

Professional Certification in Biosecurity - – Examination Content, Sample Questions, & References

The IFBA’s Professional Certification (PC) in Biosecurity identifies individuals with demonstrated competencies in the fundamental principles & practices of working securely with biological materials and sensitive scientific information in a laboratory, healthcare facility, field response to a disease outbreak and other environments where biological materials are handled. Candidates applying for this certification must first successfully complete the PC in Biorisk Management before they are eligible for examination.

The PC in Biosecurity is suited to a wide range of professionals working with and around biological materials such as biorisk management & biosafety officers, scientists, laboratory technicians, researchers, disease outbreak response personnel, facility operations & maintenance personnel, security personnel, educators, consultants and policy makers. Individuals holding this certification possess the knowledge and skills in sufficient degree to securely manage biological risks in the laboratory, healthcare facilities, field response to disease outbreaks and other settings where biological materials are handled. The Body of Knowledge (BOK) below identifies 6 domains (topic areas) and 48 knowledge/task statements that define the competency for certification. The content of the examination is based on this BOK and each question is linked to one of the statements below.

Domain A – Biosecurity Conventions, Guidelines and Standards

1. Identify the international frameworks applicable to biosecurity including conventions, treaties, codes, UN security council resolutions, guidelines & standards;
2. Understand how local laws, regulations, standards and guidelines are used in conjunction with international biosecurity instruments;
3. Understand the different meaning and use of biosecurity terminology by the UN Food and Agriculture Organization and World Organization for Animal Health as related to agriculture, food safety and food production;
4. Define biosecurity, biological weapons and biological weapons-related materials;
5. Describe how biosecurity contributes to achieving the goals of the Biological Weapons Convention, International Health Regulations, and UN Security Council Resolution 1540;
6. Understand the importance of a multidisciplinary approach to biosecurity involving scientific and security professionals;
7. Identify the range of stakeholders involved in the implementation and maintenance of biosecurity.
8. Understand the jurisdictions, roles and responsibilities of government health and security agencies involved in the implementation of biosecurity.
9. Define the elements of biosecurity program as described by the World Health Organization’s “Biorisk Management: Laboratory Biosecurity Guidance”;

10. Define the biorisk management approach to securing biological materials as described by the CWA 15793;
11. Understand the concept of “biosecurity” when used both within a laboratory setting (e.g. within a facility handling infectious materials) and “beyond the laboratory” door (e.g. in the field during an infectious disease outbreak response) and how to apply international laboratory biosecurity guidelines in settings beyond the laboratory;
12. Understand that biosecurity is not limited to the physical protection of biological material, but includes the protection of research data and analyses, access to technologies and techniques;
13. Understand the differences and similarities between biosafety and biosecurity and the complementary elements between them;
14. Describe how implementation of biosafety practices and procedures facilitates the implementation of biosecurity requirements;

Domain B- Biosecurity Risk Assessment & Program Management

15. Understand how a biosecurity risk assessment is conducted and the stakeholders involved in the process;
16. Understand the importance of designing biosecurity approaches based on a localized risk assessment;
17. Know how to identify laboratories handling biological materials, assess risks from the biological materials being handled and incorporate these biological materials in an accountability program based on the risk assessment;
18. Describe the fundamental elements of a biosecurity program management system;
19. Identify, and describe the roles and responsibilities for individuals managing biosecurity risks within an organization;
20. Describe how to measure, continually monitor performance and improve the biosecurity program management system;
21. Know how to develop emergency response plans for biosecurity incidents involving the theft or loss of biological materials;
22. Understand the importance of early reporting and the chain of communication in the implementation of biosecurity response measures;
23. Describe how to develop and implement biosecurity awareness and training programs;
24. Describe how to control and maintain records, documents and data relevant to the biosecurity management system;

Domain C- Physical Biosecurity Measures

25. Describe the unique challenges for physically securing biological materials vs chemical or radiological materials;

26. Describe physical security approaches and options to detect intrusion, and delay and restrict access to biological materials;
27. Understand the advantages, disadvantages and differences in approaches to physical security options;
28. Describe how a system of graded protection relative to risk is used to secure biological materials;
29. Understand the options for unauthorized intrusion alarm communication to, and response by, internal responders (e.g. facility guards), or external responders (e.g. local law enforcement);
30. Understand the importance of sensitive scientific information and the need for protection of the Information Technology infrastructure (i.e. cyber security);
31. Know how to identify sensitive information and describe the protection measures to be applied;

Domain D – Pathogen Accountability

32. Identify the components of a biological material accountability program;
33. Describe how to maintain, document and periodically audit elements of an inventory of biological materials;
34. Know how to determine the applicability of international treaties, agreements, import/export requirements, and national policies, for material transfer among facilities within and outside of the country;
35. Describe procedures for pathogen transfer within a facility and between different facilities to safeguard against loss, theft or diversion;

Domain E – Personnel Reliability

36. Understand the relationship between biosecurity and the integrity of individuals with access to biological materials;
37. Know how to identify individuals handling biological materials who require biosecurity training;
38. Define an insider and outsider threat;
39. Describe the advantages and limitations of pre- and post-employment personnel reliability programs and background checks;
40. Understand how to implement background checks in conjunction with regulatory and enforcement authorities and requirements;
41. Describe how to foster a culture of responsibility and accountability among individuals with access to biological materials;
42. Understand the importance of and know how to identify resources for an employee wellness program;

Domain F – Dual-Use & Bioethics

43. Define the term “dual-use” as related to biological research and biosecurity;
44. Understand the concept of “bioethics” as related to dual use and biosecurity;
45. Understand the scope of social, ethical, and legal responsibilities incumbent upon life scientist with respect to biosecurity;
46. Describe the role of life scientists in implementing biosecurity;
47. Describe policies and practices that will prevent the mis-use of knowledge gained through biological research including a code of conduct;
48. Know how to develop a mechanism for the review of biological research prior to beginning work, and periodically afterwards, to minimize risks and vulnerabilities of employees and the facility.

Exam Blueprint

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

Exam Blueprint Professional Certification in Biosecurity Passing Score – 73%	
Domain	Number of Questions
A) Biosecurity Conventions, Guidelines and Standards	30
B) Biosecurity Risk Assessment & Program Management	23
C) Physical Biosecurity Measures	13
D) Pathogen Accountability	8
E) Personnel Reliability	14
F) Dual-Use & Bioethics	12

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. National legislation to implement the Biological and Toxin Weapons Convention
 - a) must be submitted to the UN 1540 Security Council Committee for review and approval prior to entering into force.
 - b) can be different in each country based on each country's unique circumstances and legal systems.*
 - c) follows the specific implementation criteria for an effective national action plan outlined in the Convention.
 - d) must be submitted to the Convention members for review and approval prior to entering into force.

2. New laboratory activities involving biological agents that have not previously been handled in the laboratory
 - a) may proceed provided the requirements of the biosecurity program are followed.
 - b) may proceed but training must be provided on how to safely carry out the activity.
 - c) must first undergo a risk assessment to determine any unique biosecurity mitigation measures that may be necessary.*
 - d) must be reviewed during the next scheduled laboratory inspection for any additional precautions that may be necessary.

3. A _____ protection system is achieved by increasing the levels of biosecurity measures step-by-step, from the lowest security requirements to the highest, around the facility's assets based on the level of risk associated with these assets.
 - a) perimeter control
 - b) graded*
 - c) fail-safe
 - d) barrier control

4. Strengthening personnel reliability among individuals with access to biological materials can BEST be achieved by
 - a) conducting a criminal background check prior to hiring individuals.
 - b) enhancing accountability and responsibility through leadership and commitment at the institution and laboratory level.*
 - c) conducting periodic psychological testing of individuals to determine their mental and emotional status.
 - d) Investigating a new employee's employment history for evidence of previous concerning behaviours.

5. Which of the following statements BEST describes bioethics as related to the life sciences.
- the study of the ethical and moral implications of biological discoveries and biomedical advances.*
 - the biosecurity implications of research involving human subjects.
 - the study of the potential military use of dual-use research.
 - the study of the ethical and moral implications of using biological weapons.

References

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

- Biorisk Management: Laboratory Biosecurity Guidance. World Health Organization. 2006
- Laboratory Biosafety Manual. World Health Organization. 2004
- Responsible Life Sciences Research for Global Health Security – A Guidance Document. World Health Organization. 2010.
- Laboratory Biorisk Management. CEN Workshop Agreement 15793. January 2011.
- Biosafety and Biosecurity: Standard for Managing Biorisk in the Veterinary Laboratory and Animal Facilities. OIE. 2015.
- Principles of Laboratory Biosecurity. Section VI BMBL. CDC/NIH. 2009.
- Security Guidance for Select Agent or Toxin Facilities. Centers for Disease Control. 2013.
- Final Document of the 7th BTWC Review Conference. United Nations. 2011.
- Biological Weapons Convention Biosafety and Biosecurity Background Paper. BTWC Implementation Support Unit.
- Guide to Participating in the Confidence Building Measures of the BWC. United Nations. 2015.
- Global Health Security Action Packages. GHSA. 2015.
- Guidance for Enhancing Personnel and Strengthening the Culture of Responsibility. NSABB. 2011.
- Being a Scientist: A Guide to Responsible Conduct in Research. National Academy of Sciences. 2009

(All of these resources and others are available for download on the IFBA website at www.internationalbiosafety.org)