



## **Professional Certification in Biological Risk Assessment** *Examination Content, Sample Questions & References*

The IFBA's Professional Certification (PC) in Biological Risk Assessment identifies individuals with demonstrated competencies in conducting structured and systematic biosafety and biosecurity risk assessments. Individuals holding this certification possess advanced knowledge and skills in sufficient degree to implement a risk-based decision-making approach in mitigating biological risks in the clinical laboratory, public and animal health laboratory, research laboratory and healthcare setting. Candidates applying for this certification must first successfully complete the prerequisite PC in Biorisk Management before they are eligible for examination.

The PC in Biological Risk Assessment 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, disease outbreak response personnel, facility operations & maintenance personnel, biocontainment design engineers & architects, educators, consultants, and policy makers. The Body of Knowledge (BOK) below identifies 6 domains (topic areas) and 49 knowledge/task statements that define the competency for certification in Risk Assessment. 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 Biological Risk Assessment**

1. Identify how risk assessment is fundamental to inform the decision-making process in reducing and mitigating risks from biological agents, materials and related information;
2. Identify how risk-based biosafety and biosecurity approaches enable effective allocation and use of time and resources, locally practical and sustainable mitigation measures;
3. Explain why classification of biological agents & risk control measures can vary from laboratory to laboratory, institution to institution, country to country, and region to region;
4. Identify the importance of conducting risk assessments using empirical information in a standardized, consistent, and repeatable way;
5. Define and identify the differences between, advantages, and disadvantages of using qualitative, semi-quantitative and quantitative methods;

6. Recognize prospective hazard analysis techniques (e.g., SWIFT, HAZOP, FMEA, HEART, Fishbone and Bowtie), and risk assessment frameworks (e.g., Rasmussen's model of boundaries, BioRAM, WHO VRAM, THIRA), how these tools can be adapted for use within the laboratory and healthcare settings, and their limitations;
7. Identify how experience-based risk assessments (i.e., based entirely on the personal experience of the individual conducting it) may underrate rare events with catastrophic consequences and/or future unforeseen risks;
8. Identify the role of human bias and risk perception in estimating and evaluating risks under uncertainty (i.e., shortage of information and knowledge to inform the risk assessment process);
9. Explain each step in the risk assessment process (i.e., gather information, identify hazards, evaluate risks, develop risk control strategy, select risk control measures impacting likelihood and/or consequences, validation, review and reassess);
10. Explain how to collect and input quality data and information into the biosafety and biosecurity risk assessment process;
11. Evaluate factors that affect the likelihood and consequence of a negative outcome, such as exposure, misuse or accidental/intentional release of a biological agent;
12. Evaluate a risk with multiple possible types and values of likelihood and consequences;
13. Identify linear and non-linear relationships between likelihood and consequences;
14. Explain how to plot a risk assessment matrix, identify the limitations on its use, and describe risk matrix alternative approaches;
15. Explain how a risk control measure can be applied to likelihood and/or consequences to lower a risk to an acceptable residual risk level;
16. Identify the factors that influence risk acceptance and the impact of risk perception on risk control strategies;
17. Explain who should be involved in the biosafety and biosecurity risk assessment process, when to seek external expertise, and how to achieve and communicate the appropriate level of awareness, training and competency for implementation of risk review and control strategies;

## **Domain B – Implementing a Biosafety Risk Assessment**

18. Evaluate the types and characteristics of biological agents and materials, and the adverse human health, animal health and environmental effects they may cause;
19. Identify potential sources of biological agents, and procedural situations, that have a potential for causing harm;
20. Determine the likelihood of exposure or release of a biological agent from the work and the consequences of such;
21. Explain what data should be collected and how to establish the risk of the work to be performed in the context of the local conditions and decide whether these risks are acceptable or not;

22. Identify how different biosafety control measures address specific factors that contribute to the likelihood and/or consequence of a potential exposure and/or release;
23. Explain how to select, implement and validate appropriate, and proportionate biosafety control measures required to bring the risk to an acceptable level for work to proceed safely;
24. Identify how to use alternative work methods to replace high-risk activities with low-risk activities to reduce the initial risk of the work before applying any risk control measures;
25. Evaluate if the biosafety control measures implemented are effective, reliable, and sustainable over the long term;

### **Domain C – Implementing a Biosecurity Risk Assessment**

26. Explain how to identify and assess the threat environment that may impact an organization and work with biological agents and materials;
27. Identify and assess assets with dual-use potential, emerging technologies, and assets that can be used for malicious purposes to cause disease in human or animal populations, or public fear;
28. Identify and assess biosecurity risks presented from tangible (e.g., pathogens, equipment, animals), intangible (e.g., scientific information, organization reputation) and people (e.g., personnel, scientists, students, contractors) assets;
29. Explain how to develop and prioritize an inventory of biological agents and materials based on the assets qualities and severity of compromise resulting from asset compromise;
30. Explain how to conduct a vulnerability assessment and identify biosecurity related events that could result in loss, theft, misuse, diversion of, or intentional unauthorized release of biological materials and related information;
31. Identify adversaries (i.e. insiders and outsiders) that may have the motive, means, and capability to carry out a biosecurity related event, and how these adversaries could exploit vulnerabilities and circumvent the organization’s mitigation measures;
32. Evaluate the likelihood of a biosecurity related event and the consequences of such an event occurring to public health, animal health, the environment, and the organization;
33. Explain how to select and implement effective, appropriate, and proportionate biosecurity control measures at all stages of incident management (i.e. prevention, detection, response, and recovery);
34. Explain how to align interrelated and potentially contradictory biosafety and biosecurity control measures;

### **Domain D – Risk-based Biocontainment Facility Infrastructure**

35. Explain the risk-based approach to infrastructure where facilities are appropriately tailored to local risks and available resources, provide for a graded and balanced protection relative to risk, without compromising biosafety and biosecurity;

36. Explain how the processes of laboratory programming and design development are based on local contextual issues, available resources, and local biosafety and biosecurity risk assessments;
37. Identify how to balance highly technical engineering solutions that may require outsourced maintenance with simple, practical, cost-effective solutions that can be locally maintained and sustained over the long-term life-cycle of the facility;
38. Identify the role of human factors and standard operating procedures in the risk assessment process as compared to facility infrastructure and equipment in conferring safety through proper training and proficiency practices;

### **Domain E – Clinical Laboratories, Novel & Dangerous Pathogens**

39. Identify biological hazards, assess biosafety and biosecurity risks, and implement mitigation measures at all stages of the clinical analysis process (i.e., specimen collection and transport; specimen processing and handling; microscopy; molecular and nonmolecular diagnostic assays; culturing; inventory control; decontamination and disposal);
40. Assess and mitigate risks where a clinical specimen may potentially contain more than just the biological agent for which it is being tested;
41. Identify the principle of applying a set of precautionary practices to a situation, when the biological agent of infection is not yet known, and explain how to implement more specific precautions as a clearer diagnosis is learned;
42. Identify and evaluate risks from the use of clinical diagnostic instruments, equipment and consumables, and determine what controls should be used to mitigate them;
43. Identify the impact of human factors (e.g., unfamiliarity with all types of potential pathogens that might be encountered, lack of awareness of the potential for laboratory-acquired infections, workload, carelessness, and complacency) on managing biological risks in the clinical laboratory setting;
44. Evaluate and control biosafety and biosecurity risks associated with the collection and transport of biological specimens in the field, and between laboratories, during a disease outbreak;
45. Explain how to identify the risks associated with the presence of scientific uncertainties regarding the severity of the biological hazard itself, the harm it may cause, or the likelihood that the hazard will affect workers (e.g., at the start of a novel outbreak where there is either no or conflicting data regarding the characteristics of the biological hazard);
46. Explain how to assess risks remotely during a crisis, bridge gaps in knowledge, and apply the precautionary principle in the context of the hierarchy of controls;

## Domain F – Genetic Engineering, Synthetic Biology, & Evolving Biotechnologies

47. Identify the international frameworks and guidelines applicable to, and the misuse potential of genetic engineering, genome editing, synthetic biology and other rapidly evolving biotechnologies;
48. Identify and assess factors impacting the risk of accidental or deliberate misuse of emerging technologies (e.g., genetic engineering, synthetic biology technologies, gene editing) at the institutional (organizational), national, and international level;
49. Identify and assess the potential adverse effects of the accidental and deliberate misuse of emerging technologies (e.g., genetic engineering, synthetic biology technologies, gene editing) on human health, animal health, and the environment;
50. Determine at which stage of research to assess the dual-use potential of emerging technologies (e.g., research planning, funding applications, conducting research, publication);
51. Identify risk control measures to prevent the accidental or deliberate misuse of emerging technologies (e.g., genetic engineering, synthetic biology technologies, gene editing);
52. Identify any potential high complexity and high uncertainty presented by synthetic biology and other rapidly evolving biotechnologies with no comparators in predicting risks;
53. Identify how to balance biosafety and biosecurity control measures, and any conflicts that may arise, while enabling scientific and technological advances in the field of genetic engineering and synthetic biology;
54. Identify and evaluate approaches, strategies, and tools for promoting situational awareness among life sciences professionals of the risks related to the misuse of emerging technologies.

### Exam Blueprint

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

Exam Blueprint Professional Certification in Risk Assessment Passing Score – 70%	
Domain	Number of Questions
A) Fundamentals of Biological Risk Assessment	26
B) Implementing a Biosafety Risk Assessment	16
C) Implementing a Biosecurity Risk Assessment	16
D) Risk-Based Biocontainment Facility Infrastructure	8
E) Clinical Laboratories, Novel & Dangerous Pathogens	15
F) Genetic Engineering, Synthetic Biology, & Evolving Biotechnologies	9

### *Sample Questions*

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 risk-based approach to biosafety and biosecurity in the laboratory will
  - a) eliminate all biological risks to allow the work to proceed safely and securely
  - b) use all available resources to prevent the exposure of laboratory staff to biological materials
  - c) prioritize available resources towards risks with a higher likelihood and consequences\*
  - d) standardize risk control measures for all laboratories handling biological materials
  
2. Which of the following statements is TRUE?
  - a) Qualitative risk assessments have a high requirement for data in order to assign numerical values to probability and consequence.
  - b) Qualitative risk assessments seek to maximize objectivity through the use descriptive language or interval scales to rate probability and consequences.
  - c) Examples of high-quality data for risk assessments of a new emerging pathogen include expert opinions and non-referenced literature.
  - d) At the beginning of a novel disease outbreak, data including patient medical information and epidemiological data can be used to aid the risk assessment process.\*
  
3. The \_\_\_\_\_ analysis provides a structured method for evaluating diverse and potentially conflicting criteria in the risk analysis process.
  - a) prospective hazard
  - b) multi-criteria decision\*
  - c) fishbone
  - d) failure-mode effect
  
4. When conducting a biosafety risk assessment in the laboratory, which of the following factors will MOST affect the consequences and severity of harm?
  - a) The standard operating procedures that are being followed in the laboratory
  - b) The motive of potential adversaries who may wish to use the biological agents for malicious purposes.
  - c) The inherent pathogenic properties of the biological agent being assessed\*
  - d) The physical design features of the laboratory facilities

5. When conducting research with emerging technologies for which limited information currently exists, it is recommended that \_\_\_\_\_. Select the BEST choice.
- the international regulations prohibiting such research be followed until more information is obtained.
  - the precautionary principle be applied to stop the research unless all potential risks can be identified and eliminated.
  - risk mitigation measures be adopted based on surrogate data or indirect evidence to bridge knowledge gaps until additional information is obtained over time.\*
  - the research be allowed to continue without any additional risk mitigation measures.

### References

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

- [Laboratory Biosafety Manual](#). 4<sup>th</sup> edition. World Health Organization. 2020
- [Laboratory Biosafety Manual Monograph: Risk Assessment](#). 1<sup>st</sup> edition. World Health Organization. 2020
- [Laboratory Biosafety Manual Monograph: Outbreak Preparedness & Resilience](#). 1<sup>st</sup> edition. World Health Organization. 2020
- [Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document](#). Sandia National Laboratories. 2014
- [Biosafety Risk Assessment Methodology](#). Sandia National Laboratories. 2010
- [Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facilities](#). World Organization for Animal Health. 2015
- [Pathogen Risk Assessment Guideline](#). Public Health Agency of Canada. 2018
- [Conducting a Biosecurity Risk Assessment](#). Public Health Agency of Canada. 2018
- [Biorisk Management for Laboratories and Other Organizations](#). ISO 35001. International Standards Organization. 2019
- [Guidelines for Responsible Conduct in Veterinary Research: Identifying, Assessing and Managing Dual Use](#). World Organization for Animal Health. 2019
- [Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences \(Self\) Assessment Framework](#). International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences. 2020.
- [Assessing the Security Implications of Genome Editing Technology: Report of an International Workshop](#). The Interacademy Partnership. 2017
- [Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research](#). National Science Advisory Board for Biosecurity. 2016