



Laboratory Biosafety and Biorisk Management Course: ISO 35001 System Implementation



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Introduction:

Laboratory biosafety and biorisk management course for ISO 35001 system implementation is a 5-day course for laboratory management, biosafety and quality staff that ends with a Biorisk Management System Gap Assessment for a case clinical laboratory. Laboratories face worker exposures, unaccounted biological materials and audit findings when risk assessments, containment equipment, inventories and incident arrangements are managed piecemeal rather than as one system. Nominees already supervise or assure laboratory work, and they learn through case studies built on laboratory documents, registers and floor plans. CoreConcept Training Center delivers this laboratory biosafety and biorisk management course.

Course Objectives:

- Explain the biorisk management cycle and assign biorisk duties to top management, the biosafety officer and the biosafety committee
- Structure a biorisk management system against ISO 35001 clauses and integrate it with existing laboratory quality management systems
- Conduct a biological risk assessment and select controls through the risk control hierarchy, laboratory design features, biosafety cabinets and protective equipment programmes
- Establish biosecurity controls for biological material inventory, physical access, personnel reliability and sensitive information
- Organise decontamination, specimen transport, occupational health surveillance and exposure incident response arrangements
- Assess a laboratory against ISO 35001 using competence records, internal audit evidence and a scored gap assessment

Target Audience:

- Laboratory management staff responsible for the safe operation of hospital, public health, university or research laboratories
 - Biosafety and biosecurity officers responsible for biological risk assessments, laboratory inspections and biosafety committee business
 - Quality management staff responsible for integrating biorisk requirements into laboratory management systems and internal audits
 - Occupational health and safety staff responsible for laboratory worker health surveillance and exposure follow-up
 - Facilities and engineering staff responsible for containment laboratory ventilation, biosafety cabinets and building services
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Course Outline:

Day 1: Biorisk Management Foundations and Laboratory Current-State Review

- Biosafety and Biosecurity Definitions in the WHO Laboratory Biosafety Manual
- Biorisk Management Cycle Linking Assessment, Mitigation and Performance Review
- Laboratory-Acquired Infection Case Records and Recurring Failure Patterns
- Biorisk Roles of Top Management, Biosafety Officer and Committee
- Current-State Biorisk Walk-Through Checklist for Hospital and Research Laboratories

Day 2: ISO 35001 Management System and the WHO Risk-Based Approach

- ISO 35001 Clause Structure From Organisational Context to Improvement
- Biorisk Policy, Objectives and Plan-Do-Check-Act Cycle Mapping
- WHO Risk-Based Approach Balancing Control Measures With Actual Risk
- Risk Group Classification and Biosafety Levels in General Terms
- ISO 35001 Integration With Existing Laboratory Quality Management Systems

Day 3: Biological Risk Assessment and Containment Control Selection

- Biological Risk Assessment Worksheet From Hazard Identification to Rating
- Risk Control Hierarchy From Elimination to Personal Protective Equipment
- Laboratory Design Features Including Directional Airflow, Surfaces and Handwash Stations
- Biosafety Cabinet Selection, Installation and Periodic Certification Records
- Personal Protective Equipment Programme With Fit Testing and Donning Checks

Day 4: Biosecurity Governance, Decontamination, Transport and Exposure Response

- Biological Material Inventory and Material Accountability Register
- Access Control, Personnel Reliability and Information Security Measures
- Decontamination Validation and Laboratory Waste Inactivation Records
- Specimen Transport Packaging and Category Labelling in General Terms
- Exposure Incident Response, Occupational Health Surveillance and Investigation Steps

Day 5: Case Study Workshop on a Clinical Laboratory Biorisk Gap Assessment

- Case Clinical Laboratory Document Pack and Floor Plan Review
 - Gap Scoring of Risk Assessments, Controls and Biosecurity Arrangements
 - Biosafety Training Matrix and Competence Records Check for the Case
 - Internal Biorisk Audit Findings, Nonconformity Grading and Corrective Actions
 - Biorisk Management System Gap Assessment Completed and Presented to Panel
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Skills You Will Gain:

- Biorisk Management System Design
- Biological Risk Assessment
- Containment Control Selection
- Biosafety Cabinet Oversight
- Laboratory Biosecurity Governance
- Exposure Incident Management
- Biorisk Internal Auditing
- Gap Assessment Reporting

Why Attend This Course:

- Deliver a Biorisk Management System Gap Assessment for a case clinical laboratory to the laboratory director and the biosafety committee
- Decide which control measures each laboratory activity needs on the basis of a documented biological risk assessment rather than habit
- Avoid worker exposures, unaccounted biological materials and failed cabinet certifications caused by unmanaged biorisk gaps
- Pass risk assessment worksheets, inventory registers and audit checklists to laboratory colleagues and safety committees

Conclusion:

Back at work, the participant hands the Biorisk Management System Gap Assessment to the laboratory director, the biosafety committee and the quality manager. They use it to decide which ISO 35001 gaps to close first, which risk assessments to repeat and which biosecurity or exposure arrangements need resources. After the first internal biorisk audit that follows, the unit should compare findings, incident reports and cabinet certification records with the baseline and update the gap assessment and its action plan.

Frequently Asked Questions FAQ:

What should participants know before a laboratory biosafety and biorisk management course?

Participants should already work in or oversee a laboratory and understand basic laboratory practice and quality records. No prior ISO 35001 experience is needed. Bringing anonymised risk assessments, inventories or inspection reports helps participants test the gap assessment method on their own laboratory.

How does laboratory biosafety and biorisk management differ from a general laboratory chemical safety course?

This course treats biological risk as a management system under ISO 35001, covering risk assessment, biosecurity, transport, exposure response and auditing. A chemical safety course focuses on chemical hygiene, labelling and spills, and touches biological hazards only briefly.

Why do laboratories adopt ISO 35001 for laboratory biosafety and biorisk management?

ISO 35001 gives laboratories a process to identify, assess, control and monitor risks from hazardous biological materials, and it complements existing laboratory quality standards. It turns separate biosafety rules into one system with defined roles, objectives, audits and improvement.

What does a participant take back from the laboratory biosafety and biorisk management course?

Participants take back a Biorisk Management System Gap Assessment for a case clinical laboratory, plus a risk assessment worksheet, material inventory register template, training matrix and internal audit checklist that can be adapted to their own laboratory.
