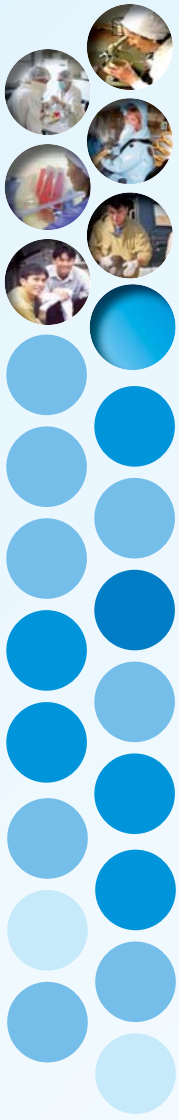
IFBA

International Federation of Biosafety Associations

Certification Program



# Candidate Handbook

## Ensuring Quality Biorisk Management Through Certification of Professionals

IFBA Certified Professional

www.internationalbiosafety.og

**IFBA Certification Body**

The Certification Body (CB) of the International Federation of Biosafety Associations (IFBA) is a multi-stakeholder, administratively independent board which provides direction for and administration of the certification of biorisk management professionals worldwide. The CB strives to ensure safe, secure and responsible work with biological materials by certifying that qualified and competent personnel are engaged in the management of biological risks. The CB is structured to and conducts its operations in harmony with ISO/IEC 17024:2012 *"Conformity Assessment – General Requirements for Bodies Operating Certifications of Persons".* The CB acts impartially and ensures fair and equitable treatment in relation to its applicants, candidates and certified persons.

***The mission of the IFBA Certification Body is to provide excellence in certification of technical competencies for biorisk management professionals worldwide.***

**About the Candidates Handbook:**

This handbook contains information on the IFBA's professional certification process and assists candidates in preparing for the examination and maintaining their certification. It is the candidate's responsibility to read and understand the contents of this handbook before applying for certification. Specifically, information is provided on:

- Eligibility requirements
- Applying for certification
- Studying and preparing for the examinations
- Scheduling and taking the examinations
- Maintaining certification and recertification requirements
- Certification fees
- General policies and procedures governing the certification program

**Statement of Non-discrimination:** Certification is offered to all eligible persons regardless of age, gender, religion, national origin, marital status, sexual orientation or disability. The CB ensures fair and equitable treatment of all candidates throughout all phases of the certification process.

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# 1.0 About the Certification Program

## 1.1. Introduction

The International Federation of Biosafety Associations' Certification Body (CB) is launching a new certification program available to a wide range of professionals working with and around biological materials in functions such as biorisk management and biosafety officers, laboratory scientists, technicians, researchers, facility operations and maintenance personnel, biocontainment engineers and architects, educators, consultants and policy makers. This distinctive program promotes safe, secure and responsible work with biological materials by ensuring that qualified and competent personnel are engaged in the management of biological risks. Individuals with an IFBA certification bring increased value to their employers by demonstrating competence to carry out their responsibilities and by achieving high standards of excellence, professionalism, and continuous learning. By earning certifications from the IFBA, individuals reap the benefits of safer workplaces, career advancement, and international recognition among colleagues.

**Objectives of Certification:**

- Enhanced safety and security of biorisk management professionals, laboratorians, scientists, and the general public;
- Increased government and public confidence in biosafety and biosecurity practices and programs;
- Increased government and public confidence in those who work with biological materials;
- Enhanced recognition and endorsement of biorisk management as a credible and skilled profession;
- Increased incentive for biorisk management professional competency requirements to be included in standards, guidelines, and legislation; and
- Greater demand for services of biorisk management professionals with demonstrated competence.

The IFBA's certification program was developed in compliance with ISO/IEC 17024: 2012 "*Conformity assessment - General Requirements for Bodies Operating Certification of Persons*" to ensure that all candidates meet a common standard, through a consistent application and testing process, and an objective evaluation of professional knowledge and skills. Certifications are based on a Body of Knowledge (BOK) developed by international subject matter experts and validated through a Job Task Analysis (JTA) process designed to identify and validate the knowledge and tasks that are required to demonstrate competence. The IFBA's JTA process

included an international survey of biorisk management professionals to assess the criticality and frequency of each knowledge and task statement, the results of which serve as the blueprint for the design and content of the examinations.

## 1.2 Certification

The IFBA CB will be offering certifications at "Level 1 - Professional Certification (PC)" and "Level 2 – Specialist Professional Certification (SPC)" in a number of technical disciplines related to the field of biosafety, biosecurity and 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. To become certified, each individual must pass the IFBA CB's examinations. Each successful candidate will receive a certificate and is entitled to use "IFBA PC" and "IFBA SPC" designations after their names. A PC designation demonstrates that individuals have the understanding and knowledge they need for a specific technical discipline. An SPC designation enables individuals to demonstrate that they are highly specialized within their technical discipline and can apply their knowledge and analyse solutions applicable to their workplace. Certifications are effective from the date the examination is passed and valid from that date through a 5-year period which begins on January 1st of the year following the date of passing the examination. Certificants must then undergo a recertification process to ensure continued competence.

The CB is launching the certification program in a step-wise approach, one certification level at a time. PC certifications in the following disciplines are currently being offered:

- Basic Biorisk Management *(Currently offered at Level 1 Professional Certification; Pre-requisite certification for all others*)
- Biological Waste Management *(Currently offered at Level 1 Professional Certification)*

***Steps to Certification***

1. Decide which certification is right for you and verify eligibility requirements
2. Prepare for the exam by reviewing the examination content and studying
3. Complete your application on-line at https://ifba.certifior.com
4. Submit the application fee
5. Receive instructions on scheduling the exam
6. Take the exam
7. Receive your certification
8. Maintain your certification and recertify every 5 years

*Certifications are offered worldwide and the IFBA's CB does not discriminate among applicants as to age, gender, race, religion, national origin, disability, marital status or sexual orientation.*

# 2.0 Applying for Certification

## 2.1 Eligibility Requirements

IFBA certifications are available to a wide range of professionals working with and around biological materials in functions such as biorisk management and biosafety officers, laboratory scientists, technicians, researchers, facility operations and maintenance personnel, biocontainment design engineers and architects, educators, consultants and policy makers. Each applicant must take time to assess and judge his/her own readiness to apply and take the certification examinations. A careful review of the knowledge and task statements in the examination content outline, the sample exam questions, and references are essential before candidates make the decision to apply for certification.

Candidates who are ready to apply for the Level 1 Professional Certification (PC) in Biorisk Management can apply at any time. While there are no specific eligibility requirements and pre-requisites, we emphasize that this certification is geared towards individuals who have knowledge and experience in the field of managing biological risks. A valid Level 1 Professional Certification (PC) in Biorisk Management is a pre-requisite certification required before candidates are eligible to apply for IFBA certification in additional technical disciplines. Candidates applying for the Level 2 Specialist Professional Certifications (SPC) must also first successfully complete the Level 1 PC certification in that technical discipline before they are eligible for examination.

## 2.2 Application Procedure

Applications for certification are accepted at any time but must be submitted via the *Certifior* website only at https://ifba.certifior.com. The Guide to Using Certifior will assist individuals through the application process. Applicants must acknowledge that he or she has the pre-requisite certifications (e.g. Biorisk Management) to allow the applicant to take any further certification examinations. Applicants are required to agree to abide by the IFBA Certification Code of Conduct and Statement of Confidentiality before they are eligible to sit for an examination (this process is completed electronically within the *Certifior* system)
*(Please refer to Section 4.2 of this handbook for a copy of the Code of Conduct and Section 5.2 for the Statement of Confidentiality).*

*For a copy of the Guide to Using Certifior, please contact the IFBA Secretariat at secretariat@internationalbiosafety.org*

## 2.3 Certification Fees

### Fee Structure

The certification application fee for Level 1 Professional Certification in each technical discipline is set at **$200.00 USD**, to cover administration costs for each candidate. For convenience, the online *Certifior* application system enables payment of fees on the website. Certification application fees **are non-refundable** regardless of the outcome of the examination. If a candidate's application is rejected because of ineligibility, only a portion of the fee (i.e. $100.00 USD) will be returned to cover costs of processing and reviewing the application. The recertification fee for Level 1 Professional Certification in each technical discipline is set at **$150.00 USD** to cover the costs of reviewing the application and administering the recertification process for each candidate. Recertification application fees **are non-refundable** regardless of the outcome.

### International Scholarships

In order to increase accessibility of the certification program internationally and in particular to resource-limited countries around the globe, the IFBA's CB implements an international scholarship fee structure. The scholarship program is designed to empower those in need of international credentials in biorisk management, who live in resource-limited countries where economic circumstances impact their ability to pay the full certification and recertification fees. Applicants who currently reside and have responsibility for biorisk management in eligible countries will receive discounted fee pricing of **$100.00USD** for all PC certifications (if a candidate's application is rejected because of ineligibility, only $50.00USD of the fee will be returned), and, a non-refundable fee pricing **of $70.00USD** for all PC recertifications.

*For a current list of eligible countries for discounted pricing, please contact the IFBA Secretariat at secretariat@internationalbiosafety.org*

# 3.0 Examination Procedures

## 3.1 Preparing for the Examinations

The IFBA CB's examinations are a standardized measurement of the knowledge and skills expected of professionals in specific technical disciplines related to the management of biological risks. The IFBA CB publishes the content outline for each examination, outlining the domains, task and knowledge statements specific to each technical discipline. The content outline also notes the percentage of exam questions (called "items") per domain. Candidates

are strongly encouraged to become thoroughly familiar with this content as part of their preparation.

In order to familiarize candidates with the nature and form of the examination questions, sample questions have been provided. These questions reflect the range of content and difficulty that would be typical on the examination; however, this small sample does not provide a complete picture of the diversity that candidates should expect to encounter on the actual examination. Following each question is the correct or best response (called the "key"). Examination questions are written from a wide variety of publications and resources in the field and some suggested references have also been provided to assist candidates in preparing for the examination.

Potential applicants may also contact the IFBA's Member Biosafety Associations which offer training courses relevant to biorisk management. Current Members and available training providers are listed on the IFBA's website at www.internationalbiosafety.org

*The IFBA neither sponsors, nor endorses, nor financially benefits from any training or review courses for the IFBA examinations.*

## 3.2 Examination Content and Blueprints

Examinations for Level 1 Professional Certifications (PC) are objective, multiple-choice computer based tests consisting of 100 questions. All questions are randomly placed throughout the examination. Four possible answers are provided for each (a, b, c, and d), with only one designated as the correct or best choice. It is to the candidate's advantage to answer every question on the examination, since the final score is based on the total number of questions answered correctly. There is no penalty for selecting an incorrect choice.

The examination content is based on a Job Task Analysis which surveyed biorisk management professionals worldwide on the knowledge they require and tasks they perform under major categories (called "domains"). Each question on the examination is directly linked to these task and knowledge statements. Data collected on the importance, criticality, and frequency of the knowledge and task statements was used to determine the percentage of examination questions related to each domain (called the exam "blueprint"). All examination questions were written and reviewed by both subject matter experts and test development experts. The methodology used to set the minimum passing score is the modified Angoff method, applied during the performance of a passing point study by a panel of experts in the field. Experts

evaluated each question on the examination to determine how many correct answers are necessary to demonstrate the knowledge and skills required to pass the exam.

*Please refer to Appendix A "Professional Certification in Biorisk Management – Examination Content" and Appendix B "Professional Certification in Biological Waste Management – Examination Content" for a complete list of task and knowledge statements, sample questions and references.*

## 3.3 Taking the Examination

Computer-based testing using the *FastTest* system is the standard method of administering IFBA's examinations, using *Remote Proctor Now* technology for remote proctoring at the candidate's site. The Guide to Online Certification Exams will assist individuals through the application process. Paper-based testing is used in certain situations with CB appointed invigilators (i.e. exam proctors) to administer and supervise these written examinations. The invigilator will enforce the time allocated for candidates to complete the examination and ensure that no external assistance or reference material is used. At the end of the examination, all paper-based tests are sealed, signed across the seal by the candidate and given to the invigilator. Candidates will have a number of opportunities to take the certification exams as follows:

- A computer-based examination using *Remote Proctor Now* at the candidate's site or other pre-approved suitable location. Candidates will receive a link to the test, an exam code, and further instructions on accessing the examination through *FastTest,* and accessing the secure remote proctoring software.
- A computer-based examination or written paper-based exam with an approved IFBA physical proctor may be available at the candidate's site, proctor's site, or other pre-approved suitable location. For the computer-based examination, the proctor will access the examination engine *FastTest* and enter a code that will grant the candidate access to their exam. For the paper-based examination, the proctor will hand the candidate their own sealed exam envelope with their unique identification number. Test documentation is then imported into *FastTest* for scoring and reporting of results.
- A computer-based exam or paper-based written exam with an IFBA approved proctor at IFBA Member Biosafety Association conferences and other events.

*For a copy of the Guide to Online Certification Exams, please contact the IFBA Secretariat at secretariat@internationalbiosafety.org*

Candidates who are eligible to take the examination must present valid photo identification with signature in order to take an IFBA examination. **Detailed instructions on taking the examination will be provided to each candidate when they register on-line through the Certifior system based on the exam format and location selected.** It is important to note that exam application fees are non-refundable. If a candidate cancels the examination or fails to appear for an examination they will not receive a refund of their application fee. If the examination is cancelled by the IFBA (e.g. inclement weather, natural disasters), candidates will be offered an alternate examination date. IFBA, however, is not responsible for any personal costs or expenses incurred by candidates in the event that an examination is cancelled. If a candidate wishes to reschedule an examination, a request must be made to the IFBA no later than 72 hours prior to the originally scheduled exam time to avoid paying an additional exam application fee. If a power outage occurs during an examination session, the candidate will be provided with an opportunity to re-take the examination using a different exam version.

The examinations are closed-book; referring to notes, study guides, books and other reference materials are not permitted during the examination. Personal items such as cell-phones, cameras, iPads and other electronic devices are also not allowed. The examinations are scheduled for ***2 hours*** with ***100 questions***. Only the questions you answer correctly are scored. There are no penalties for answering a question incorrectly, so answer as many questions as you can. If you are unsure of a response, eliminate as many options as possible, and choose an option from those that remain. The IFBA grades all examinations fairly and ***test scores are based on the number of questions answered correctly.***

All candidates taking the examination are required to abide by a statement of confidentiality which restricts candidates from sharing any information about the examination with other individuals, including discussions with fellow test takers following the examination, and the sharing of information with colleagues who might be planning to take the examination in the near future. *(Please refer to Section 5.2 of this handbook for a copy of the candidate's attestation).*

## 3.4 Examination Results

Examination results will be emailed to candidates and will include a summary of the score obtained in each exam content domain. Scores are strictly confidential and can neither be obtained over the phone nor sent to a third-party. Successful certificant names will be published by the IFBA in our online directory of certified professionals. If you do not wish for your name to be published, please email the IFBA Secretariat at *secretariat@internationalbiosafety.org* no later than 10 days before your examination.

Candidates, who fail an examination and wish to apply to take the same exam again, must complete the exam retake application and submit the required fees.

Any questions concerning examination results should be directed in writing to the IFBA Certification Body at *secretariat@internationalbiosafety.org*

## 3.5 Requests for Special Examination Accommodations

An applicant who wishes to request modifications in the examination environment because of a disability must notify the IFBA Certification Body in writing at the time of application and provide appropriate documentation about the disability and the needed modification. Unless the applicant's disability would prohibit certification for the requested technical disciplines, the CB will work directly with the applicant and examiners to make modifications in the testing environment which make it possible for an individual with a disability to take an examination under conditions which will accurately reflect the individual's aptitude or achievement level.

*To submit a request for special exam accommodations, please contact the IFBA Secretariat at secretariat@internationalbiosafety.org*

# 4.0 Maintaining Your Certification and Recertification

## 4.1 Using your IFBA Certification Credential

After successfully passing the examination, candidates are eligible to use the IFBA certification credential and will receive a packet of information including a unique certification wallet card and a certificate. The IFBA's certification logo may be used by certified individuals in their personal business (e.g. business cards, resumes and personal web site) as a way of showing pride in their professional certification. The certification logo as used by certificants, certifies that biorisk management professional services are being rendered by persons who have demonstrated professional knowledge and competency in the technical discipline to which they are certified against.

The CB's certificates and logo are available for use by certificants subject to the following requirements:

- if certification should cease for any reason, the use of the certificate and logo must be discontinued immediately;
- the logo shall not be used in any misleading manner, subject to the sole discretion of the IFBA CB;
- the certificate and logo may not be revised or altered in any way and must be displayed in the same form as provided by IFBA CB;
- the logo may be used on business cards, letterhead, promotional brochures, biographical material, advertising, website or any other literature or place that is promoting the biorisk management professionals work;
- the logo can be placed in close proximity to the certificants name, however, there should be enough clear space that it is not connected or a part of the certificant's personalization or degree;
- the logo shall not be confused with a company logo or placed in such close proximity to a company name or logo so as to give the reader the idea that the CB's logo certifies the company;
- the use of the logo does not indicate any legal guarantee by the IFBA CB, any direct endorsement of services, or that the individual is acting on the IFBA's behalf;
- the IFBA CB reserves the right in its sole discretion to require the removal of the logo from any location or item the IFBA CB feels does not comply with these terms, or which could or does discredit the IFBA; and,
- if the IFBA CB gives notice to remove the logo and/or discontinue use of the certificate, it must be done immediately.

*Each certificant accepts and assumes sole responsibility for understanding and satisfying all applicable governmental and legal professional requirements, including those requirements that may apply to the use, display and/or advertising of the IFBA CB's certification. The IFBA CB assumes no responsibility concerning the application of such governmental and legal requirements. The IFBA CB shall not be responsible or liable for any claims, complaints, suits, or damages whatsoever, relating to the use of the certification certificate and logo.*

## 4.2 Code of Conduct

The IFBA Certification Body maintains that certification carries an obligation for maintaining the value and good name of IFBA's certifications and that the candidates they certify act professionally and support and promote their profession. All certificants are thus required to subscribe to the CB's Code of Conduct as a condition of obtaining and maintaining their certification. As part of this process, candidates are required to sign an agreement to comply with the provisions of the certification scheme, to make claims regarding their certification only

with respect to the scope for which it was granted, not to use the certificate in a misleading manner, and to discontinue all claims to certification upon withdrawal of the certification. Certification may also be revoked at any time and the applicant may be barred from admission to take future certification examinations if it is established that the information contained in, or supplied in support of, an application for examination is inaccurate in any material respect or if it is established that the applicant engaged in any inappropriate conduct during the examination (such as giving or obtaining unauthorized information or aid). In the event of suspension or revocation of certification for failure to comply with the Code of Conduct or any other reason, certificants must return the certificate to CB and cease all claims to the certification title.

The Code of Conduct requires certificants to:

- Comply with the relevant provisions of the certification requirements;
- Provide accurate and truthful information to the IFBA CB concerning all certification related eligibility information and submit valid application materials for fulfillment of current certification and recertification requirements;
- Maintain the security, and prevent the disclosure, of the IFBA CB certification examination information and materials;
- Not act in any way that would prejudice the reputation of the IFBA CB or the respective certification process;
- Make claims regarding their certification only with respect to the scope for which it was granted;
- Not use the certificate in a misleading manner;
- Discontinue all claims to certification upon withdrawal of certification;
- Co-operate fully with any inquiry or investigation in the event of any complaint, appeal or alleged breach of this code;
- Act professionally and strive to increase the competence, prestige and public regard of their profession;
- Protect and promote the safety and security of people, property and the environment above any consideration of self-interest;
- Take due professional care and have the competency, skills and knowledge to perform the required work;
- Endeavour to continuously improve skills and proficiency through practice, education and professional development;
- Support and encourage fellow biorisk management professionals to develop professionally;
- Represent qualifications and competencies, or advertise services, only through factual representation without exaggeration;

- Remain free from any influence, conflict of interest, or relationship that impairs professional judgement, independence, impartiality or objectivity; and,
- Protect the confidentiality of all professionally acquired information and disclose such information only when properly authorized or when legally obligated to do so.

## 4.3 Recertification

It is essential that biorisk management professionals remain up-to-date on the latest approaches to the safe and secure handling of biological materials. Regular recertification through ongoing experience and professional/academic development ensures that individuals maintain their knowledge and skills and stay current on developments in the field. The program also promotes opportunities for both professional and personal enrichment. The IFBA's certifications are valid for a period of 5 years after which the certificants must undergo a recertification process. The 5 year period was developed appropriately reflecting the rate of change in the biorisk management field while being appropriately practical. Documented activities demonstrating continued competence and continued practice must be completed and submitted to the IFBA's Certification Body prior to the certificate expiration date. Failure to do so will result in expiry and revocation of the certification. The goals of the Recertification Program are to:

- Assess maintenance of knowledge and skills over time;
- Ensure continuing competence;
- Assess the ability to provide services at the specified level of competency throughout a certificant's professional career;
- Encourage continued professional development; and,
- Promote lifelong learning.

Recertification cycles begin the day an individual becomes certified and end on December 31st of the 5th full year following the start of the certificants cycle. The program requires that individuals holding a Level 1 Professional Certification document their activities and acquire a total of 50 points across the categories defined by the IFBA CB and earn the minimum required points in each category. Certificants will be asked to attest to attaining the required number of points and submit supporting documentation. The IFBA will send certificants a reminder at the beginning of the calendar year in which the 5 year recertification is due. However, it is recommended that certificants track their professional activities throughout the 5 year cycle and not wait until they are notified.

*For a copy of the recertification requirements (i.e. categories and minimum points required) specific to your level of certification and technical discipline, please contact the IFBA Secretariat at secretariat@internationalbiosafety.org*

# 5.0 General Policies and Procedures

## 5.1 Complaints and Appeals

The IFBA Certification Body investigates and examines all appeals and complaints received from applicants, candidates, certified persons and their employers, and other parties about the certification process and criteria, as well as policies and procedures for the performance of certified persons. If you are unhappy with aspects of the certification process, you are entitled to file a written complaint with the CB. The IFBA endeavours to investigate complaints in a timely, constructive and impartial manner. The complaint is assigned to a suitable investigator, and a correction, cause and corrective or preventative actions are determined and carried out.

If you are unsuccessful in your application for certification, and you feel that the application was handled inappropriately, you are also entitled to appeal the certification decision. A CB Appeals Board specific to the title in question will be convened to consider the candidate's reason(s) for the appeal. The Appeal Board may seek further information from the appellant or any other person, organization or office that it feels appropriate and reviews any materials that it feels appropriate to determine the appeal staying with IFBA policy and taking measures to avoid any conflict of interest. The appellant will be notified of the decision and will be provided with an explanation of the assessment decision following a re-evaluation of the evidence.

*Further details on the procedures for filing a complaint or an appeal can be obtained from the IFBA Secretariat at secretariat@internationalbiosafety.org*

## 5.2 Confidentiality

While the CB considers the certification or recertification status of its certificants to be public information, all CB certification documents relating to certification tests and examinations are considered private, confidential, and proprietary information. An individual's personal information will be kept confidential and will not be disclosed to an unauthorized party without the written consent of the individual (applicant, candidate or certificant), except where the law requires such information to be disclosed. A directory of individuals who currently hold a CB certification will be published on the certification website and will only include the certificants name, title, and mailing address.

All candidates are required to abide by a statement of confidentiality which restricts candidates from sharing any information about the examination with other individuals, including discussions with fellow examination takers following the examination, and the sharing of information with colleagues who might be planning to take the examination in the near future.

All candidates who register for a CB certification examination are required to sign the following attestation:

**Confidentiality Attestation:**

My signature below indicates that I have read, understood and agree to be bound by the requirements of the following Statement of Confidentiality:

1. *This examination and the test questions contained herein are the exclusive property of Certification Body.*
2. *This examination and the test questions contained herein are protected by copyright law. No part of this exam may be copied or reproduced in part or whole by any means whatsoever, including memorization.*
3. *The theft or attempted theft of an examination booklet is punishable.*
4. *My participation in any irregularity occurring during this examination, such as giving or obtaining unauthorized information or aid, as evidenced by observation or subsequent analysis, may result in termination of my participation, invalidation of the results of my examination or other appropriate action.*
5. *Further discussion or disclosure of the contents of the examination orally, in writing, or by any other means, is prohibited. Failure to comply can result in termination of my participation, invalidation of the results of my examination, or other appropriate action.*

## 6.3 Impartiality and Non-Discrimination

The Certification Body (CB) and its employees and volunteers understand the importance of impartiality and the consideration of any potential conflict of interests in carrying out its certification activities. Certification is offered to all eligible persons regardless of age, gender, religion, national origin, marital status, sexual orientation or disability, and the CB ensures fair and equitable treatment of all candidates throughout all phases of the certification process. All CB decisions related to certification (including granting, suspending and withdrawing) are made impartially and free from non-discriminatory judgements.

Certification of individuals is based on evidence obtained by the CB through an objective, valid and reliable assessment. The certification procedures have been designed to enable candidates to attain optimal performance on the exam by providing essential information before taking the test including exam content, sample questions and study references. Care is also taken to ensure the testing procedures and environments are conductive to good performance. Failure to pass an examination should only be the result of inadequate knowledge or skill.

The CB identifies and assesses risks which may pose a threat to impartiality and inspires confidence in its certification by:

- Safeguarding impartiality,

- Being fair and non-discriminatory,
- Being responsive to applicants, candidates and certificants,
- Ensuring transparency of processes, and
- Maintaining confidentiality.

# Appendix A - Professional Certification in Biorisk Management - Examination Content, Sample Questions and References

The IFBA's Professional Certification (PC) in Biorisk Management identifies individuals with demonstrated competencies in the fundamental principles and 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 and biosafety officers, laboratory scientists, technicians, researchers, facility operations and maintenance personnel, biocontainment design engineers and architects, educators, consultants and policy makers. Individuals holding this certification possess the knowledge and skills in sufficient degree to safely and securely manage biological risks 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 Biorisk Management Systems

1. List the goals of an effective biorisk management system;
2. Describe the fundamental elements of a biorisk management system;
3. Identify key factors in developing a successful biorisk management system;
4. Describe the fundamental role of risk assessment and risk management in implementing a biorisk management system;
5. Describe how to measure and monitor the performance of a biorisk management system; and,
6. Describe the process of the PDCA (Plan-Do-Check-Act) principle and provide examples of how PDCA can be applied to a biorisk management system.

## Domain B- CWA 15793 Laboratory Biorisk Management

7. Describe what the CWA 15793 is;
8. Define CWA 15793 terminology including biorisk, biosafety, biosecurity, and biorisk management system;
9. Identify the fundamental components of the CWA 15793;
10. Describe how the CWA 15793 can be used to establish, maintain, review and improve a biorisk management system; and,
11. Describe how national and local laws, regulations and guidelines can be used in conjunction with CWA 15793.

## Domain C – Implementing a Biorisk Management System

12. Describe how to evaluate biological hazards and determine risks;
13. Understand how to use information gathered from risk assessments to formulate site-specific risk mitigation procedures;
14. Understand how to develop and implement mitigation measures for biosafety and biosecurity risks;
15. Understand how to balance mitigation measures for biosafety and biosecurity risks;
16. Understand how to develop and implement “operational”, “facility” and “management” mitigation and control measures for biological risks;
17. Evaluate given examples of operational, facility and management mitigation and control measures and for each example, explain how the associated biological risk could be reduced;
18. Understand how to identify and address non-conformities with biorisk management systems;
19. Describe how to use performance indicators and data generated from accident/incident investigations, inspections and auditing to monitor and improve a biorisk management system;
20. Describe how to establish emergency response procedures;
21. Describe how to establish and implement personnel training, awareness and competence requirements and procedures;
22. Describe how to develop materials for the communication of relevant biorisk information; and,
23. Describe how to control and maintain records, documents and data relevant to the biorisk management system.

## Domain D – Roles and Responsibilities for Biorisk Management

24. Identify individuals responsible for managing biological risks within an organization;
25. Describe the roles, responsibilities and importance of top management, senior management and scientific management;
26. Describe the role and operation of a biorisk management committee;

27. Describe the roles and responsibilities of biorisk management advisor/officer;
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 institution: security staff, animal care staff, operations and maintenance staff.

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

| Exam Blueprint<br>Professional Certification in Biorisk Management | |
|---|---|
| **Domain** | **Number of Exam Questions** |
| A) Fundamentals of Biorisk Management Systems | 18 |
| B) CWA 15793 Laboratory Biorisk Management | 16 |
| C) Implementing a Biorisk Management System | 42 |
| D) Biorisk Management Roles and Responsibilities | 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 CEN Workshop Agreement 15793 Laboratory Biorisk Management 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 performance-based approach to managing biological risks.*
d) define the requirements for certifying laboratories to Biosafety Levels 2 and 3.

**2. The risk assessment process is used to**

a) determine what measures should be put in place that are proportionate with the risks involved with the work.*
b) define how much funding is needed to implement a biorisk management program.
c) outline the roles the responsibilities of individuals within the facility 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) Washing hands and disinfecting benchtops.
b) Working in biological safety cabinet and using sealed centrifuge cups.*
c) Washing hands and using sealed centrifuge cups.
d) Working in a biological safety cabinet and disinfecting benchtops.

**4. One of the roles of a biorisk management officer is to**

a) ensure sufficient 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) provide guidance on the development of biorisk management procedures.*

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

1. Laboratory Biorisk Management. CEN Workshop Agreement 15793. January 2011.
2. Laboratory Biorisk Management - Guidelines for the Implementation of CWA 15793. CEN Workshop Agreement 16393. January 2012.
3. Laboratory Biosafety Manual. World Health Organization. 2004
4. Biorisk Management – Laboratory Biosecurity Guidance. World Health Organization. 2006

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

# Appendix B - Professional Certification in Biological Waste Management - Examination Content, Sample Questions and References

The IFBA's Professional Certification (PC) in Biological Waste Management identifies individuals with demonstrated competencies in the fundamental principles and practices of managing biological waste generated from laboratories and healthcare settings. Candidates applying for this certification must first successfully complete the PC in Biorisk Management before they are eligible for examination.

The PC in Biological Waste Management is suited to a wide range of professionals working with and around biological materials in functions such as biorisk management and biosafety officers, laboratory scientists, technicians, researchers, facility operations and maintenance personnel, biocontainment design engineers and architects, educators, consultants and policy makers. Individuals holding this certification possess the knowledge and skills in sufficient degree to safely and securely manage (e.g. segregate, package, label, collect, store, treat, transport and dispose of biological wastes. The Body of Knowledge (BOK) below identifies 5 domains (topic areas) and 37 knowledge/task statements that define the competency for certification in Biological Waste 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 – Types and Risks of Biological Waste

1. Define biological waste management terminology;
2. Describe the fundamental principles of disinfection, decontamination, incineration, and sterilization;
3. Identify different types of biological waste including biological laboratory waste (solid and liquid), sharps, anatomical waste, blood and body fluids, and animal waste (e.g. tissues, body fluids, carcasses, bedding);
4. Identify different types of mixed biological waste including mixed biological/chemical waste and mixed biological/radioactive waste;
5. Understand the relative resistance of different classes of microorganisms to heat and chemical decontamination (e.g. prions, protozoan cysts, bacterial spores, mycobacteria, viruses, fungi, vegetative bacteria);
6. Describe how to evaluate hazards and assess risks from waste handling to waste handlers, the general public and the environment from all types of biological wastes;
7. Understand how to evaluate different risks associated with biological wastes generated from diverse settings including clinical laboratories, research laboratories, Biosafety Level 2, 3 and 4 laboratories, production laboratories, and animal facilities.

## Domain B- Biological Waste Management

8. Describe the basic elements of a comprehensive biological waste management system including segregation, packaging, labelling, collection, storage, transport, treatment, and disposal;
9. Describe the proper procedures for documentation, record keeping, review and improvement of a biological waste management system;
10. Describe the advantages and disadvantages of on-site vs off-site when selecting waste management options for treatment and disposal;
11. Identify the individuals responsible for the management of biological waste within an organization;
12. Understand how to evaluate the risk related to activities and processes that generate biological waste;
13. Describe procedures for the segregation, packaging, labelling, collection, storage, transport, treatment, and disposal of different types of biological waste generated from diverse settings including clinical laboratories, research laboratories, Biosafety Level 2, 3 and 4 laboratories, and animal facilities;
14. Describe strategies for reducing the quantities of biological waste that is generated (e.g. minimize the packaging brought into laboratories);
15. Understand the applicability of local/national regulations and regulatory framework that govern the management, treatment and disposal of biological waste;
16. Describe how to develop and implement training programs for personnel in the proper handling and risks associated with biological waste;
17. Describe the safety measures (e.g. personal hygiene, personal protective equipment) and security measures (e.g. physical security, restricted access) needed to manage untreated biological wastes;
18. Understand how to establish emergency response procedures for responding to accidents and incidents involving biological wastes and how to establish contingency plans for dealing with the disruption or inoperability of waste treatment and disposal methods.

## Domain C – Treatment and Disposal of Biological Waste

19. Describe the basic principles, advantages and limitations of treatment and disposal options for biological waste including steam autoclaving, irradiation, incineration, chemical disinfection and decontamination, gaseous decontamination, effluent treatment systems and disposal to landfill;
20. Understand how to evaluate and select appropriate treatment and disposal procedures applicable to different types of biological waste generated from diverse settings including clinical laboratories, research laboratories, Biosafety Level 2, 3 and 4 laboratories, and animal facilities;

21. Describe the principles, advantages and limitations of different types of autoclaves and autoclave cycles;
22. Describe the procedures for properly packaging, loading, running, and unloading the autoclave to ensure adequate steam penetration;
23. Describe the principles, advantages and limitations of different types of incinerators for the treatment of biological wastes;
24. Describe the procedures for properly packaging, loading, operating and cleaning incinerators;
25. Understand the applicability of local/national regulations and regulatory framework that govern incinerators related to off-site transportation, operation, emissions and ash disposal;
26. Describe the principles, advantages and limitations of different types of effluent treatment systems including heat-based systems, chemical-based systems, batch and continuous flow systems;
27. Understand the unique treatment methods required for the decontamination of prion contaminated materials; and
28. Understand how to evaluate and select proper treatment and disposal options for animal carcasses and anatomical waste including alkaline hydrolysis, rendering and composting.

## Domain D – Chemical Disinfectants and Sterilants

29. Describe the differences between a sanitizer, disinfectant and sterilant;
30. Describe the intrinsic and inherent resistance of different classes of microorganisms to chemical disinfectants;
31. Describe the germicidal properties, advantages and limitations of commonly used classes of chemical disinfectants and sterilants including chorine-based products, iodine and iodophors, alcohols, phenolic compounds, quaternary ammonium compounds, glutaraldehyde, formaldehyde, hydrogen peroxide and peracids;
32. Describe the factors (e.g. concentration, contact time, organic load, temperature, humidity, diluent, pH, stability) that affect the efficacy of common classes of disinfectants; and,
33. Understand how to evaluate and select the appropriate disinfectant for use against different classes of microorganisms (i.e. prions, protozoan cysts, bacterial spores, mycobacteria, viruses, fungi, vegetative bacteria) in diverse settings including clinical laboratories, research laboratories, Biosafety Level 2, 3 and 4 laboratories, and animal facilities.

## Domain E – Validation and Efficacy Monitoring

34. Describe the biological validation and efficacy monitoring methods applicable to different types of biological waste treatment options;

35. Describe the procedures for proper documentation and record keeping of validation and efficacy monitoring;
36. Understand how to evaluate and select the appropriate biological indicator for its intended use (e.g. liquid versus dry loads, self-contained system, enzyme-based rapid method); and,
37. Describe procedures for the proper use of biological indicators to establish effective operating parameters for autoclaves using representative loads and determining their processing times.

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

| Exam Blueprint<br>Professional Certification in Biological Waste Management | |
|---|---|
| **Domain** | **Number of Exam Questions** |
| A) Types and Risks of Biological Waste | 27 |
| B) Biological Waste Management | 35 |
| C) Treatment and Disposal of Biological Waste | 21 |
| D) Chemical Disinfection and Sterilants | 11 |
| E) Validation and Efficacy Monitoring | 6 |

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. A/an _____ is a chemical or mixture of chemicals that is used to kill microorganisms on laboratory benchtops, but not necessarily spores.**

a) antiseptic
b) sporocide
c) disinfectant*
d) sanitizer

**2. Segregation of waste from laboratories and healthcare facilities is**

a) not needed if the facility only generates a small amount of waste materials.
b) important to determine the type of treatment and disposal practices that should be applied to each type of waste generated.*
c) always carried out at the final site where the waste is disposed of.
d) only required if the facility is handling human tissues or body parts that must be separated from other non-pathological wastes.

**3. Which of the following should be placed directly into an autoclave bag and processed through the autoclave as infectious laboratory waste?**

a) Paper towels used to dry hands when leaving the laboratory.
b) Needles contaminated with blood.
c) A container of sodium hypochlorite used to decontaminate pipettes.
d) Petrie dishes used to grow cultures of *Salmonella*.*

**4. Which of the following best describes the parameters of alkaline hydrolysis used to decontaminate infected animal carcasses?**

a) Dry oxidation process at 850°C
b) Saturated steam under pressure at 121°C
c) Strong alkali solution and heat*
d) Dry heat under pressure

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

1. Safe Management of Wastes from Health-Care Activities. World Health Organization. 2014
2. Laboratory Biosafety Manual. World Health Organization. 2004
3. Compendium of Technologies for Treatment/Destruction of Healthcare Waste. United National Environment Programme. 2012
4. Canadian Biosafety Standards and Guidelines. Public Health Agency of Canada. 2013

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