# Evaluating Your Risk Management and Quality Improvement Program

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# About DLS

## Vision

Exemplary laboratory practice and systems strengthen clinical care, public health, emergency response, and health equity.

## Mission

Improve public health, patient outcomes, and health equity by advancing laboratory systems.

# Developing and Maintaining a Comprehensive Risk Management and a Quality Improvement Plan

- Introduction to laboratory quality
- Quality Management Systems (QMS)
- Benefits of a QMS
- Implementing a QMS
- Introduction to risk management
- Conducting Risk Assessments
- Implementing a Risk Assessment Plan
- Communication

# *What* Does Quality Mean to Your Laboratory

The degree to which a product or service meets requirements and fulfills customers' needs and expectations.

That could mean . . .

- . . . accuracy, reliability, and timeliness of the reported test results.
- . . . measures put in place to eliminate the risk of non-conforming events.

# Fundamentals of Laboratory Quality Management

Laboratories must produce dependable testing with accurate results.

Complexity of laboratory testing requires systematic approaches to ensure accuracy and reliability of services.

A Quality Management System (QMS) is a systematic approach to describing, documenting, implementing, measuring, and monitoring operations.

# Evolution of Implementing Quality In Laboratories

| Elements | Quality Control (QC) | Quality Assurance (QA) | Quality Management |
|---|---|---|---|
| Focus | Method Control | Process Management | Laboratory Systems |
| Scope | Verified examination method controlled through use of internal/external controls | Examination of the performance throughout the total testing process | Evaluation of systematic (management, technical, etc.) processes for laboratory work |
| Limitations | No or limited evaluation of pre-/post-analytical errors | Assessing errors occurring outside workflow processes | Includes all aspects of laboratory functions |
| Evolution | Foundation of quality practices | These processes encompass QC method(s) | System wide focus that is broader than QA and QC |

*Adapted from CLSI QMS01 5th Ed.

## Poll Question 1 – Quality Management Systems

**Select the best answer:** What is the status of quality practices in your laboratory?

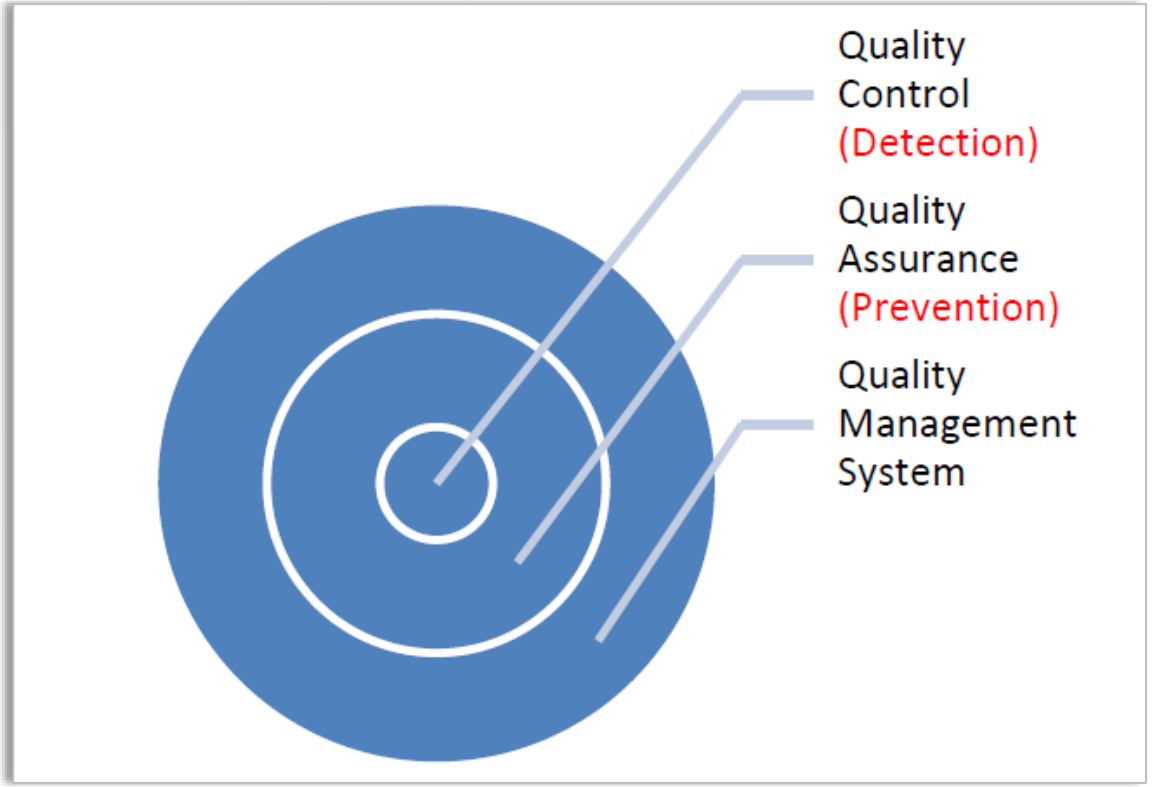
A. Quality Control metrics are fully developed, monitored, and are effective.
B. In addition to QC, Quality Assurance measures are fully developed, monitored, and are effective.
C. My laboratory has a fully developed Quality Management System that systematically evaluates all practices and procedures.
D. What is quality?

**Options:**

A. A
B. B
C. C
D. D

# Quality Management Systems (QMS)

- A formalized and documented system that ensures operational activities are adequately resourced and managed.
- Opportunities to identify improvements and implement change.
- Actively manages all laboratory activities and, to the extent possible, related organizational functions that impact laboratory science.
  - Many functions of a QMS are already being performed in many laboratories, e.g., document control, records management, QC, and QA.

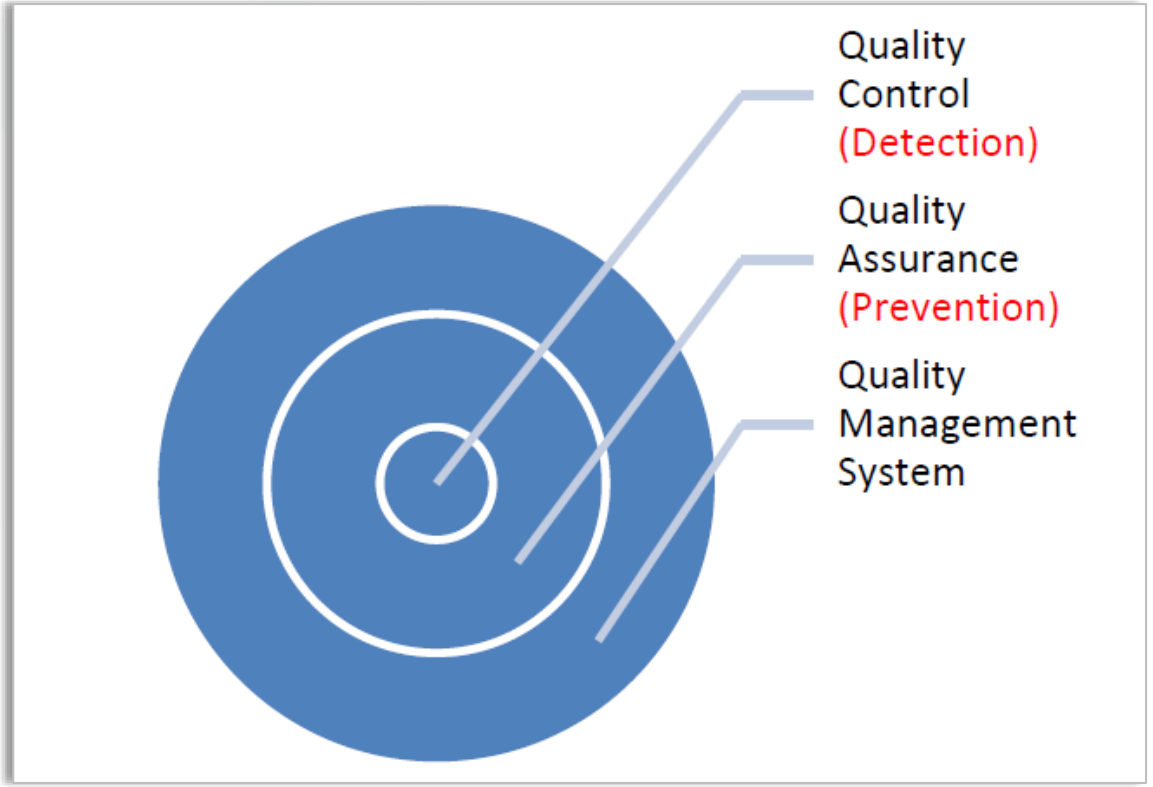



Adapted from eLearning course *Fundamentals of Quality Management Systems*

# Quality Management Systems (QMS)

A structured system that documents processes, procedures, and responsibilities for:

- Meeting requirements of quality policies and objectives
- Coordinating and controlling an organization's activities
- Achieving regulatory compliance
- Satisfying customer requirements
- Continually improving operational effectiveness and efficiency



# Benefits of a QMS

A properly functioning QMS in your laboratory provides many benefits, including but not limited to:

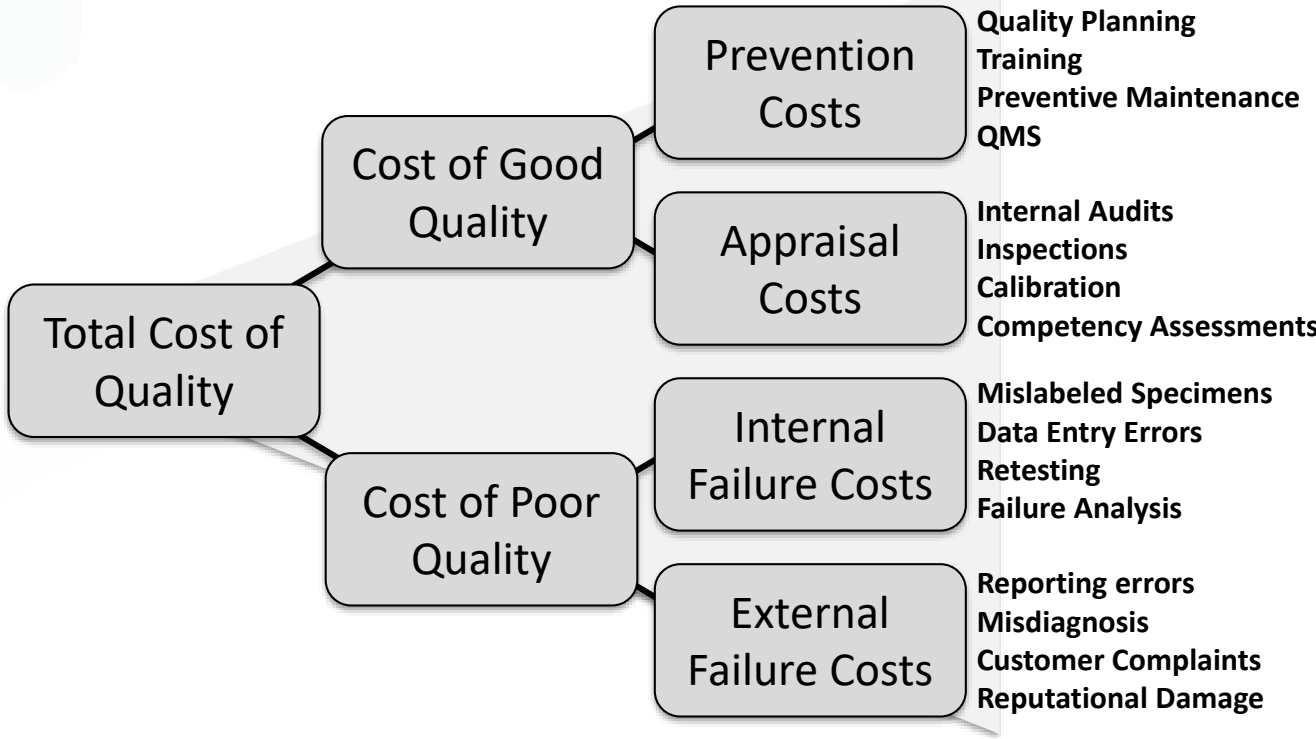
- Identifying and improving laboratory processes
- Preventing mistakes
- Boosting customer satisfaction
- Increasing operational efficiency
- Supporting continual improvement
- Lowering costs
- Reducing waste
- Upholding scientific excellence
- Establishing organization priorities and direction

Adapted from eLearning course *Fundamentals of Quality Management Systems*

# The Cost of Quality

Quality management impacts laboratory resources including direct costs

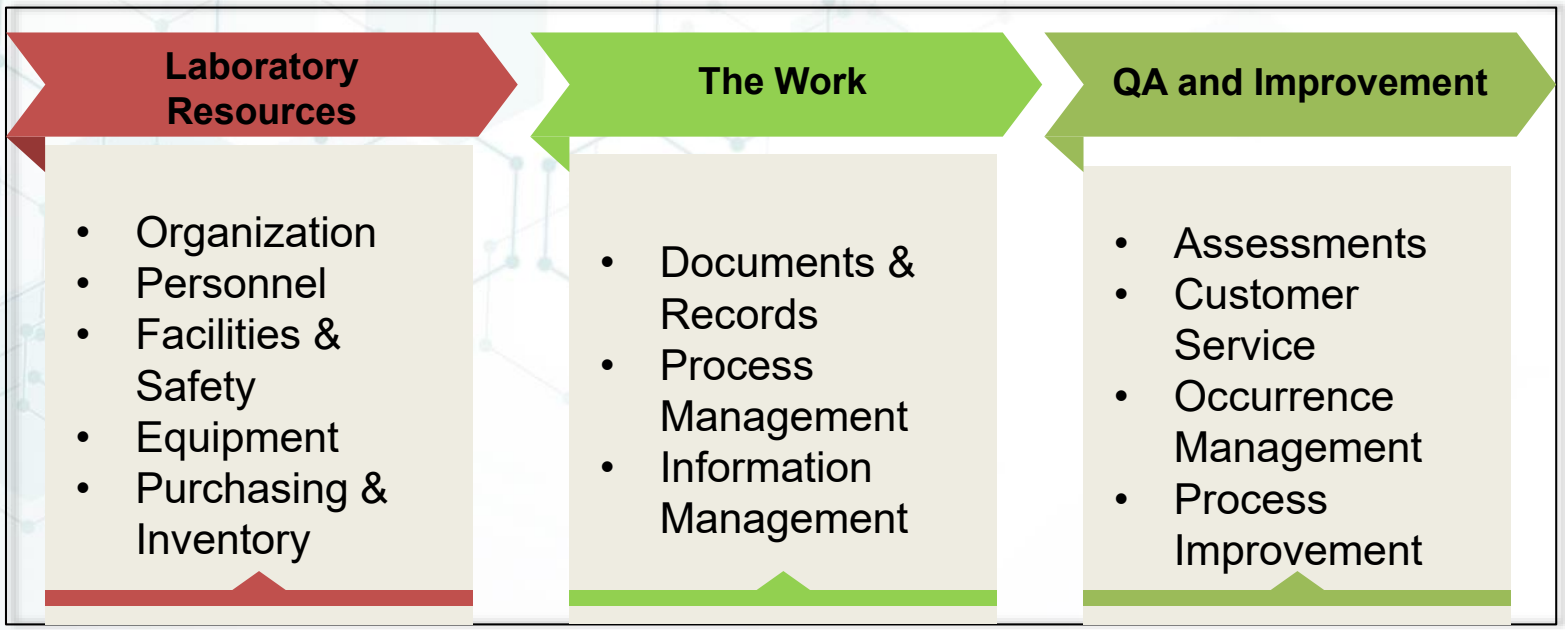
- The resources used to maintain processes, quality, investigate nonconformance vs costs incurred from failures




Adapted from eLearning course *Fundamentals of Quality Management Systems*

# Elements and Common Themes

CLSI's 12 Quality System Essentials




American Society for Quality Identifies Themes

- The organization's quality policy and quality objectives
- Quality manual
- Procedures, instructions, and records
- Data management
- Internal processes
- Customer satisfaction from product quality
- Improvement opportunities
- Quality analysis

# Implementing a QMS

- Selecting a standard that meets objectives, needs, services, products.
- Published structures aid in development and continuous improvement of a QMS:
  - Design
  - Build
  - Deploy
  - Control
  - Measure
  - Review
  - Improve
- Changes that can impact quality
  - Standing up a new laboratory, discipline, operation, facility
  - New instruments or methods
  - Changing existing processes

A few considerations:

- Ethical principles and practices
- Expectations that quality is foundational
- Areas exempt from aspects of the QMS
  - e.g., Financial management
- Active participation
  - E.g., medical director, laboratory director, supervisors
- Key steps for a Culture of Quality

# Implementing a QMS

The Laboratory's Quality Policy

- Defines intention for a culture of quality:
  - Customer-focused intent
  - Statement on the standard of service
  - Commitment to professional practice, quality services, and compliance with its QMS.
  - Commitment to compliance with applicable regulatory requirements and other standards.
  - Incorporated in the laboratory's quality manual and other processes

The Scope of Laboratory Service

- Documentation of the scope of services.
- Meeting expectations of all customers.

Documenting the QMS

- Policies, Processes, Procedures, Forms
- Roles and Responsibilities

Reviewing testing process or Path of Workflow

*Adapted in part from CLSI QMS01 5th Ed.

# Example Personnel Roles and Responsibilities

## Laboratory Director

- Overall responsibility for the laboratory QMS.
- Provides oversight, leadership, and coordination for the development, implementation, management, and operation of the laboratory QMS.
- May assign roles (e.g., laboratory supervisor), delegate authority, and/or assign selected QMS operational responsibilities
  - Delegated authorities and assigned operational responsibilities must be communicated to the involved employees and comply with the requirements of the QMS standards.

## Laboratory Supervisor

- Can serve as the first-level manager with director designated responsibility for a laboratory group or organizational unit.
- Aid in establishment and maintenance of a QMS that meets regulatory and accreditation requirements for the laboratory.
- Ensures appropriate personnel are familiar with, understand the quality documentation, and implement the policies and procedures relevant to their work
- They must also ensure that laboratory staff are adequately trained to implement the policies and procedures applicable to their work.

Adapted from eLearning course *Fundamentals of Quality Management Systems*

# Example Personnel Roles and Responsibilities

## Laboratory Quality Manager(s)

- Can be appointed or assigned by the laboratory director or designee.
- Has defined responsibility and authority for ensuring that quality system components of the QMS are implemented and consistently followed
- Ensures processes needed for the QMS are established, implemented, and maintained.

## Laboratory Personnel

- Full time employees, fellows, etc. are responsible for quality documentation and implementing laboratory QMS policies and procedures applicable to their work.
- They are also actively engaged in supporting the implementation and continual improvement of the QMS.
- Aid in identification and reporting of nonconformance or other departures from laboratory procedures.

Adapted from eLearning course *Fundamentals of Quality Management Systems*

## Poll Question 2 – Quality Management Systems

**Select the best answer:** What is the status of quality practices in your laboratory?

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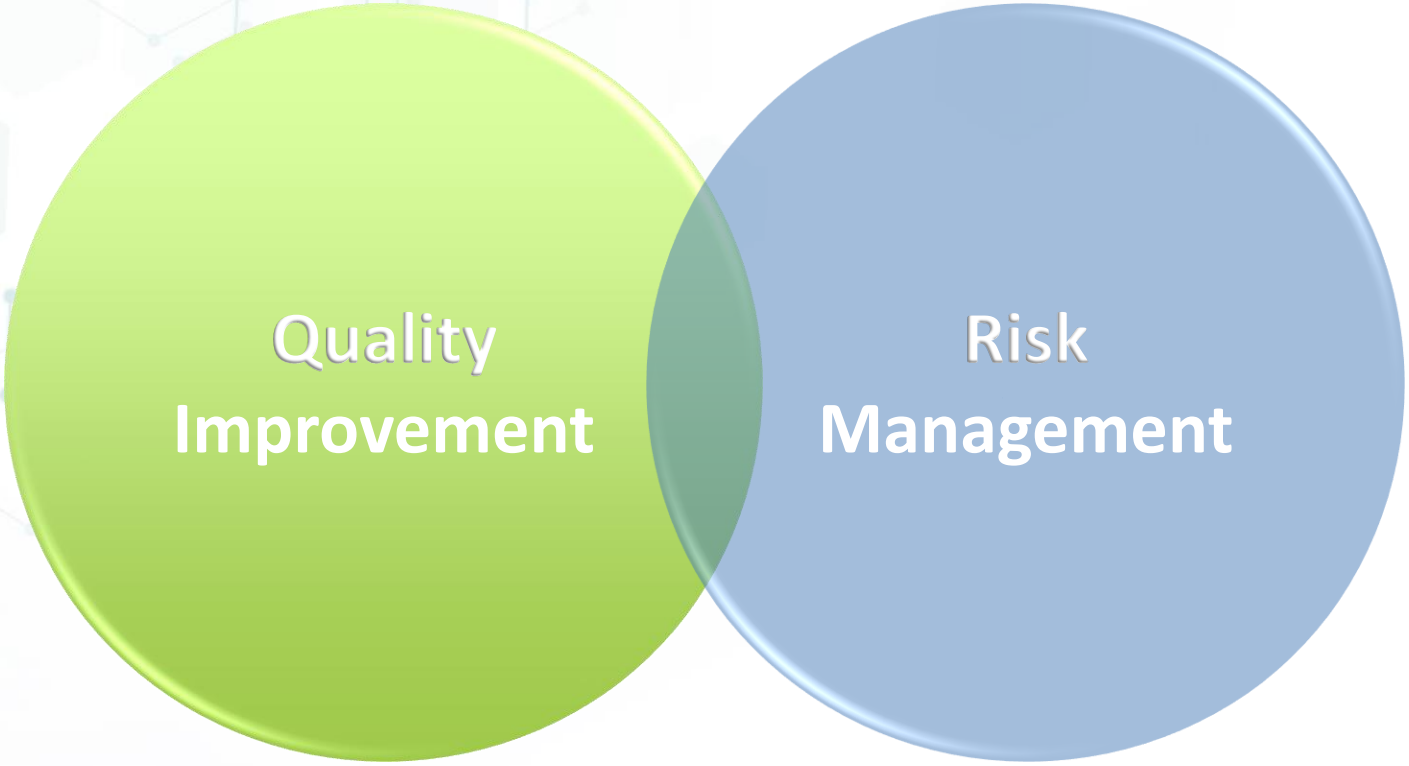
**Options:**

A. A
B. B
C. C
D. D

# Selection of QMS Standards and Guidance

- CLSI and the 12 Quality System Essentials
- International Organization for Standardization (ISO) – 9001:2015
- World Health Organization – TRS 1025
- College of American Pathologists – Laboratory General Checklist and Standards for Accreditation
- Clinical Laboratory Improvement Amendments (CLIA) of 1988

# Link Between Quality and Risk




Quality management may be used to prevent risk and risk management may be used to improve quality

# Risk Management Process


Continuous process to identify, assess (evaluate), control, and monitor risks

Collaborative

Dynamic

Continual

Documented and Communicate

Introduction to Laboratory Risk Management (LRM)

# Risk Management

Evaluate controls


Accessing the risk

Appropriate controls

— **A**ssessment, **M**itigation, and **P**erformance Evaluation **(AMP)**

# Risk Management and Risk Assessment

## What is a Risk assessment?


— A systematic process of **evaluating** the potential risks

## Risk assessment goal

— Evaluate what could go wrong and consider steps required to **mitigate** the risks


## Risk assessment process


— Define the **situation**, **activity**, **risks**, and **hazards**

— Define **criteria** to determine the likelihood and consequence

— Analyze the **likelihood** and **consequence**

Introduction to Laboratory Risk Management (LRM)

# Risk Assessment Process


**Documented policies and procedures for activity-specific risk assessments**


- Assessments are conducted for agents, facility design, laboratory equipment
- Documented and communicated to staff

**Risk assessments are conducted and reviewed**


- Commencement of new work or changes
- modifications to laboratories, equipment, or operations; or new construction
- Existing management system review process


Introduction to Laboratory Risk Management (LRM)

## Poll Question 3

**Select the best answer:** Risk assessments are conducted and reviewed

A. When there are significant alterations to Standard Operating Procedures or working practices
B. When unexpected events that may have relevance for the management of biorisks are observed
C. When the actual or potential non-conformity with internal/external rules and regulations is identified
D. As part of the existing management system review process (e.g., annually
E. Do it right the first time, and you should not have to do it again

**Options:**

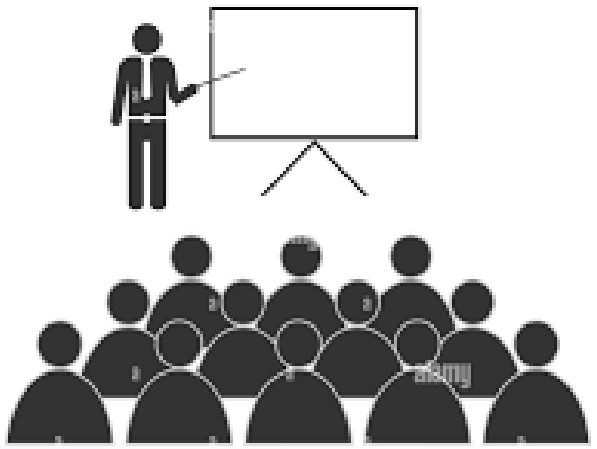
A. A, E
B. B, C, D
C. A, B, C, D
D. E, B

# Risk Assessment Process


**Risk Mitigation**

- Control measures to eliminate or mitigate risks to an acceptable level
- A formal process and informal process to identify and manage risk
- Identification and implementation of control measures

# Risk Management



**Training and competency**

- Provide just-in-time and appropriate training
- Plan for mental or physical health support for personnel responding to high-stress or high-volume events
- Training program includes feedback opportunities

# Risk Management


**Performance Evaluation**

- Ensure mitigation strategies are reducing risks to acceptable levels
- Continually evaluating performance
- Monitor, report results, and act on findings

# Risk Management

## Poll Question 4

**Select the best answer.**

Which of the activities below are involved in performance evaluation?

A. Acting on findings
B. Conducting the initial risk assessment
C. Monitoring controls and collecting data
D. Determining whether the risks are acceptable or unacceptable
E. Reporting and evaluating results

**Options:**

A. A, C, E
B. B, D
C. C, D, E
D. A, D, B

# Risk Assessment Management


## Communication

- Culture of safety depends on effective communication
- Institutional leadership engages with workers
- Staff report issues, including incidents and near misses, without fear of reprisal

# Summary

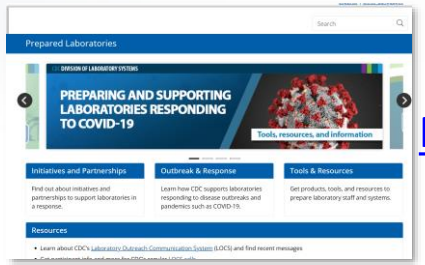

- Risk management is essential for the success and sustainability of any organization
- Identifying, assessing, and mitigating potential hazards and risks within laboratory environment
- Risk management is an ongoing process

# Resources – Division of Laboratory Systems


[Introduction to Laboratory Risk Management (LRM) | OneLab REACH (cdc.gov)]


[Laboratory Training | CDC]


[Safe Labs | CDC]




[Prepared Laboratories | CDC]


[OneLab REACH | OneLab REACH (cdc.gov)]

# Risk Management & Quality Management Resources

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) (6th Edition)
- Introduction to Laboratory Risk Management (LRM)
- Public Health Agency of Canada Pathogen Safety Data Sheets
- ABSA International Risk Group Database
- WHO Laboratory Biosafety Manual, 4th CWA 15793 Laboratory biorisk management pdf

- WHO Laboratory Quality Management
- WHO Laboratory Quality Stepwise Implementation Tool
- Clinical and Laboratory Standards Institute
- American Society of Quality QMS Roles and Responsibilities Job Aids
- APHL How to Write a Laboratory Quality Manual
- CFSAN FDA Laboratory Quality Assurance Manual
- CMS Proficiency Testing Programs

# Questions?

## Contact:
## DLSinquiries@cdc.gov

# Thank you!

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