical Decision Support presents healthcare providers with information regarding the effective utilization of laboratory services. This support requires an analysis and evaluation of services that is patient-focused and results in positive outcomes.*

### Competency 1

**Ensure optimal test utilization in compliance with clinical standards that are aligned with the organizational mission.**

#### Level I

Not applicable at this time

#### Level II

- Consult with the laboratory medical director to ensure the test menu is appropriate for the client base
- Maintain an ongoing mechanism to evaluate the overuse, misuse, and under-use of laboratory procedures
- Consult with healthcare providers regarding current guidelines and protocols for proper test utilization

#### Level III

- Communicate opportunities for improved utilization to appropriate healthcare providers
- Consult with providers regarding compliance and medical necessity issues
- Incorporate pay for performance quality metrics into the Electronic Medical Records (EMRs) with alerts, reminders, and standardized order sets

### Competency 2

**Investigate new methodologies, tests, and equipment to ensure the laboratory is offering the highest quality and most cost-effective services.**

#### Level I

Not applicable at this time

#### Level II

- Evaluate test complexity of current test menu and evaluate alternatives that may improve the quality of service

## **Domain 9**

### **Medical Decision Support**

#### **Level III**

- Apply evidence-based methods and comparative effectiveness tools regarding decisions to modify, maintain, or eliminate any change
- Communicate to the multidisciplinary team the findings of evaluation
  - Instruct all staff effected by any changes or improvement
  - Develop an evaluation process to measure quality improvement

### **Competency 3**

**Seek physician/healthcare provider's involvement in decision making regarding optimal laboratory services.**

#### **Level I**

Not applicable at this time

#### **Level II**

Not applicable at this time

#### **Level III**

- Collaborate with other healthcare providers to analyze and streamline test utilization and develop order sets, care pathways, and algorithms

### **Competency 4**

**Improve service levels based upon results of laboratory performance assessments.**

#### **Level I**

Not applicable at this time

#### **Level II**

Not applicable at this time

#### **Level III**

- Evaluate and benchmark against current best practices for pre-analytic, analytic, and post-analytic laboratory procedures

### **Competency 5**

**Create an institutional culture that places emphasis on patient-focused activities.**

#### **Level I**

Not applicable at this time

#### **Level II**

- Convey to the lab staff their responsibility to communicate effectively and

interact with other healthcare providers the vital information that results in positive patient outcomes.

**Level III**

- Participate with case management team to reduce length of stay, improve efficiency, and employ appropriate testing



## Domain 10

# Professional Development

**Definition:** Professional Development includes the skills and knowledge necessary for both personal development and career advancement.

### Competency 1

**Demonstrate professionalism.**

#### Level I

- Possess generalized and systematic knowledge with a theoretical base
- Strive to grow professionally through continuous study and preparation
- Display well-oriented professional knowledge
- Respond to all communications within a reasonable and appropriate time

#### Level II

- Hold a high degree of self-control of behavior
- Display loyalty to the profession
- Govern by a code of ethics

#### Level III

- Maintain associations that advance the goals of the profession
- Contribute to the advancement of medical laboratory management by enhancing the Body of Knowledge (i.e., speaking engagements, publishing papers)
- Promote favorable legislation
- Publish information and research to explain the profession's uniqueness
- Provide subordinates with definite, positive assistance to correct professional difficulties

### Competency 2

**Identify professional goals for career development.**

#### Level I

- Review job descriptions that contain opportunities for professional growth

#### Level II

- Identify management skills for specific job descriptions
- Develop personal attributes for a leadership role
- Identify instructional or experiential activities that promote job skills
- Network with individuals holding similar job titles and develop mentoring relationships

**Level III**

- Develop management skills for job placement

**Competency 3**

**Develop personal attributes for a leadership role.**

**Level I**

- Demonstrate good judgment in selecting the proper mode of communication in oral and written formats
- Listen to others and objectively consider their ideas
- Convey competence, confidence, and enthusiasm

**Level II**

- Present a positive disposition and maintain constructive interpersonal relationships
- Maintain perspective in viewing issues or situations

**Level III**

Not applicable at this time

**Competency 4**

**Identify continuing education opportunities to develop areas of weakness and advance personal knowledge base and leadership.**

**Level I**

- Seek training to address technical skill and knowledge deficiencies
- Read professional journals to keep informed of new developments and terminology in the field
- Build on individual strengths

**Level II**

- Attend laboratory professionals' seminars and in-service workshops to develop non-technical skills, such as communication and personnel relations skills
- Enroll in formal academic education, training, and structured experiential activities which aid in the growth of professional expertise
- Consider mentoring by aligning with a higher level leader in or out of respective department

**Level III**

- Strengthen collegiality by participating in a professional network (e.g., laboratory professional organization committees, board of directors)
- Assume challenging or unfamiliar assignments
- Contribute to professional journals and organizations
- Present at professional meetings optimizing available tools and technology

## **Domain 10**

### **Professional Development**

#### **Competency 5**

**Evaluate the effectiveness of instructional programs and professional growth.**

##### **Level I**

- Maintain a personal employee portfolio that reflects continuing education activity and areas of professional development
- Continually identify areas of growth opportunities based on self-evaluation

##### **Level II**

- Prepare to demonstrate competency in skill acquisition: for example, sit for specialist exams such as Certified Specialist in Chemistry (SC), Diplomate in Laboratory Management (DLM), or Continuous Quality Improvement (CQI)

##### **Level III**

- Acquire an objective understanding of professional growth achieved by seeking external feedback

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# Glossary

## Definitions from Wikipedia

**Information management (IM)** is the collection and management of information from one or more sources and the distribution of that information to one or more audiences. This sometimes involves those who have a stake in, or a right to that information. Management means the organization of and control over the structure, processing and delivery of information.

**Information Technology (IT)** is "the study, design, development, implementation, support or management of computer-based information systems, particularly software applications and computer hardware."

**Information Systems (IS)** is a professional and academic discipline concerned with the strategic, managerial and operational activities involved in the gathering, processing, storing, distributing and use of information, and its associated technologies, in society and organizations.

## Definitions from A Laboratory Quality Handbook of Best Practices and Relevant Regulations, Donald C. Singer, Editor, 2001

### **Acceptance Testing**

Formal testing conducted to determine whether or not a system satisfies its acceptance criteria and to enable the customer to determine whether or not to accept the system.

### **Assurance**

A measure of confidence that the security features and architecture about a laboratory information management system accurately mediate and enforce the security policy.

### **Audit**

Qualitative and quantitative evaluation of the documentation and procedures associated with the laboratory information management system to verify that resulting laboratory information management system raw data are acceptable quality.

### **Change Control**

Management and implementation methodologies associated with increasing or correcting system capabilities, a partial system redesign, or determining software obsolescence.

### **Commercially Available Software**

Software that is readily available through lease or purchase in the commercial market.

### **Data**

A representation of facts, concepts, information, or instructions suitable for communication, interpretation, or processing by humans (or by a laboratory information system).

### **Design (Software Lifecycle)**

This stage that specifies the automated and manual functions and procedures, the computer programs, and data storage techniques that meet the requirements

# Glossary

*identified and the security and control techniques that assure the integrity of the system.*

**Documentation**

*The process of gathering written or electronic information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.*

**Facility**

*The premises and operational unit(s) that are necessary for operating a laboratory information system.*

**Hardware**

*Physical equipment such as the computer and its related peripheral devices, tape drives, disk drives, printers, etc.*

**Information**

*Any communication or reception of knowledge such as fax, data, or opinions, including numerical, graphic, or narrative forms, whether oral or maintained in any medium, including computerized databases. (e.g., floppy disk and hard disk, papers, microfilm (microfiche or microfilm), or magnetic tape.*

**Initiation (Software Lifecycle)**

*A request for the development of a system to meet a need for information or to solve a problem for the individual making the request.*

**Inspect**

*To measure, examine, test, or gauge one or more characteristics of an entity and compare the results with specified requirements in order to establish whether conformance is achieved for each characteristic.*

**Installation and Operation (Software Lifecycle)**

*Incorporation and continuing use of the new system by the institution.*

**Integrity**

*Sound, unimpaired, or perfect condition. That computer security characteristic that ensures that computer resources operate correctly and that the data in the databases are correct. This characteristic protects against deliberate or inadvertent unauthorized manipulation of the system and ensures and maintains the security of the entities of a computer system under all conditions. Integrity is concerned with protecting information from corruption.*

**LIMS**

*Laboratory Information Management System*

**Laboratory Management**

*Those individuals directly responsible and accountable for planning, implementing, and assessing work, and for the overall operation of facility.*

**LIMS Raw Data LRD**

*Original observations recorded by the laboratory information management system that are needed to verify, calculate, or derive data for potential reporting.*

**LIMS Raw Data Storage Media**

*The media to which the laboratory information system raw data are first recorded.*

# Glossary

## **Maintenance/Enhancement (Software Lifecycle)**

*Resolving problems not detected during testing, improving the performance of the product and modifying the system to meet changing requirements. (Full scale enhancements require full life cycle analysis).*

## **Original Observations**

*The first occurrence of human-readable information.*

## **Programming (software lifecycle)**

*Coding of the program modules that implement the design.*

## **Quality Assurance Unit**

*Any person or organizational element designated by laboratory management to monitor the laboratory information system functions and procedures.*

## **Records**

*All books, papers, maps, photographs, machine-readable materials, or other documentary materials, regardless of physical form or characteristics, made or received by an agency of the government under law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of organizational, functions, policies, decisions, procedures, operations, or other activities of the government or because of the informational value of the data in them. Library and museum material made or acquired and preserved solely for reference or exit exhibition purposes, extra copies of documents preserved only for convenience of reference, and stocks of publications and other processes documents are not included.*

## **Requirements Analysis (software lifecycle)**

*Determination of what is required to automate the functions identified by the institution.*

## **Retirement (software lifecycle)**

*The stage which ends the use of the system.*

## **Security**

*The set of laws, rules, and practices that regulate how an institution manages, protects, and distribute sensitive data.*

## **Software**

*Software computer programs, procedures, rules, and associated documentation pertaining to the operation of a computer system.*

## **Software Lifecycle**

*The purity of time beginning when a software product is conceived and ending when the product no longer performs the function for which it was designed. The software lifecycle is typically broken into phases such as initiation, requirements analysis, design, programming, testing and quality assurance, installation and operation, maintenance, and retirement.*

## **Software Version Control**

*Management of changes or revisions to a specific baseline software module or application. Software version control provides a mechanism to control changes and to return to any previous revision of the application or module.*

# Glossary

## **Standard Operating Procedures (SOPs)**

*Documentation setting forth methods of operation that laboratory management is satisfied are accurate to ensure the quality and integrity of laboratory information system raw data.*

## **Testing**

*The examination of the behavior of a program by executing the program on sample data sets.*

## **Testing and Quality Assurance (software lifecycle)**

*Ensuring that the system works as and as intended and that it meets applicable organizational standards of performance, reliability, integrity, and security.*

## **Validity**

*A state or quality of software that provides confirmation that the particular requirements for specific intended use are filled. In design and development, validity concerns the process of examining a product or result to determine conformance to users needs.*

## **Verify**

*To review, inspect, test, check, audit, or otherwise establish and document whether or not laboratory information system raw data are accurate.*

## **Definitions from *Clinical Laboratory Management*,**

### **Eleanor M. Travers, 1997**

## **Billing System**

*A hardware and software system that provides a business with the ability to identify the products and services it performs or sells using a coding system, an accounting system, and a system for setting rates, charges, or prices.*

## **Return on Investment (ROI)**

*The financial analysis performed to determine if there is potential for self-sufficiency of an investment (e.g., project, purchase, and proposal) and if it will generate enough revenue to repay the infrastructure costs (e.g., buildings, land, equipment) required to initiate and sustain the investment.*

## **Strategic Plan**

*(1) A written plan that is a reflection of an institution's vision of its future. (2) A long-range plan. (3) A process that directs an institution's attention to the future, enabling it to adapt more readily to change and determine the direction(s) in which it chooses to move.*

## **Technology Assessment**

*(1) A process of evaluation used to estimate if a technology does what the manufacturer says it is supposed to do. (2) A formal method using cost-effectiveness and cost-benefit analysis to determine if a new or existing technology still adds value to the institution in a cost effective, efficient manner.*

## **Workstation**

*(1) The place where a test or service is produced. (2) The point at which the production of a test or service creates and expense. (3) A cost centre.*

## Glossary

### Mix of sources for the acronym definitions

<b>CD</b>	<b>Compact Disk</b>
<b>CLSI</b>	<b>Clinical and Laboratory Standards Institute</b>
<b>CPU</b>	<b>Central Processing Unit</b>
<b>DVD</b>	<b>Digital Video Disk</b>
<b>HIS</b>	<b>Hospital Information System</b>
<b>IRM</b>	<b>Information Resources Management</b>
<b>LIMS</b>	<b>Laboratory Information Management System</b>
<b>LIS</b>	<b>Laboratory Information System</b>
<b>LRD</b>	<b>LIMS Raw Data</b>
<b>MIS</b>	<b>Management Information System</b>
<b>MRI</b>	<b>Magnetic Resonance Imaging</b>
<b>MS</b>	<b>Microsoft</b>
<b>NIST</b>	<b>National Institute of Science and Technology</b>
<b>ROI</b>	<b>Return on Investment</b>
<b>SOP</b>	<b>Standard Operating Procedure</b>
<b>EMRs</b>	<b>Electronic Medical Records</b>

## Glossary

**Additional definitions from OIG Compliance Program  
Guidance for Clinical Laboratories, Federal Register,  
Vol. 63, No. 163, August 24, 1998, p. 45076-45087**

<b>FCA</b>	<b>False Claims Act</b>
<b>FERA</b>	<b>Fraud Enforcement Recovery Act of 2009</b>
<b>CCI</b>	<b>Correct Coding Initiative</b>
<b>OIG</b>	<b>Office of the Inspector General</b>
<b>OCE</b>	<b>Outpatient Code Editor</b>
<b>ESRD</b>	<b>End Stage Renal Disease</b>
<b>CLIA</b>	<b>Clinical Laboratory Improvement Amendments</b>
<b>HCPCS</b>	<b>Healthcare Common Procedure Coding System</b>
<b>CPT</b>	<b>Current Procedural Terminology</b>
<b>NCD</b>	<b>National Coverage Determination</b>
<b>ICD 9/10</b>	<b>International Statistical Classification of Diseases</b>
<b>FMEA</b>	<b>Failure Mode and Effect Analysis</b>
<b>LCD</b>	<b>Local Coverage Determinations</b>
<b>MUE</b>	<b>Medically Unlikely Edits</b>
<b>DOT</b>	<b>Department of Transportation</b>
<b>OSHA</b>	<b>Occupational Safety and Health Administration</b>
<b>HIPAA</b>	<b>Article I. Health Insurance Portability and Accountability Act</b>
<b>CMS</b>	<b>Centers for Medicare and Medicaid Services</b>

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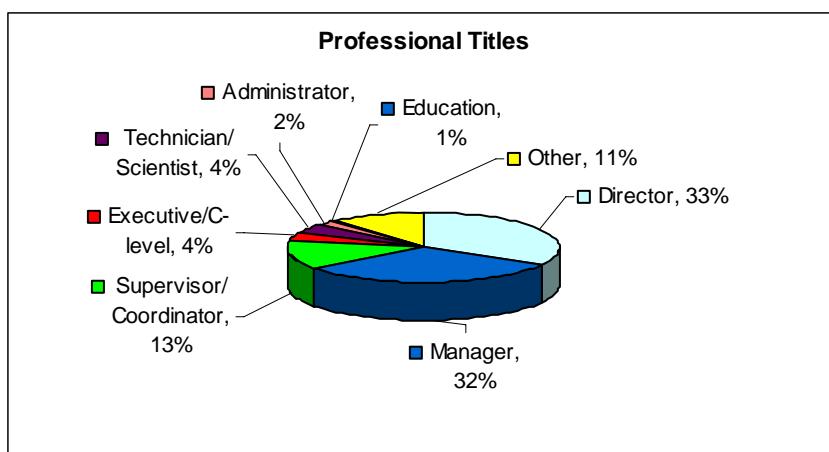
# About CLMA

Founded in 1976, CLMA is an international association of nearly 3,000 clinical laboratory professionals. CLMA provides leadership in the clinical laboratory industry, supporting laboratory professionals at any stage of their career. The association educates and advocates on behalf of members, and plays a leadership role in enhancing the image and increasing the visibility of the laboratory management profession.

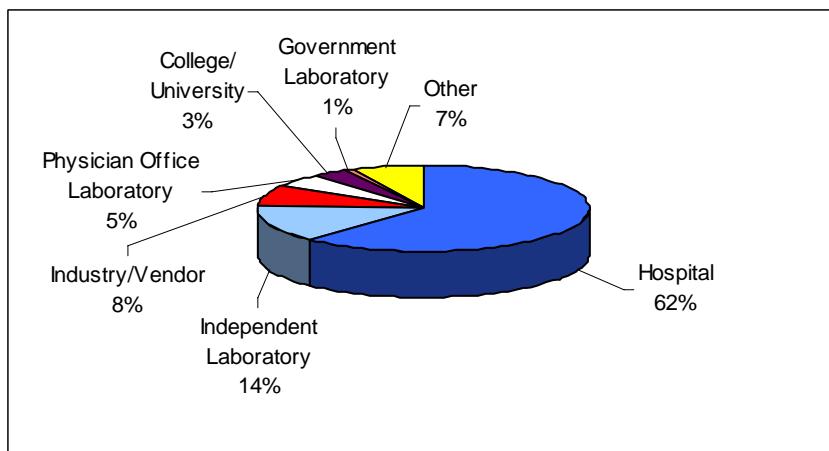
## Mission

CLMA empowers laboratory professionals to achieve excellence in leadership through forward-thinking educational, networking, and advocacy opportunities.

## Who We Are



## Where We Work



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