



Biorisk Management Professional Certification Program

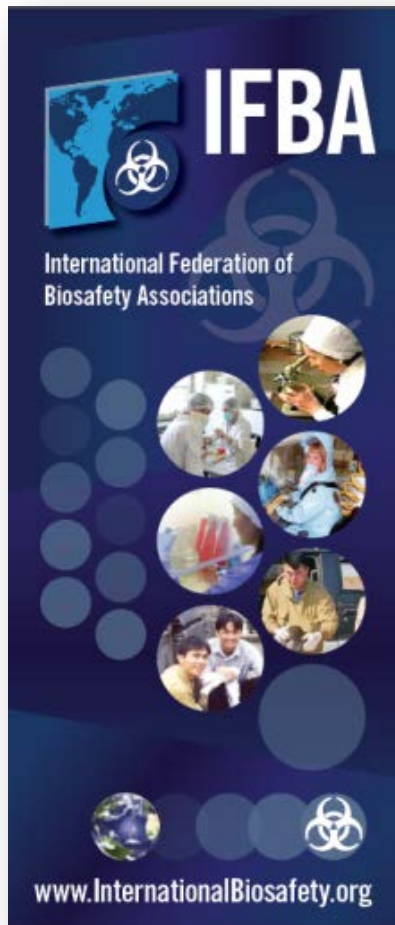
Maureen Ellis
Executive Director
International Federation of Biosafety Associations

International Federation of Biosafety Associations

- 37 Member national & regional biosafety associations from around the world
- Observer organizations - government, academia, NGOs, international agencies (including BWC ISU, Bradford University, Canada's Global Partnership Program)



International Federation of Biosafety Associations



IFBA's activities:

- Advocacy at international levels
- Participation in international initiatives (Stop TB, UN1540, BWC, IHR)
- Creating partnerships, link & leverage expertise
- Promote improved biosafety & biosecurity practices worldwide (**competency of biosafety professionals**)
- Technical input into international guidelines & best practices
- Empower sustainable development of Member national and regional associations



“Safe, Secure & Responsible Work with Biological Materials”

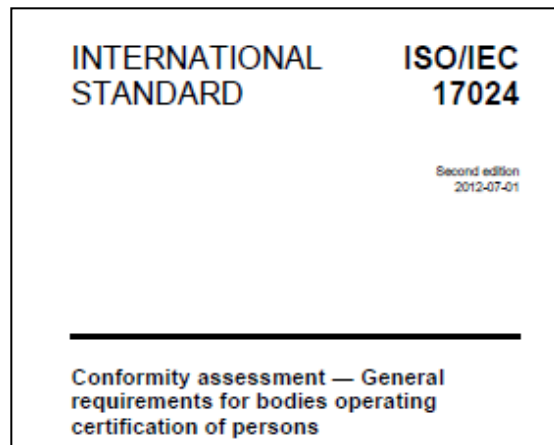
IFBA Certification Program

- Previously no international program to measure competency of individuals carrying out biosecurity, biosafety, biorisk management activities
- IFBA's new program provides confidence that individuals are competent and knowledgeable in specific technical disciplines
- Incentive for furthering biorisk management & biosecurity skills
- Fosters a sense of responsibility and accountability



Program Development

- Developed collaboratively with worldwide members and stakeholders (Technical Committees)
 - Body of Knowledge, Job Task Analysis, Angoff Cut Score Study
- Follows ISO 17024 psychometrically sound principles for measuring knowledge and competency
 - Valid, fair, reliable, defensible certifications



Angoff Cut Score Study - “When establishing a passing score, how does the certification body know that this is the point that separates the candidates that pass from those who fail?”

Certifications Offered

- Professional Certification currently offered in Biorisk Management & Biological Waste Management

(Certification in Biorisk Management is a pre-requisite to all other certifications)

Exam Blueprint 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

Exam Blueprint 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

New Certifications - 2016

— Biocontainment Facility Design, Operations & Maintenance

Domain	Sum I x T	Test plan percentage	N items for 100- item exam
Biocontainment guidelines & standards	81.51	15.1	15
Programming, Planning, Design & Construction	238.38	44.1	44
Commissioning, Validation & Certification	107.43	19.9	20
Facility Operations & Maintenance	112.65	20.9	21
Grand Total	539.97	100.0	100

— Biosecurity

Domain	Sum I x T	Test plan percentage	N items for 100- item exam
Biosecurity Conventions, Guidelines and Standards	131.48	30.3	30
Biosecurity Risk Assessment & Program Management	98.54	22.7	23
Physical Biosecurity Measures	56.88	13.1	13
Pathogen Accountability	35.84	8.3	8
Personnel Reliability	58.91	13.6	14
Dual-Use & Bioethics	51.98	12.0	12
Grand Total	433.63	100.0	100

— Biological Safety Cabinets Selection, Installation & Safe Use

Domain	Sum I x T	Test plan percentage	N items for 100- item exam
Biosafety Cabinet Guidelines & Standards	53.66	13.2	13
Types, Proper Selection and Placement of Biosafety Cabinets	174.48	43.0	43
Safe Use and Maintenance of Biological Safety Cabinets	115.52	28.5	29
Certification of Biosafety Cabinets	62.39	15.4	15
Grand Total	406.06	100.0	100

Biosecurity Exam Content

- Series of knowledge and task statements related to each domain area developed by Technical Committee

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;

Biosecurity Exam Content

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;

Biosecurity Exam Content

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;

Biosecurity Exam Content

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 Delivery

- Exams are being offered in conjunction with our Member's conferences and other events
- Exams can also be taken online using Remote Proctoring System



SoftwareSecure Remote Proctor

Please fill out the Exam Code as provided to you.

Exam Code

Exam Information

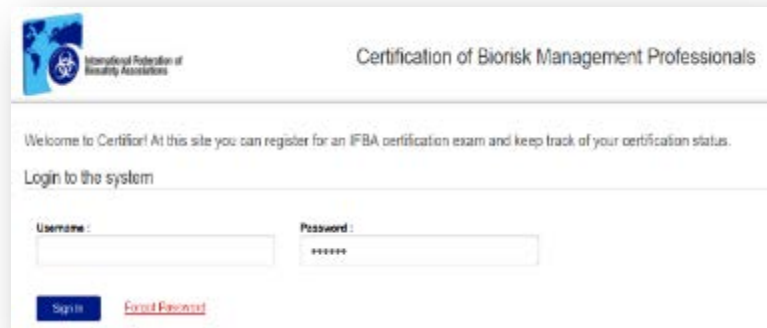
Your EXAM NAME

Duration

Exam Statistics to Date

- Register and track certifications through Certifior system
- 100 individuals have participated in *Professional Certification in Biorisk Management* (63 certified, 37 more are in progress)
- 20 individuals have participated in *Professional Certification in Biological Waste Management* (12 certified, 8 more in progress)

Program	All	Completed	In Progress	Waiting Ve...	Failed	Expired	Lapsed
Biological Waste Management	20	12	8	0	1	0	0
Biorisk Management	100	63	37	0	7	0	0



The screenshot shows the login interface for the IFBA Certifior system. At the top left is the IFBA logo (a globe with a biohazard symbol) and the text "International Federation of Biotechnology Associations". To the right is the title "Certification of Biorisk Management Professionals". Below this, a welcome message reads: "Welcome to Certifior! At this site you can register for an IFBA certification exam and keep track of your certification status." Underneath is the heading "Login to the system". There are two input fields: "Username:" and "Password:". The password field has a masked display with asterisks. At the bottom, there is a blue "Sign In" button and a red "Forgot Password" link.

Exam Statistics to Date

- Certification participants representing 25 countries from around the world
 - Latin America - Argentina, Brazil, Mexico
 - Africa - Kenya, Uganda, Nigeria, Cameroon, Morocco, Egypt, Algeria
 - South & Central Asia - Pakistan, Georgia
 - South East Asia - Indonesia, Malaysia, Korea, Singapore, Thailand, Vietnam, Philippines, PNG
 - Europe – UK, Finland, Austria
 - Australia, New Zealand
- Current project underway with 46 candidates in Middle East region (funded by US Biosecurity Engagement Program)

Publish a Directory of Certified Individuals

Professional Certification in Biorisk Management

1. Aamer Ikram, Pakistan
2. Albert Bunyasi, Kenya
3. Alejandra Contreras M., Mexico
4. Brett Cole, Australia
5. Carina Marshall, Australia
6. Cheng Siang Tan, Malaysia
7. Christian Rantzau, Australia
8. Dale Howard, Australia
9. Dewajani Purnomosari, Indonesia
10. Deo Ndumu, Uganda
11. Faizatul Jafar, Malaysia
12. Gela Mgeladze, Georgia
13. Hee Il Lee, Korea
14. Helen Gregg, Australia
15. Indrawati Sendow, Indonesia
16. Joan Leonard, Australia
17. Joanna Gray, Australia
18. Kemperly Dynon, Australia
19. Kenny Chee, Singapore
20. Klinty Torres-Hernandez, Mexico
21. Larbi Bassii, Morocco
22. Lela Bakanidze, Georgia
23. Lia Vizzotti, Argentina
24. Lora Grainger, USA
25. Maria Amodio, Australia
26. María del Carmen Sarabia León, Mexico

IFBA Certified Individuals

- Use the designation “IFBA Certified” and “Professional Certification in Biorisk Management” (IFBA PC)
- Wallet card and certificate
- Use of IFBA certification logo on business cards, correspondence



Ongoing Activities

- Translation of exams into multiple languages (Spanish, French, Arabic, Russian)
- Development of Level 2 Specialist Professional Certifications (practical examination)
- Addition of certifications in more technical disciplines