



## **Professional Certification in Biocontainment Facility Design, Operations & Maintenance**

### ***Examination Content, Sample Questions & References***

The IFBA's Professional Certification (PC) in Biocontainment Facility Design, Operations & Maintenance identifies individuals with demonstrated competencies in the fundamental principles & practices of biocontainment design, construction, commissioning, validation, certification and facility operations and maintenance. Candidates applying for this certification must first successfully complete the PC in Biorisk Management before they are eligible for examination..

The PC in Biocontainment Facilities is suited to a wide range of professionals with responsibilities for biocontainment design, construction, commissioning, certification, and facility operations and maintenance. These may include biocontainment design engineers & architects, facility operations & maintenance personnel, biorisk management & biosafety officers, laboratory scientists and researchers, biocontainment consultants and policy makers. Individuals holding this certification possess biocontainment knowledge and skills in a sufficient degree such that they are able to understand and implement the requirements for the design, construction, commissioning, and operations & maintenance of facilities which are appropriate for the safe handling of biological materials. The Body of Knowledge (BOK) below identifies 4 domains (topic areas) and 63 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 – Biocontainment Guidelines & Standards**

1. Identify relevant international guidelines & standards applicable to human, animal (invertebrate and vertebrate) and plant biocontainment facilities;
2. Understand how relevant national/local laws, regulations, standards and guidelines are used in conjunction with international biocontainment guidelines & standards;
3. Define the biorisk management approach to biocontainment facility infrastructure as described by the ISO 35001 Biorisk Management for Laboratories;

4. Define the laboratory design considerations of core requirements, heightened control measures and maximum containment measures as described by the World Health Organization's "Laboratory Biosafety Manual" and "Laboratory Design and Maintenance" supporting monograph;
5. Understand the relationship between Risk Groups of biological agents and laboratory physical containment features;
6. Understand how the design features of laboratory facilities as described by World Health Organization's "Laboratory Biosafety Manual" is based on a local risk assessment;
7. Define the features of a low-risk TB laboratory, moderate-risk TB laboratory and high-risk TB containment laboratory as described by the World Health Organization's "Tuberculosis Laboratory Biosafety Manual";
8. Define the risk-based approach to biocontainment facilities as described by the World Organization for Animal Health's "Standard for Managing Biological Risk in the Veterinary Laboratory and Animal Facility";
9. Understand how other guidelines, standards and codes (e.g., related to building construction, life safety, clean rooms, biological safety cabinets) are used in conjunction with biocontainment guidelines & standards;

## Domain B- Programming, Planning, Design & Construction

### Instructional Notes

*For the purposes of this Body of Knowledge, the definitions below apply. Depending on national guidelines and approaches the definitions for each of these processes may be slightly different from country to country.*

*Programming – the pre-planning phase of conducting a risk assessment and needs assessment*

*Basis of Design – a user requirement brief and specification that communicates the outcomes of the programming phase and design requirements for the project*

10. Understand why having qualified, experienced and trained persons involved in the programming, planning, design and construction process is important and define their roles;
11. Understand the programming process and how to develop a basis of design based on the risk assessment and function of the facility and in consultation with key internal and external stakeholders;
12. Understand the typical design stages including concept design, schematic design, and detailed design;
13. Understand the advantages, disadvantages and differences in designing the renovation of a biocontainment facility vs designing a new facility including the possible impact of renovations on adjacent areas;
14. Explain the decommissioning process and safety factors to be considered when renovating an existing biocontainment facility;

15. Understand the requirement to communicate, adjust requirements and document design decisions made during the programming and planning process to meet operational and biocontainment objectives;
16. Understand what regulatory authorities may have jurisdiction over specific elements of the biocontainment facility and the design and construction implications of these authorities' regulatory requirements;
17. Know how to read and interpret architectural, mechanical, electrical and other building services drawings and specifications;
18. Understand the basic inherent characteristics of biological agents (i.e., non-aerosol or aerosol mode of transmission) in order to conduct a risk assessment and define appropriate biocontainment design solutions;
19. Understand why it is important to design and construct biocontainment facilities using site-specific design approaches that are based on a local risk assessment specific to each facility;
20. Describe the factors to be considered when conducting a risk assessment to determine the essential design features and know where and from whom to gather this information;
21. Understand how to balance highly technical engineering solutions that may require outsourced maintenance with simple, practical, cost-effective solutions that can be locally maintained using available expertise and resources;
22. Distinguish between biocontainment concepts to prevent the release of biological agents from a facility, and, to prevent exposure of individuals working within the facility;
23. Understand the advantages and limitations of mobile (i.e., constructed on wheels, or for lifting onto a trailer, or as a temporary structure to be relocated frequently) and modular (i.e., constructed of prefabricated units which are finally assembled and permanently installed on-site) biocontainment applications;
24. Explain the differences between a modular and an in-situ (i.e., constructed on-site using permanent and fixed construction methodology) approach to the design and construction of biocontainment facilities;
25. Describe types of primary, secondary and tertiary containment barriers, their indications for use, how they reinforce operational practices, and how they mitigate specific biological risks;
26. Understand the importance of clearly defining the containment perimeter within a facility and the perimeter design factors that may impact airflow, pressure control and facility decontamination;
27. Describe architectural biocontainment design features, workflow diagrams for the movement of individuals/materials/samples/waste and how they mitigate specific biological risks;
28. Describe mechanical and electrical building services biocontainment design features and how they mitigate specific biological risks;
29. Describe critical biocontainment equipment in the laboratory, mechanical spaces and building service areas and how they mitigate specific biological risks;

30. Understand building control systems, including the sequence of operations during failure modes, and how they mitigate specific biological risks;
31. Describe security design features and how they mitigate biosecurity risks of pathogen theft or diversion;
32. Understand the importance of redundancy in the design of biocontainment facilities;
33. Understand how design and biocontainment equipment decisions impact maintenance activities including accessibility requirements and decontamination of equipment prior to maintenance;
34. Understand the need to develop a commissioning plan (including facility acceptance criteria) and involve the commissioning team early on in the design process;
35. Know how to effectively communicate biocontainment design features including redundancy and failure scenarios to the scientific staff, laboratory managers, biosafety staff, and operations and maintenance staff;
36. Understand the importance of capital and maintenance budget planning, and identifying all the anticipated costs, during the planning and design process for the construction and long-term operations & maintenance of the facility;
37. Understand the importance of peer review and how to evaluate value engineering solutions as they relate to both cost reduction and safe operations;
38. Describe how the construction phase is generally executed including quality control and documentation;

## Domain C – Commissioning, Validation & Certification

### Instructional Notes

*For the purposes of this Body of Knowledge, the definitions below apply. Depending on national guidelines and approaches the definitions for each of these processes may be slightly different from country to country.*

*Commissioning – a systematic process to review and document that each specified facility component and system has been installed and functionally tested to be in good working order (including failure-mode testing).*

*Validation – a systematic and documented process to confirm that each specified facility component and system is performing in accordance with the design intent.*

*Certification – a structured assessment and formal documentation to confirm that the facility is in compliance with relevant national and/or international guidelines and standards applicable to biocontainment facilities.*

39. Understand the importance of having qualified, experienced and trained individuals involved in the commissioning, validation and certification process;
40. Describe the differences between commissioning, validation and certification and understand why they are important;
41. Understand when to perform commissioning, validation and certification processes;
42. Define the responsibilities and roles of all relevant persons in the commissioning, validation and certification process;
43. Define and describe the components of a commissioning plan and of a validation plan;
44. Define component testing, systems testing and integrated systems testing;
45. Understand why failure-mode testing is critical for the biocontainment integrity and safe performance of the facility;

46. Describe how to interpret validation test results and acceptance criteria and why record-keeping is important;
47. Understand how local laws, regulations, standards and guidelines dictate the need for and influence a certification process;
48. Describe how to use commissioning test results, acceptance criteria, and data generated from on-site facility inspections to certify a biocontainment facility;
49. Understand the need to communicate the importance of commissioning, validation and certification to the scientific staff, laboratory managers, biosafety staff, and operations and maintenance staff;
50. Understand the importance of acceptance and handover, and carefully transitioning a biocontainment facility from a building site to an operational facility;
51. Understand when to perform re-commissioning, re-validation and re-certification processes and why they are important;

## Domain D – Facility Operations & Maintenance

52. Understand the importance of properly operating biocontainment equipment (in the laboratory, mechanical spaces and building service areas) and facility maintenance;
53. Understand the importance of using properly calibrated and certified testing equipment;
54. Describe how to develop a maintenance plan, operational manuals, records and inspections for critical biocontainment equipment and systems to assure continued safe operation of the facility;
55. Understand why ensuring biocontainment maintenance staff are qualified, experienced, and trained for their specific duties is important;
56. Understand the advantages, disadvantages, and limitations of externally-sourced facility maintenance services;
57. Understand why maintaining day-to-day communication between facility operations and maintenance staff, biosafety staff, and scientific staff is important to maintain the biocontainment facility in safe working order;
58. Describe the differences between reactive breakdown, predictive, and planned preventive maintenance;
59. Understand how to plan facility maintenance work including ensuring adequate supplies of spare parts;
60. Know how to conduct a risk assessment before conducting maintenance activities on biocontainment systems or biocontainment equipment;
61. Describe the training required for maintenance personnel entering and exiting biocontainment facilities and containment service areas;
62. Understand emergency procedures to be followed during a loss of containment and/or improper functioning of biocontainment systems or biocontainment equipment;
63. Understand how to safely shut-down a biocontainment facility for maintenance including decontamination processes (e.g., surface disinfection, gas & vapor).

### *Exam Blueprint*

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

<b>Exam Blueprint</b> <b>Professional Certification in Biocontainment Facility Design, Operations &amp; Maintenance</b> <b>Passing Score – 71%</b>	
<b>Domain</b>	<b>Number of Questions</b>
A) Biocontainment Guidelines & Standards	15
B) Programming, Planning, Design & Construction	44
C) Commissioning, Validation & Certification	20
D) Facility Operations & Maintenance	21

### *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 World Health Organization’s Tuberculosis Laboratory Biosafety Manual outlines
  - a) recommendations for the design and operation of TB laboratories based on the assessment of risks associated with different TB laboratory procedures.\*
  - b) detailed criteria for the physical construction of TB biocontainment laboratories.
  - c) recommendations for where TB laboratories can be safely constructed in proximity to populated areas.
  - d) the requirements for certification of a TB biocontainment laboratory by national regulatory authorities.
  
2. When building a new laboratory facility, the laboratory \_\_\_\_\_ phase involves a detailed risk assessment of the proposed activities to identify the new facility’s architectural and mechanical concepts.
  - a) design
  - b) programming\*
  - c) construction
  - d) certification

3. A fundamental principle when designing heightened control measures and mechanical systems for a biocontainment laboratory handling biological agents transmitted by the aerosol route is to
- use pressure control to achieve inward directional airflow.
  - create a directional airflow from areas of lower hazard towards areas of higher hazard.\*
  - provide a separate supply and exhaust air handling system for areas of every different hazard.
  - ensure air flows into the laboratory at 100 feet per minute, even when the door is opened.
4. Which of the following is NOT generally included during failure scenario testing of a biocontainment laboratory during the commissioning process?
- Testing of the backup ventilation systems to determine whether or not they function as designed.
  - Testing the ventilation system during recovery of simulated failure conditions.
  - Verification of the correct operation of alarms generated by failure scenarios.
  - Quantifying the force required to open an exit door during a fan failure.\*
5. The long-term maintenance plan for a new biocontainment laboratory should be
- determined once construction of the laboratory has been completed.
  - planned for well in advance in order to drive some of the design details.\*
  - determined by the maintenance staff once they have been operating the building for a period of 6 months.
  - determined during the commissioning phase when the systems and equipment are functionally tested.

### *References*

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

- [Laboratory Biosafety Manual](#). World Health Organization. 2020.
- [Laboratory Biosafety Manual Monograph: Laboratory Design and Maintenance](#). World Health Organization. 2020.
- [Tuberculosis Laboratory Biosafety Manual](#). World Health Organization. 2012.
- [Biosafety and Biosecurity: Standard for Managing Biorisk in the Veterinary Laboratory and Animal Facilities](#). OIE. 2015
- [ANSI/ASSP Z9.14 Testing and Performance-Verification Methodologies for Ventilation Systems for BSL3 and ABSL3 Facilities](#). 2020.
- [Biosafety Cabinetry: Design, Construction, Performance, and Field Certification](#). NSF/ANSI 49. 2020
- [Biorisk Management for Laboratories and Other Organizations](#). ISO 35001. International Standards Organization. 2019