ISO 35001:2019 Biorisk Management System Training Program

Duration – 05 Days

Course Objective:

This training program provides participants with a comprehensive understanding of ISO 35001:2019, covering the principles, requirements, and implementation of a Biorisk Management System (BMS). The course combines theoretical knowledge, case studies, and practical exercises to equip professionals with the skills needed to establish, implement, and maintain an effective biorisk management system.

Target Audience

This course is designed for professionals involved in biosafety, biosecurity, and risk management in laboratories and organizations handling biological materials, including:

- **Biosafety Officers**
- **Laboratory Managers & Supervisors**
- **Quality & Compliance Managers**
- **Researchers & Scientists** working with biological agents
- **Health & Safety Officers** in laboratories and healthcare facilities
- **Risk Management Professionals**
- **Regulatory & Compliance Officers**
- **Facility Managers** handling biological hazards
- **Government & Public Health Officials** responsible for biosafety regulations

Course Outline

Day 1: Introduction to Biorisk Management and ISO 35001

Session 1: Overview of Biorisk Management

- Introduction to biological risks and their impact
- Importance of biorisk management in laboratories and related organizations
- Key concepts: Biosafety, biosecurity, and biorisk assessment

Session 2: Understanding ISO 35001:2019

- Purpose and scope of ISO 35001
- Relationship with other standards (ISO 9001, ISO 45001, ISO 15189)
- Structure of ISO 35001 (High-Level Structure - HLS)

Session 3: Principles of Biorisk Management

- Risk-based thinking in biosafety and biosecurity

- ALARA (As Low As Reasonably Achievable) principle in biorisk management
- The PDCA (Plan-Do-Check-Act) cycle for continuous improvement

Activity: Case study on biorisk incidents and discussion on lessons learned

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Day 2: Context of the Organization and Leadership in Biorisk Management

Session 4: Organizational Context and Stakeholder Analysis

- Identifying internal and external factors affecting biorisk management
- Understanding stakeholder needs and expectations
- Legal, regulatory, and compliance requirements

Session 5: Leadership and Commitment

- Role of top management in biorisk management
- Defining policies, roles, and responsibilities
- Integrating BMS with the organization's overall management system

Session 6: Biorisk Management Policy and Objectives

- Developing and implementing a BMS policy
- Setting measurable biorisk management objectives
- Aligning objectives with risk assessment outcomes

Activity: Developing a biorisk management policy and objectives

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Day 3: Risk Assessment and Operational Controls

Session 7: Biorisk Assessment Process

- Identifying biological hazards and threats
- Assessing likelihood and consequences of exposure
- Risk evaluation and mitigation strategies

Session 8: Operational Controls for Biorisk Management

- Facility design and engineering controls
- Personal protective equipment (PPE) and administrative controls
- Safe handling, transportation, and storage of biological agents

Session 9: Emergency Preparedness and Response

- Developing a biological incident response plan
- Containment and mitigation strategies for biological releases

- Case studies on biorisk-related emergencies

Activity: Case discussion

Day 4: Performance Evaluation and Continuous Improvement

Session 10: Monitoring and Measurement of Biorisk Performance

- Key performance indicators (KPIs) for biorisk management
- Internal audits and inspections for biosafety and biosecurity
- Incident reporting and learning from non-conformities

Session 11: Corrective Actions and Continuous Improvement

- Root cause analysis and corrective action planning
- Implementing improvements to reduce biorisk exposure
- Management review and performance evaluation

Activity: Audit case study

Day 5: Implementation, Certification, and Course Assessment

Session 12: Documentation and Record-Keeping

- Importance of documentation in BMS compliance
- Requirements for records management under ISO 35001
- Best practices for document control in biosafety

Session 13: Implementing ISO 35001 in an Organization

- Step-by-step approach to ISO 35001 implementation
- Challenges and best practices in establishing a BMS
- Training and competency requirements for personnel

Course Outcomes

By the end of this course, participants will be able to:

1. **Understand ISO 35001:2019**
    - Explain the purpose, scope, and structure of the standard.
    - Recognize the relationship between ISO 35001 and other management system standards (e.g., ISO 9001, ISO 45001, ISO 15189).

2. **Identify and Assess Biological Risks**
    - Conduct biorisk assessments using systematic methodologies.
    - Identify potential biosafety and biosecurity hazards in their organization.
3. **Implement a Biorisk Management System (BMS)**
    - Develop and implement a Biorisk Management Policy aligned with ISO 35001.
    - Establish risk control measures, including engineering, administrative, and PPE controls.
4. **Develop Operational and Emergency Response Procedures**
    - Establish best practices for safe handling, storage, and disposal of biological materials.
    - Create and test emergency response plans for biological incidents.
5. **Monitor, Evaluate, and Improve Biorisk Management**
    - Implement performance monitoring, internal audits, and corrective actions.
    - Analyze incidents and non-conformities to drive continuous improvement.
6. **Prepare for ISO 35001 Certification**
    - Understand the certification process and requirements.
    - Develop a roadmap for implementing and maintaining ISO 35001 compliance.