

# Πιστοποιήσεις Ειδικών Βιοασφάλειας

## Διονύσης Βούρτσης

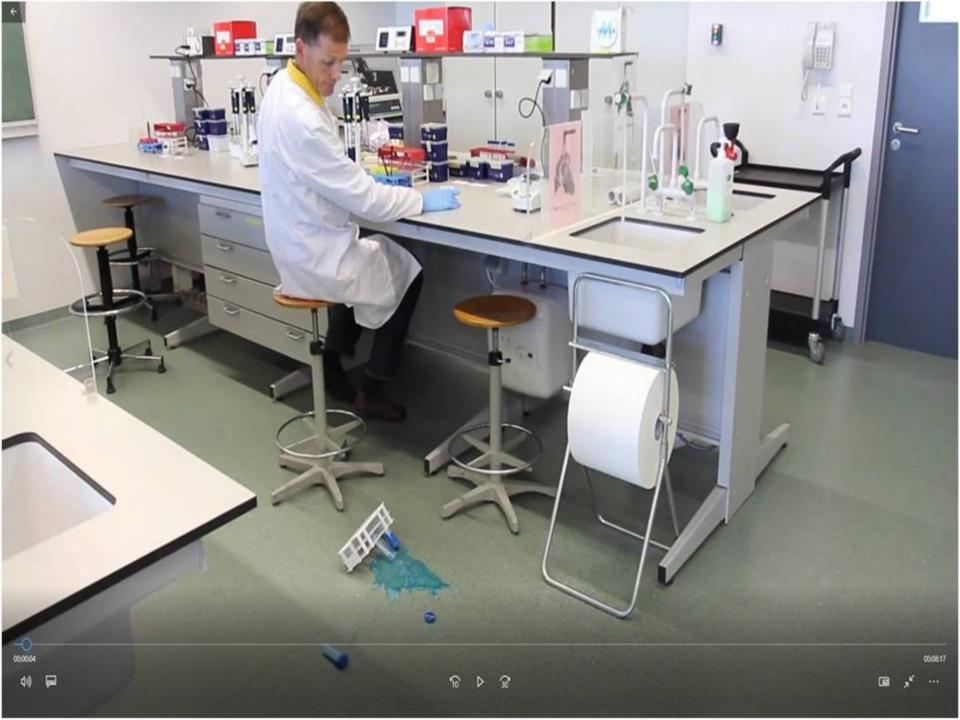
Τεχνολόγος Ιατρικών Εργαστηρίων, ASCP LMU, IFBA PC Υπεύθυνος Σχεδιασμού & Επικοινωνίας IFBA Μέλος Διοικητικού Συμβουλίου EBSA Γενικός Γραμματέας Ελληνικής Εταιρείας Βιοασφάλειας















www.internationalbiosafety.org



### Strengthening Global Health Security: The Role of Professional Biosafety Organizations



## Ρόλος Επιστημονικών Εταιριών

- Δικτύωση και Συνεργασία
- Προώθηση πρακτικών και διαδικασιών διαχείρισης βιολογικών κινδύνων
- Πιστοποίηση ικανοτήτων επαγγελματιών
   βιοασφάλειας για τον ασφαλή και υπεύθυνο χειρισμό υλικών και παραγόντων

### APBA Collaborating Partners

A-PBA is evolving and will continue to stay relevant serving the Asia-Pacific Region and be an active partner of the international biosafety community at the same time.



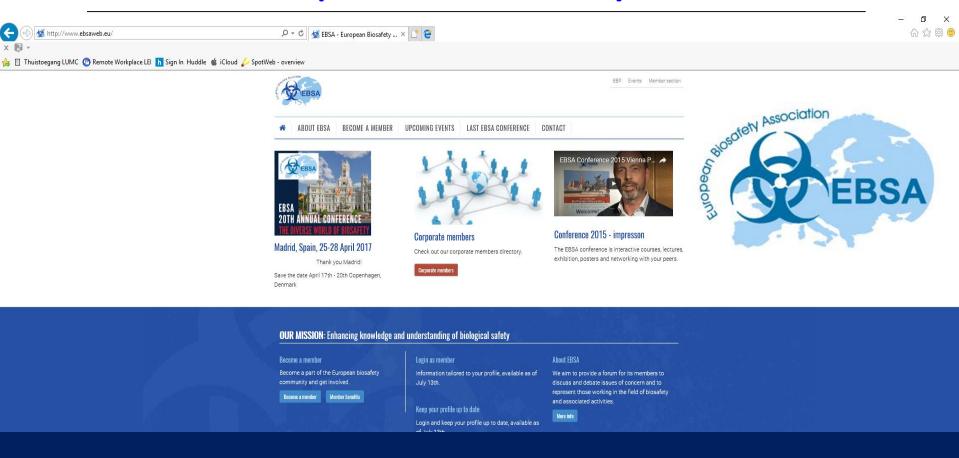


**Industrial Partners** 





### EBSA - European Biosafety Association



# www.ebsaweb.eu



### EBSA - European Biosafety Association

- Μη κερδοσκοπικός οργανισμός, ανοιχτός σε όποιον εργάζεται ή έχει σχέση με την Βιοασφάλεια
- Ιδρύθηκε το 1996
- Μέλη: Διάφοροι κλάδοι επαγγελματιών:
  - Υγειονομική περίθαλψη, ακαδημαϊκή κοινότητα,Έκτακτες ανάγκες, φαρμακευτική / βιοτεχνολογικήΒιομηχανία, Κανονιστικές Ρυθμιστικές υποθέσεις
- Εκπροσωπεί την κοινότητα της Βιοασφάλειας στην Ευρώπη



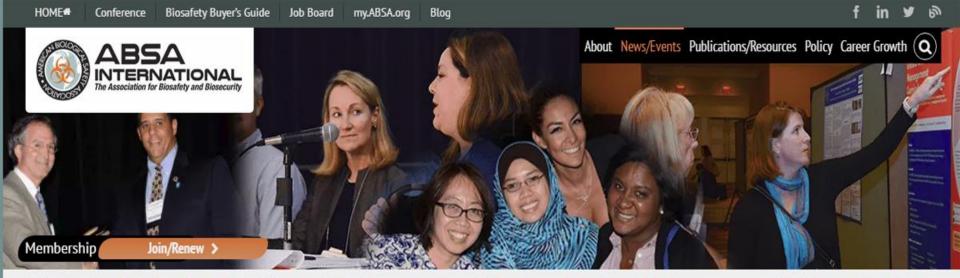
22nd annual conference of the european biosafety association

**Burning topics in Biosafety** 

# **Bucharest - Romania**

EBSA Courses April 2 - 3, 2019 EBSA Conference April 4 - 5, 2019

www.ebsaweb.eu/bucharest



ABSA International (ABSA) was founded in 1984 to promote biosafety as a scientific discipline and serve the growing needs of biosafety professionals throughout the world. Its goals are to provide a professional association that represents the interests and needs of practitioners of biological safety, and to provide a forum for the continued and timely exchange of biosafety information. (learn more)

### News



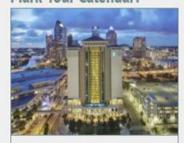
### Basic Biosafety On-demand Module

Basic Biosafety is an on-demand module designed to provide guidance on the basic principles and practices of biological safety for biosafety professionals, biosafety officers, and other professionals involved in workplace safety in laboratories and facilities throughout the world.

### Online Resources



### Mark Your Calendar!



Principles & Practices of Biosafety

February 18, 2018 -

February 23, 2018

### **ABSA International Blog**



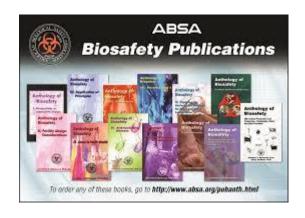
Human Salmonella Typhimurium Infections Linked to Exposure to Clinical and Teaching

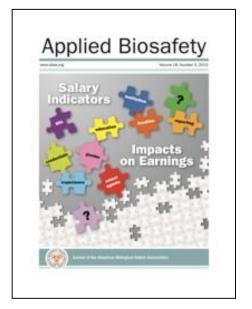
www.absa.org



### **ABSA**

- Ιδρύθηκε το 1984
- Σκοπός:
  - Να προωθήσει τη βιοασφάλεια ως επιστημονικό κλάδο
  - Να δώσει λύσεις στις αυξανόμενες ανάγκες των επαγγελματιώνβιοασφάλειας σε όλο τον κόσμο
  - Φόρουμ για τη συνεχή και έγκαιρη ανταλλαγή πληροφοριών για τη βιοασφάλεια







governmental organization of regional and national Biosafety Associations.







# www.internationalbiosafety.org





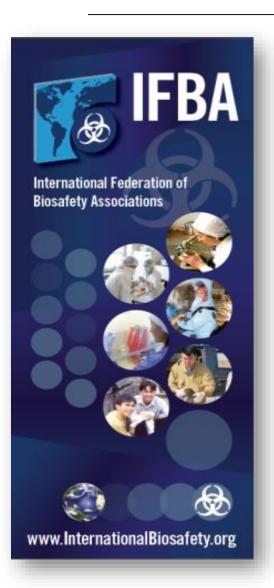
www.internationalbiosafety.org



# **Biosafety and Global Public Health**



### **IFBA**



- Διεθνής μη κερδοσκοπικός Οργανισμός
- Ιδρύθηκε το 2001

"Ασφαλής & Υπεύθυνη Εργασία με Βιολογικά Υλικά"



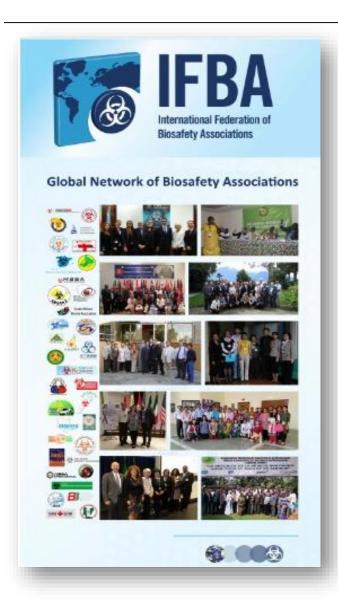
Certification of Biorisk Management Professionals



www.internationalbiosafety.org



### **IFBA**



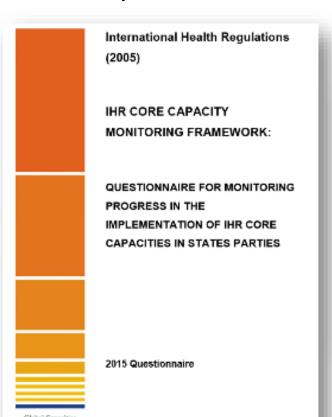
- Η IFBA έχει μέλη 40περιφερειακές και εθνικέςΕνώσεις Βιοασφάλειας
- Επίσης, υπάρχουν και μέλη
   Παρατηρητές (Κυβερνήσεις,
   Πανεπιστήμια, Διεθνείς
   Οργανισμοί)





### Διεθνής Βιοασφάλεια

Η IFBA παρέχει βοήθεια για την υλοποίηση των βασικών σημείων υλοποίησης του IHR (International Health Regulations) για την Βιοασφάλεια



Component	8.2	Laboratory biosafety and biosecurity	
Indicator	8.2.1	*Laboratory biosafety and laboratory biosecurity (Biorisk management <sup>71</sup> ) practices in place and implemented	

- 8.2.1.1 Are biosafety guidelines accessible to laboratories?
- 8.2.1.2 Are regulations, policies or strategies 72 for laboratory biosafety available?
- 8.2.1.3 Has a responsible entity 13 been designated for laboratory biosafety and laboratory biosecurity?
- 8.2.1.4 Are relevant staff trained in laboratory biosafety and laboratory biosecurity guidelines?
- 8.2.1.5 Has an institution or person<sup>74</sup> responsible for inspection, (could include certification of biosafety equipment) of laboratories for compliance with biosafety requirements been identified?
- 8.2.1.6 Has a biorisk<sup>75</sup> assessment been conducted in laboratories to guide and update biosafety regulations, procedures and practice, including for decontamination and management of infectious waste?



### Διεθνής Βιοασφάλεια

### Η IFBA είναι μέλος:

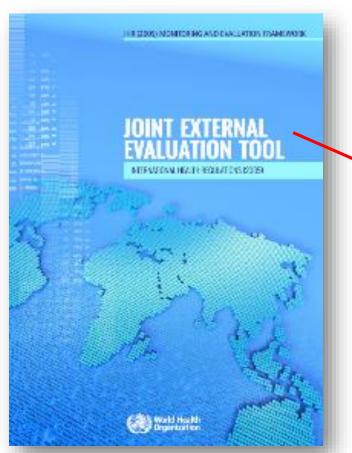
- Global Health Security Action Group (Μη Κυβερνητικής Ομάδας Δράσης για την Ασφάλεια της Παγκόσμιας Υγείας)
- JEE Alliance (Joint External Evaluation)
- Παγκόσμιας πρωτοβουλίας συνεργασίας: Stop TB Partnership





## Πιστοποίηση Βιοασφάλειας

- WHO Joint External Evaluation Tool (Εργαλείο Εξωτερικής Αξιολόγησης)
  - Action Package Prevent 3 Biosafety & Biosecurity



#### **Documentation or Evidence for Level of Capability:**

- Documentation of dangerous pathogen collections housed in the country
- Establishment, enactment and enforcement of any relevant national legislation on biosafety & biosecu
- Biosafety officers certified and stationed at all laboratories that have the potential to handle dangerous
- Policy document for biorisk or biosafety management in a facility is a written policy statement that is s
- Membership in good standing of a regional or international biosafety association
- OIE Country PVS report (also included for Prevent 2- Zoonoses)
- OIE Country PVS Gap Analysis report (also included for Prevent 2- Zoonoses)
- OIE Country PVS Laboratory Mission Report



## Πρόγραμμα Πιστοποίησης IFBA

- Προηγουμένως δεν υπήρχε ανεξάρτητος, διεθνώς τυποποιημένος μηχανισμός για την αξιολόγηση και την επικύρωση των Γνώσεων, Δεξιοτήτων και Ικανοτήτων ενός επαγγελματία στη διαχείριση της Βιοασφάλειας
- 2010 Η IFBA δημιούργησε σε συνεργασία με μέλη της και άλλους εταίρους ένα νέο πρόγραμμα πιστοποίησης για την Βιοασφάλεια





## Πρόγραμμα Πιστοποίησης IFBA

- Το πρόγραμμα IFBA αναπτύχθηκε σε εναρμόνιση με το πρότυπο ISO 17024
- 100 ερωτήσεις πολλαπλής επιλογής 2 ώρες
- Οι εξετάσεις προσφέρονται Online ή τοπικά με επιτήρηση από εγκεκριμένους επιτηρητές της IFBA, στα συνέδρια μελών της για τη Βιοασφάλεια και σε άλλες εκδηλώσεις









### Διαχείριση Βιολογικής Ασφάλειας

Η απόκτηση της πιστοποίησης Διαχείριση Βιολογικής Ασφάλειας
 αποτελεί προϋπόθεση για όλες τις άλλες πιστοποιήσεις

# Exam Blueprint Professional Certification in Biorisk Management Passing Score – 74%

Domain	Number of 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 & Responsibilities	24



## **Biosecurity**

# 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



# Διαχείριση βιολογικών αποβλήτων

# Exam Blueprint Professional Certification in Biological Waste Management

Passing Score - 72%

Domain	Number of Questions
A) Types and Risks of Biological Waste	27
B) Biological Waste Management	35
C) Treatment & Disposal of Biological Waste	21
D) Chemical Disinfection and Sterilants	11
E) Validation & Efficacy Monitoring	6



### Σχεδιασμός, λειτουργία και συντήρηση Εγκαταστάσεων

### **Exam Blueprint**

# Professional Certification in Biocontainment Facility Design, Operations & Maintenance

### Passing Score – 71%

Domain	Number of Questions
A) Biocontainment Guidelines & Standards	15
B) Programming, Planning, Design & Construction	44
C) Commissioning, Validation & Certification	20
D) Facility Operations & Maintenance	21



# Επιλογή, εγκατάσταση και ασφαλής χρήση Θαλάμων Βιολογικής ασφάλειας

### **Exam Blueprint**

# Professional Certification in Biosafety Cabinet Selection, Installation & Safe Use Passing Score – 70%

Domain	Number of Questions
A) Biosafety Cabinet Guidelines & Standards	13
B) Types, Proper Selection and Placement of Biosafety Cabinets	43
C) Safe Use and Maintenance of Biological Safety Cabinets	29
D) Certification of Biosafety Cabinets	15



## Πρόγραμμα Πιστοποίησης IFBA

- Χρησιμοποίηση της ονομασίας "IFBA Professional Certification"
  - IFBA PC
- Ισχύει για περίοδο 5 ετών











About Us

IFBA Members

Professional Certification

Programs & Activities

News & Events

Resources

Members

You are here: Home > Professional Certification > IFBA Professional Certifications > Directory of Certified Individuals

### Directory of Certified Individuals, 22/09/2017

Details Calegory: Directory of Certified Individuals Published: 20 December 2015. Hits: 7651





The IFBA publishes a global directory of individuals who are Professionally Certified by the IFBA's Certification Body. If you are unable to locate an individual in this directory, this does not necessarily mean that the individual is not certified as new certificants are continually added to the list. Please contact the IFBA Secretariat at secretariat@internationalbiosafety.org to verify an individual's certification status.



Directory of Certified Individuals, Updated: 22/09/2017

#### Professional Certification in Biorisk Management

- Aamer Ikram, Pakistan.
- 2. Abderrahmen Selmania, Algeria
- 3. Abdoulaye Hassane, Mali
- 4. Abdulaziz Zorgani, Libya
- 5. Abeer Elsayed Abdelaziz Mohamed, Egypt
- 6. Abigail Padua, Philippines
- 7. Abiodun Denloye, Nigeria
- 8. Abraham Van Rensburg, South Africa
- 9. Absalom Mai, Papua New Guinea
- 10. Adam Ben Nasr, Tunisia Adriana Miyagi, Argentina.
- 12. Adriano Muñoz Martinez, Spain
- 13. Ahlam ElSayed Gamal ElDin Younes, Egypt 14. Ahmad Razi Mohamed Yunus, Malaysia
- 15. Alastair Reid, United Kingdom
- 16. Albert Bunyasi, Kenya
- 17. Alejandra Contreras M., Mexico
- Alie H Wurie, Sierra Leone.

# Skills of the future (big 7)

- Mental Elasticity and Complex Problem Solving
- Critical Thinking
- Creativity
- People Skills
- STEM
- SMAC (Social, Mobile, Analytics, Cloud)
- Interdisciplinary Knowledge







United Nations Educational, Scientific and Cultural Organization

UNESCO Chair in
 Entrepreneurship Education,
 J.J. Strossmayer University in Osijek, Croatia





### Κουλτούρα Βιοασφάλειας

Ευαισθητοποίηση και δημιουργία συνείδησης για τους

κινδύνους

Αναφορό αποδίδοι

Να αναδειχ για την προ

Κατάλληλη

Βέλτιστες Ε

Κατάλληλα

Εκπαίδευση

Υπεύθυνος



### ΒΙΒΛΙΟΓΡΑΦΙΑ

### The Biological Weapons Convention:

### **IHR, International Health Regulations, WHO:**

http://www.who.int/topics/international health regulations/en/

**UN Security Council Resolution 1540:** https://www.un.org/en/sc/1540/

GHSA, Global Health Security Agenda: https://www.ghsagenda.org/

ABSA: https://absa.org/

EBSA: https://ebsaweb.eu/

**Laboratory Biorisk Management Standard: CEN Workshop Agreement 15793:** 

https://ebsaweb.eu/sites/default/files/cwa\_15793\_english.pdf

IFBA: www.internationalbiosafety.org

Global Health Security Action Group: http://www.ghsi.ca/english/index.asp

JEE Alliance: https://www.jeealliance.org/

GLI, Global Laboratory Initiative: http://www.stoptb.org/wg/gli/

HBS: www.hellenicbiosafety.org

Advancing Global Health Security, WHO:

http://www.who.int/ihr/publications/WHO\_HSE\_GCR\_2016\_15/en/

Joint external evaluation tool: International Health Regulations (2005), WHO:

http://apps.who.int/iris/bitstream/handle/10665/204368/9789241510172\_eng.pdf?sequence=1



Καμιά κρατική αρχή δεν μπορεί να τα καταφέρει μόνη της.

Μόνο μέσω μόνιμης και ουσιαστικής συνεργασίας με τις Επιστημονικές Εταιρίες και Συλλόγους Βιοασφάλειας, μπορεί να υπάρξει πρόληψη και προετοιμασία για την αντιμετώπιση των βιολογικών κινδύνων και των επικίνδυνων βιολογικών περιστατικών

### SAFETY RESPONSIBILITY



DEPENDS ON EVERYONE

## SAFETY RESPONSIBILITY



DEPENDS ON EVERYONE



### Sample Questions - IFBA Biorisk Management Exams

### **Sample Question 1**

The primary objective of a biorisk management system is to

- a. train employees in the safe handling of biological agents.
- b. protect employees, the community and environment from biological agents that are handled within the facility.
- c. identify and assess risks from biological agents that are handled within the facility.
- d. implement policies and practices to prevent the release of biological agents from the facility into the environment.



# **Sample Question 1**

The primary objective of a biorisk management system is to

- a. train employees in the safe handling of biological agents.
- b. protect employees, the community and environment from biological agents that are handled within the facility.
- c. identify and assess risks from biological agents that are handled within the facility.
- d. implement policies and practices to prevent the release of biological agents from the facility into the environment.



### **Sample Question 2**

What is MOST essential to the overall effectiveness of an organization's biorisk management system?

- a. Full implementation of every element
- b. Flawless execution of the system
- c. Direction from all levels of management
- d. Employee participation



### **Sample Question 2**

What is MOST essential to the overall effectiveness of an organization's biorisk management system?

- a. Full implementation of every element
- b. Flawless execution of the system
- c. Direction from all levels of management
- d. Employee participation



# **Sample Question 3**

What is the first consideration in the hierarchy of risk management controls?

- a. Substitution of the hazard with an alternative organism/activity
- b. Isolation of the hazard through the use of engineering controls
- c. Isolation of personnel through the use of protective equipment
- d. Elimination of the work producing the hazard



# **Sample Question 3**

What is the first consideration in the hierarchy of risk management controls?

- a. Substitution of the hazard with an alternative organism/activity
- b. Isolation of the hazard through the use of engineering controls
- c. Isolation of personnel through the use of protective equipment
- d. Elimination of the work producing the hazard



### **Sample Question 4**

What does the acronym AMP stand for in biorisk management?

- a. Application, mitigation, program
- b. Assessment, mitigation, performance
- c. Assessment, methods, performance
- d. Agreement, methods, practice



# **Sample Question 4**

What does the acronym AMP stand for in biorisk management?

- a. Application, mitigation, program
- b. Assessment, mitigation, performance
- c. Assessment, methods, performance
- d. Agreement, methods, practice



### **Sample Question 5**

#### Biorisk is defined as the

- a. combination of the likelihood and consequences of an adverse event involving a biological agent.
- b. accidental release or loss, theft, misuse, diversion, unauthorized access or intentional release of a biological agent.
- c. containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.
- d. process of evaluating the risk arising from a biological agents.



### **Sample Question 5**

#### Biorisk is defined as the

- a. combination of the likelihood and consequences of an adverse event involving a biological agent.
- b. accidental release or loss, theft, misuse, diversion, unauthorized access or intentional release of a biological agent.
- c. containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.
- d. process of evaluating the risk arising from a biological agents.



# **Sample Question 6**

Management systems are frameworks that often integrate procedures built around the concepts of PDCA. PDCA stands for

- a. Plan, Decontaminate, Control, Assess
- b. Plan, Do, Check, Act
- c. People, Documents, Controls, Actions
- d. Plan, Document, Check, Audit



# **Sample Question 6**

Management systems are frameworks that often integrate procedures built around the concepts of PDCA. PDCA stands for

- a. Plan, Decontaminate, Control, Assess
- b. Plan, Do, Check, Act
- c. People, Documents, Controls, Actions
- d. Plan, Document, Check, Audit



### **Sample Question 7**

Where any requirement of CWA 15793 is in conflict with local regulations, the

- a. requirements of CWA 15793 are given priority.
- b. local regulations are given priority.
- c. independent third-party mediator should decide which requirements are given priority.
- d. organization should decide which requirements are given priority.



# **Sample Question 7**

Where any requirement of CWA 15793 is in conflict with local regulations, the

- a. requirements of CWA 15793 are given priority.
- b. local regulations are given priority.
- c. independent third-party mediator should decide which requirements are given priority.
- d. organization should decide which requirements are given priority.



# **Sample Question 8**

In the framework of the CWA 15793, laboratory biosecurity is intended to

- a. protect agricultural resources and food supplies from contamination with unwanted biological agents.
- b. prevent the loss, theft, misuse, or diversion of biological agents.
- c. screen personnel to identify those who are vulnerable to threats and physical attacks.
- d. minimize security breaches in laboratories.



# **Sample Question 8**

In the framework of the CWA 15793, laboratory biosecurity is intended to

- a. protect agricultural resources and food supplies from contamination with unwanted biological agents.
- b. prevent the loss, theft, misuse, or diversion of biological agents.
- c. screen personnel to identify those who are vulnerable to threats and physical attacks.
- d. minimize security breaches in laboratories.



# **Sample Question 9**

What combination of control measures would provide the BEST option for facilities working with a blood borne transmitted biological agent?

- a. HEPA filtration of the exhaust air and using sharps containers
- b. HEPA filtration of the supply air and wearing gloves
- c. Using sharps containers and wearing gloves
- d. Sealing bench tops and using sharps containers



# **Sample Question 9**

What combination of control measures would provide the BEST option for facilities working with a blood borne transmitted biological agent?

- a. HEPA filtration of the exhaust air and using sharps containers
- b. HEPA filtration of the supply air and wearing gloves
- c. Using sharps containers and wearing gloves
- d. Sealing bench tops and using sharps containers



# **Sample Question 10**

What combination of control measures would provide the BEST protection for an employee handling a biological agent transmitted by the ingestion route?

- a. Wearing gloves, disinfecting bench tops, and washing hands
- b. Working in a biological safety cabinet, disinfecting bench tops, and washing hands
- c. Wearing a respirator, washing hands, and disinfecting bench tops
- d. Wearing gloves, working in a biological safety cabinet, and washing hands



# **Sample Question 10**

What combination of control measures would provide the BEST protection for an employee handling a biological agent transmitted by the ingestion route?

- a. Wearing gloves, disinfecting bench tops, and washing hands
- b. Working in a biological safety cabinet, disinfecting bench tops, and washing hands
- c. Wearing a respirator, washing hands, and disinfecting bench tops
- d. Wearing gloves, working in a biological safety cabinet, and washing hands