International Federation of Biosafety Associations

Professional Certification in Biorisk Management

Examination Content, Sample Questions & References

The IFBA's Professional Certification (PC) in Biorisk Management identifies individuals with demonstrated competencies in the fundamental principles & practices of biorisk management. A valid PC in Biorisk Management is a pre-requisite certification required before candidates are eligible to apply for IFBA certification in additional technical disciplines. Candidates who are ready to apply for the Biorisk Management certification can apply at any time and take the examination – there are no specific eligibility requirements, pre-requisites, and time limits.

The PC in Biorisk Management is suited to a wide range of professionals working with and around biological materials in functions such as biorisk management & biosafety officers, laboratory scientists, technicians, researchers, facility operations & maintenance personnel, biocontainment design engineers & architects, educators, consultants and policy makers. Individuals holding this certification possess the knowledge and skills in sufficient degree to manage biological risks safely and securely in the laboratory and healthcare setting. The Body of Knowledge (BOK) below identifies 4 domains (topic areas) and 29 knowledge/task statements that define the competency for certification in Biorisk Management. The content of the examination is based on this BOK and each question on the examination is linked to one of the statements below.

Domain A – Fundamentals of a Biorisk Management System

1. List the goals of an effective biorisk management system;
2. Design a comprehensive biosafety and biosecurity program based on the essential components of a biorisk management system;
3. Evaluate key factors in establishing and implementing a successful biorisk management system in a local context and in compliance with local laws, regulations, standards and guidelines;
4. Describe suitable methodologies to identify, assess, prioritize and mitigate biorisks;
5. Apply processes to evaluate, monitor, and improve the performance of a biorisk management system; and,
6. Describe the Plan-Do-Check-Act (PDCA) principle and how it can be applied to a biorisk management system.

Domain B - ISO 35001 Biorisk Management Standard

7. Describe the scope, objectives and structure of the ISO 35001 framework;
8. Define ISO 35001 terminology including biorisk, biohazard, biosafety, biosecurity, and biorisk management system;
9. Describe the essential components of ISO 35001 and understand how to apply and integrate them into the organization's processes;
10. Understand the requirements of ISO 35001 to be able to identify, assess, control, and monitor the risks associated with biological materials; and,
11. Understand how ISO 35001 can be implemented in conjunction with national laws, regulations, standards and guidelines.

Domain C – Implementing a Biorisk Management System

12. Identify and evaluate biological hazards and threats, and assess risks;
13. Understand how to use information gathered from risk assessments to identify and implement suitable risk control procedures;
14. Understand how to develop and implement risk-based biosafety and biosecurity control measures relevant to the local context;
15. Understand the complementarity of biosafety and biosecurity control measures and how to align the mitigation of safety and security risks;
16. Understand how to develop and apply control measures to ensure that facilities, equipment and processes are designed, operated and maintained in a safe and secure manner with respect to biological hazards and/or threats;
17. Evaluate given examples of facility, equipment and process biorisk control measures and explain their suitability in addressing identified risks.
18. Understand how to identify, evaluate and manage incidents and non-conformities within the biorisk management system;
19. Describe how to analyze, evaluate and use performance indicators and data generated from accident/incident investigations, inspections & auditing to monitor and improve a biorisk management system;
20. Describe how to establish, implement and practice emergency response plans and procedures;
21. Describe how to establish and implement personnel training and competency assessment programs;
22. Understand how to implement internal and external communication processes relevant to the biorisk management system; and,
23. Describe how to create, update and control documented information necessary for the effectiveness of the biorisk management system.

Domain D – Roles, Responsibilities and Authorities for Biorisk Management

24. Identify individuals with responsibility and authority for managing biological risks within an organization;
25. Describe the roles, responsibilities and authorities of top management, senior management and scientific management;
26. Describe the membership, role and activities of a biorisk management committee;
27. Describe the role and functions of a biorisk management advisor;
28. Identify individuals responsible for, and describe their respective roles for, monitoring performance and improving the biorisk management system; and,
29. Explain how each of the following roles interacts with and influences biorisk management within an organization: security staff, animal care staff, housekeeping staff, facility operations and maintenance staff.

The following represents the percentage of questions in each domain that are included in the examination:

Exam Blueprint Professional Certification in Biorisk Management Passing Score – 70%	
Domain	**Number of Questions**
A) Fundamentals of a Biorisk Management System	18
B) ISO 35001 Biorisk Management Standard	16
C) Implementing a Biorisk Management System	42
D) Roles, Responsibilities and Authorities for Biorisk Management	24

In order to familiarize candidates with the nature and form of the examination questions, the following are provided as examples. An asterisk marks the correct answer.

1. The objective of the ISO 35001 Biorisk Management Standard is to
   a) instruct individuals how to classify biological agents into risk groups.
   b) outline the legally binding mandatory requirements for managing biological risks.
   c) describe the components of a framework for managing biological risks.*
   d) define the requirements for the certification of biomedical laboratories.

2. The risk assessment process is used to
   a) determine what control measures should be put in place to mitigate the risks involved with the work.*
   b) determine how much funding is needed to implement a biorisk management program.
   c) outline the roles the responsibilities of individuals within the organization for managing biological risks.
   d) measure the effectiveness of personal protective equipment and other safety equipment.

3. Which of the following control measures would provide the BEST protection for an employee handling a biological agent that is easily transmitted by the aerosol route?
   a) Disinfecting benchtops and using glass-ware instead of plastic-ware.
   b) Working in biological safety cabinet and using sealed centrifuge cups.*
   c) Vaccinating employees working in the lab and disinfecting bench tops.
   d) Using sharps containers and wearing a buttoned lab coat.

4. One of the roles of a biorisk management advisor is to
   a) ensure enough resources are provided to safely work with biological agents.
   b) discipline employees who refuse to wear protective equipment and follow safety practices.
   c) conduct background checks on employees to ensure they are suitable for working with biological agents.
   d) participate in the reporting, investigation and follow-up of accidents and incidents.*

Some suggested preparation for examination might include, but should not be limited to, the following resources:

1. ISO 35001:2019 Biorisk management for laboratories and other related organizations.
2. Laboratory Biosafety Manual . World Health Organization. 2020
3. Biorisk Management – Laboratory Biosecurity Guidance. World Health Organization. 2006
4. Biosafety & Biosecurity: Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facilities. OIE. 2015
5. Laboratory Biosafety & Biosecurity Risk Assessment Technical Guidance Document. Sandia National Laboratories/International Federation of Biosafety Associations.

(Please visit the IFBA website for these and other resources at www.internationalbiosafety.org)