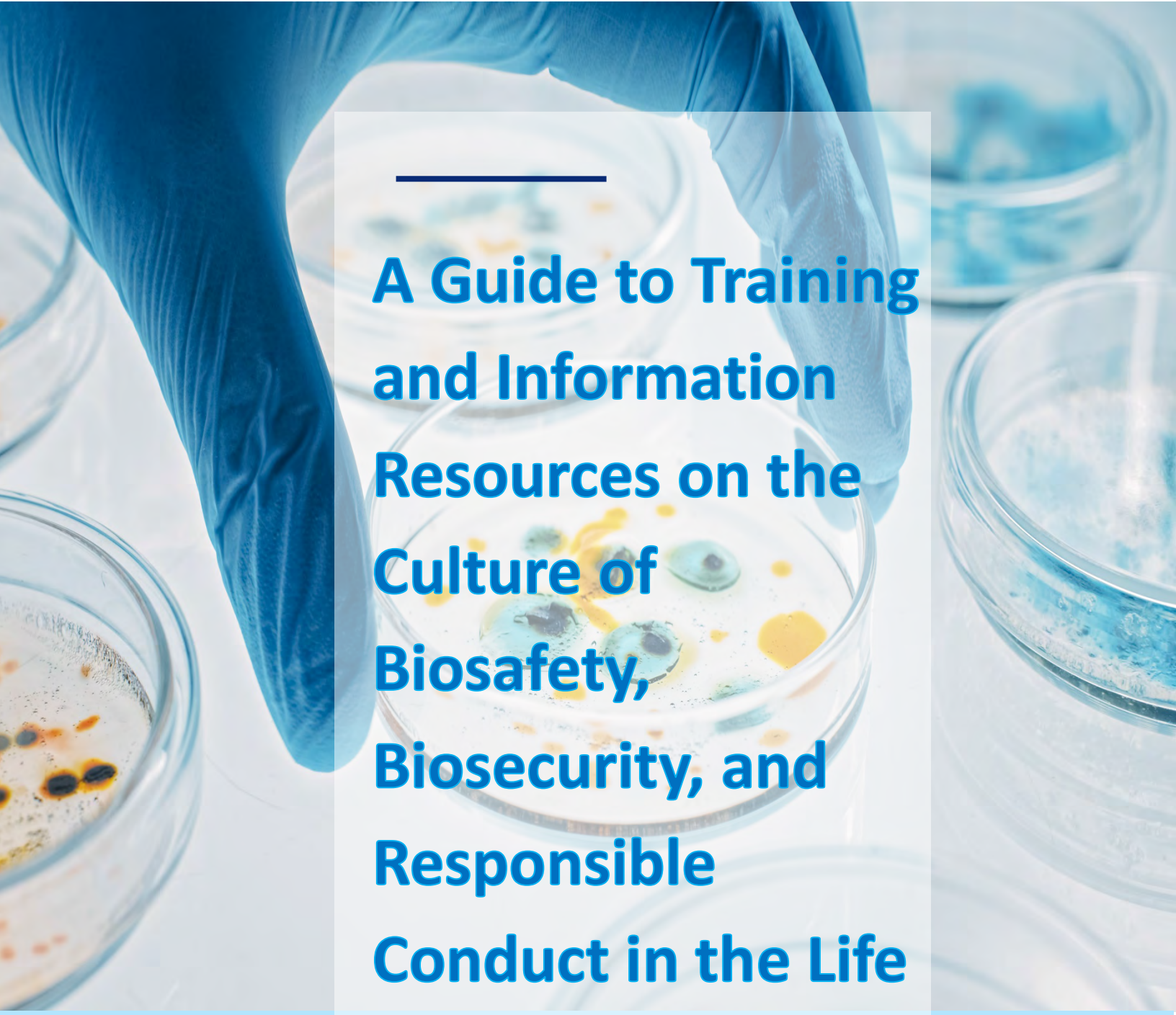

A Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

2021

International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences

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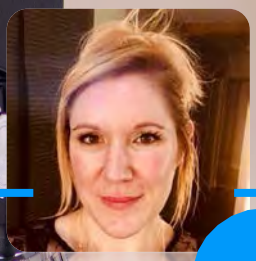
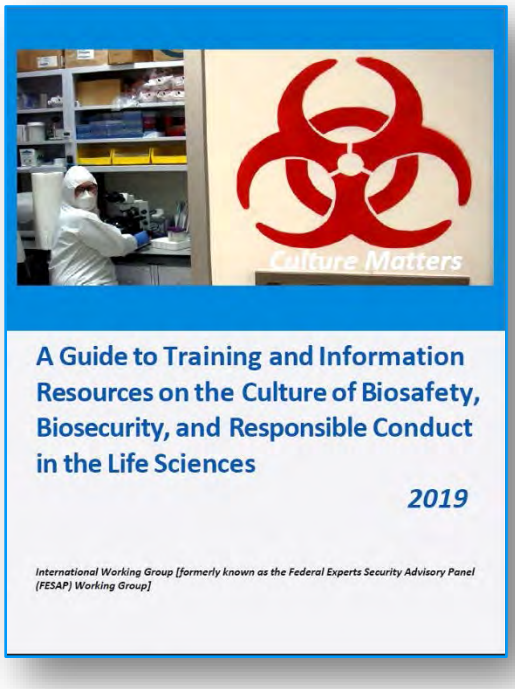


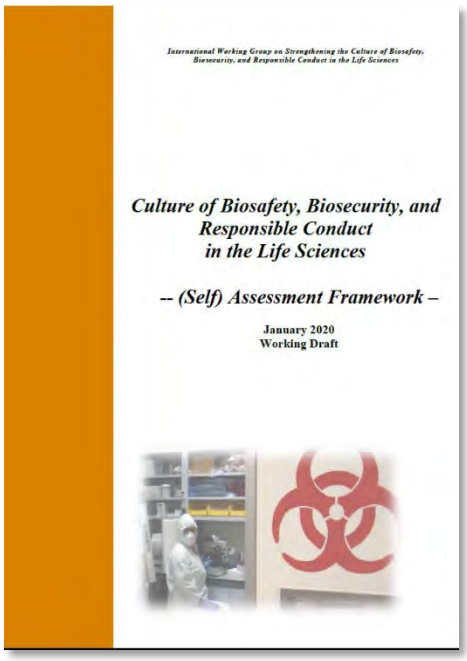
Strengthening the culture of biosafety and biosecurity requires strong laboratory leaders.

— Jennifer Lasley, MPH, Preparedness and Resilience Department, World Organization for Animal Health (OIE)

About the IWG

The International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences (IWG, for short) is a platform for collaboration and community of practice comprised of representatives of governments, academia, industry, professional and international organizations, and other organizations from across the globe, using crowdsourcing to develop guiding principles and educational/training resources to support and promote a culture of global biosafety, biosecurity, ethical, and responsible conduct in the life sciences, based on the culture model and assessment methodology developed by IAEA for the nuclear safety and security culture. The group is convened by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture. It conducts periodic webinars and shares information among its members and with the Global Health Security Agenda (GHA) Action Package Prevent-3 (Biosafety and Biosecurity) via its Community Corner monthly newsletter. The International Working Group developed in 2019 a *Guide to Training and Information Resources on the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences*. More recently, the group developed a *Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences -- (Self) Assessment Framework* – and an accompanying data collection tool. The group supports and promotes, globally, a culture of biosafety, biosecurity, and responsible conduct in the life sciences, promotes effective oversight of dual-use research, and encourages engagement among the health, scientific, biotechnology, enthusiast, and security communities to reduce the risk of misuse of science.





IWG Participants

American Association for Laboratory Animal Science (AALAS)
ABSA – International
Association of Public Health Laboratories (APHL)
American Society for Microbiology (ASM)
European Biosafety Association (EBSA)
International Federation of Biosafety Associations (IFBA)
INTERPOL
Biological Weapons Convention (BWC) Implementation Support Unit (ISU)
United Nations Office for Disarmament Affairs (UNODA)
World Health Organization (WHO)
World Organization for Animal Health (OIE)
University of Texas Medical Branch (UTMB)
Colorado State University
North Carolina State University
University of Massachusetts Dartmouth
Emory University
University of Chicago
Bradford University
London Metropolitan University
B&S Europe
Defence Science and Technology Laboratory (Dstl)
MedImmune
AECOM
BioSecure
Health Security Partners
iGEM
BUGSS
GENSPACE
CHROME Biosafety and Biosecurity Consulting
Safer Behaviors LLC
Gryphon Scientific
Royal Scientific Society of Jordan
Netherlands National Institute for Public Health and the Environment, Biosecurity Office
Denmark Centre for Biosecurity and Biopreparedness
Emlyon Business School (France)
Center for the Study of Democracy (Bulgaria)
CARPHA (Trinidad and Tobago)
Mali National Institute of Public Health (INSP)
U.S. Department of Health and Human Services [Office of the Assistant Secretary for Preparedness and Response (ASPR); Food and Drug Administration (FDA), National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC)]
U.S. Department of Agriculture
Federal Bureau of Investigation (FBI)
Environmental Protection Agency (EPA)
U.S. Department of Defense
U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)
U.S. Department of Homeland Security
U.S. Geological Survey
Sandia National Laboratories
Pacific Northwest National Laboratories
National Academies of Sciences, Engineering, and Medicine
National Biodefense Analysis and Countermeasures Center (NBACC)

What is the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences?

An assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations that can support, complement or enhance operating procedures, rules, and practices as well as professional standards and ethics, designed to prevent the loss, theft, misuse, and diversion of biological agents, related materials, technology or equipment, and the unintentional or intentional exposure to (or release of) biological agents. [1]

Elements of culture adapted from a model developed by IAEA [2, 3]

1 *Management Systems*

An organizational culture of biosafety, biosecurity, and responsible conduct in the life sciences includes policies, processes, procedures, and programs in the organization that make biosafety and biosecurity a top priority and have an important impact on biorisk management functions. Examples include but are not limited to:

- **Clear roles and responsibilities**
- **Visible safety and security policy**
- **Performance measurement**
- **Feedback process**
- **Competency-based training**

2 *Behavior of Leadership and Personnel*

Leadership behavior **(i.e., specific patterns of behavior and actions which are designed to foster more effective biorisk management) should emphasize inter alia:**

- **Expectations**
- **Decision-making**
- **Oversight**
- **Effective communication**
- **Motivation**

Personnel behavior **(the desired outcomes of the leadership efforts and the operation of the management systems) should underscore inter alia:**

- **Professional conduct**
- **Adherence to approved/validated procedures and research protocols**
- **Teamwork and cooperation**
- **Vigilance**

3

Principles for Guiding Decisions and Behaviors

Emphasis should be placed on principles for guiding decisions and behaviors as they relate to biorisk management. Examples include but are not limited to:

- **Leadership**
- **Commitment and responsibility**
- **Professionalism and competence**
- **Learning and improvement**
- **Maintaining public trust**
- **Codes of conduct (including codes of ethics)**

Beliefs and Attitudes

4

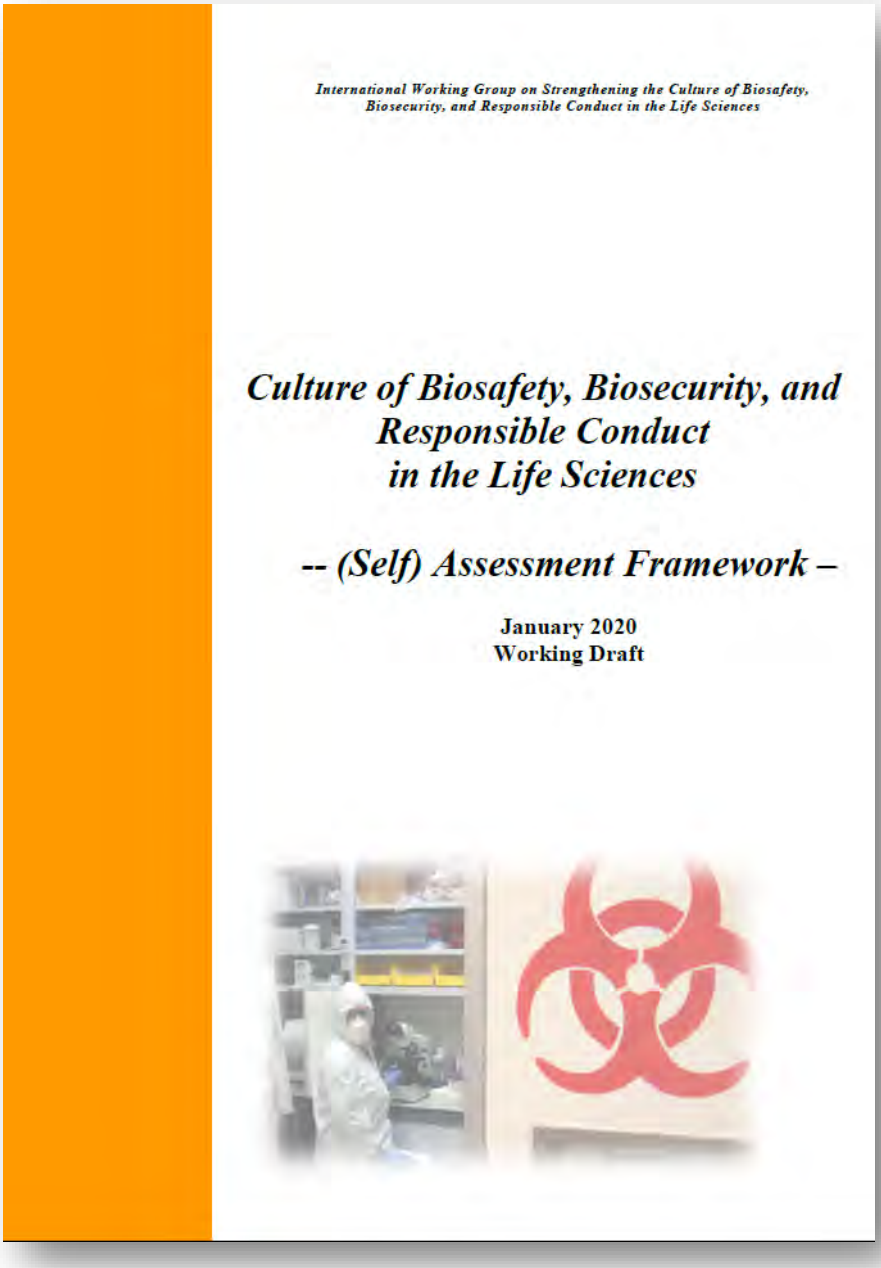
Beliefs and attitudes on biosafety and biosecurity (including on dual use research of concern and cyberbiosecurity) should be assessed periodically and reinforced through training and education aiming to:

- **Raise awareness on consequences and mitigation strategies of risks associated with working in a laboratory with biological materials (e.g., accidental exposure, infection or release; intentional theft and/or misuse; others such as cybersecurity, radiological/chemical/ physical safety and security)**
- **Increase understanding of the ethical, legal, and societal issues and consequences concerning life sciences research, development, and associated technologies**
- **Emphasize laboratory quality management**
- **Ensure compliance with regulations, policies, guidance, and procedures.[4]**

The 5th Biological Security Deliverable of the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction aims to "*reduce biological proliferation risks through the advancement and promotion of safe and responsible conduct*".

The 7th and 8th Review Conferences of the Biological Weapons Convention noted "*the value of national implementation measures…to … encourage the promotion of a culture of responsibility amongst relevant national professionals and the voluntary development, adoption and promulgation of codes of conduct.*"

The Global Health Security Agenda (GHSA) 5-year target toward promoting national biosafety and biosecurity systems: … "*biological risk management training and educational outreach are conducted to promote a shared culture of responsibility…*"



Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences
https://absa.org/wp-content/uploads/2020/02/Culture_of_Biosafety-Biosecurity_Self-Assessment_Framework.pdf

Culture of Biosafety, Biosecurity, and Responsible Conduct Data Entry Tool
https://absa.org/wp-content/uploads/2020/02/Culture_of_Biosafety-Biosecurity_Self-Assessment_Framework-Template.xlsx

Assessing the Organizational Culture of Biosafety, Biosecurity, and Responsible Conduct

The revised (4th edition) of WHO Laboratory Biosafety Manual (LBM) 4th edition now features a paragraph on Biosafety Culture under Section 7 – Biosafety Programme Management and states that a "strong biosafety culture" is the basis for the most effective biosafety program. Moreover, the Biosafety Programme Management monograph of LBM includes a full section on *Establishing a Strong Biosafety Culture* and recommends best practices such as demonstrated commitment of senior management, demonstrated commitment to biosafety throughout the organization, active engagement of laboratory personnel and support personnel, and ongoing communication and promotion of biosafety. The details are a welcome addition to our biological risk management toolkit but much work has yet to be done to address the biosafety-biosecurity interface in organizational culture and the nuances that a culture of responsibility implies.

Despite references to a culture of biosafety or a culture of responsibility in international fora and mentions sometimes found in Joint External Evaluation (JEE) Mission Reports, the practice of assessing the said culture at the organizational level, in a manner similar to the nuclear field) is not yet established. There isn't currently an international organization that, under its current mandate, is willing to provide tools, tailored support services or training on safety/security culture assessments and corrective action plans, similar to the IAEA's work in the nuclear domain.

The International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences developed a framework for assessing the organizational culture based on the IAEA's seminal work in this domain and various tools developed by other organizations. We called it a working draft to emphasize that it can be customized based on the local needs in order to understand the impact of culture on organizational performance.

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A High Reliability Organization (HRO) combines Murphy's Law with a touch of inspiration.

— Patricia Delarosa, PhD, CBSP, RBP, CTM, National Bio and Agro-Defense Facility (NBAF), U.S. Department of Agriculture

In today's regulatory climate, many high-hazard sites realize that the consequences of a mishap in their operations can be so devastating that they employ a High Reliability Organization (HRO) systems approach to minimize the vulnerability of human error.

— Paul Landon, MSH, CIH, CSP, RBP, National Biodefense Analysis and Countermeasures Center (NBACC), U.S. Department of Homeland Security

Courses, Credentialing, and Repositories of Training and Educational Resources

Professional and International Organizations Lead the Way

Advanced Biosafety Training Series:

An intermediate to advanced online offering designed for those studying for the Certified Biological Safety Professional (CBSP) exam and for those interested in advanced training:

https://absa.org/abts

Professional Credentials in Biosafety:

Registered Biosafety Professional (RBP)

RBPs are individuals with documented university education or specialized training in relevant biological safety disciplines. A RBP has an understanding of infectious diseases, their transmission, and the application of methods to safely control infectious materials in research, clinical production, testing, educational development, and other work environments.

Certified Biological Safety Professional (CBSP)

Certification as a Biological Safety Professional is available via an examination, developed by members of ABSA. Application requirements include submittal of transcripts, references, and work history.

ABSA International Laboratory Accreditation Program

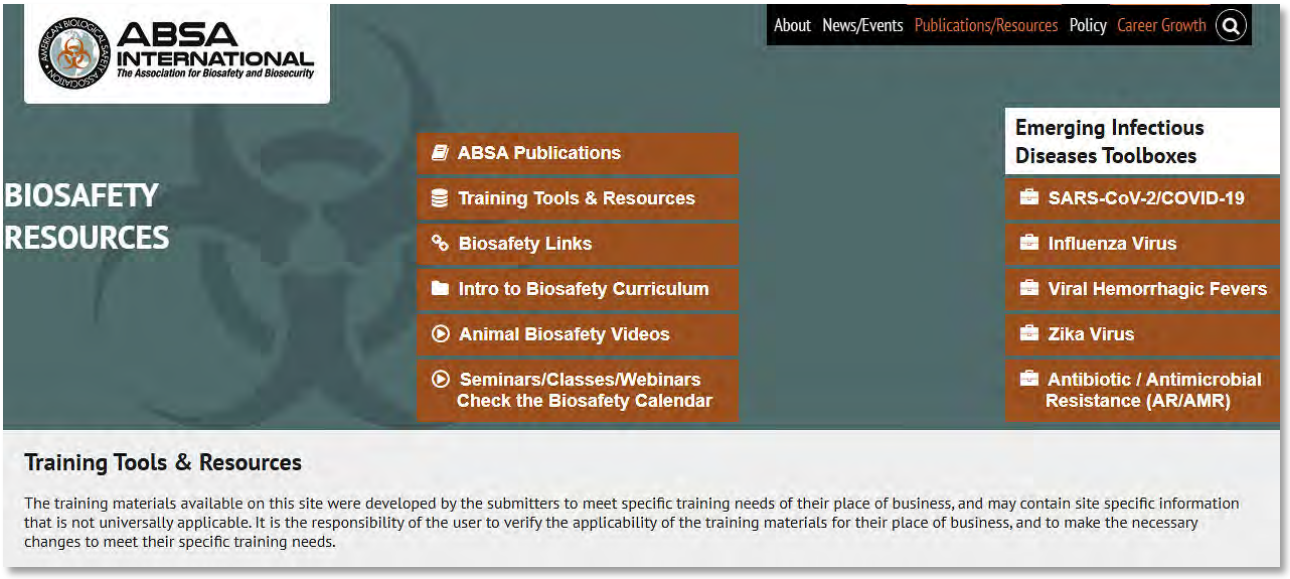
ABSA International (ABSA) has developed a voluntary ABSA Laboratory Accreditation Program for BSL–2, ABSL–2, BSL-3, and ABSL-3 laboratories that are not under the jurisdiction of the U.S. Select Agent and Toxins Regulations. ABSA accreditation will provide entities recognition of excellence and compliance with high standards, while providing facilities guidance in generating processes and policies to create a safer environment for their organization, employees, research animals, and the community.

The benefits of ABSA Accreditation include recognition within the biosafety community that an institution conducts work with biohazardous agents in a safe and secure manner and assurance to the public that the institution is conducting safe science, thus protecting its employees, research animals, the public, and the environment. The entire process is confidential. Read more at: https://absa.org/lab-accred/

https://absa.org/wp-content/uploads/2017/01/ABSAlabAccreditation.pdf

ABSA International Mentoring Program

The Mentoring Program was established in 2005 to formally promote the exchange of experience-based biosafety knowledge. Many ABSA members have been privileged to have a mentor in the workplace or in an informal relationship, but there are many new ABSA members who don't have someone at the workplace to consult with, or are not comfortable contacting a stranger to seek information. Since biosafety is not a field where all of the answers are found in books or via a classroom-based raining, ABSA's Mentoring Program provides the opportunity to acquire real experience-based knowledge. Read more at: https://absa.org/mentoring/



https://absa.org/topic/ttr/

IFBA Certification of Biorisk Management Professionals

- **Biorisk Management**
- **Biological Waste Management**
- **Biocontainment Facility Design, Operations, and Maintenance**
- **Biosecurity**
- **Biosafety Cabinet Selection, Installation, and Safe Use**

The IFBA's certification program is the only internationally recognized program to certify the competency of individuals in biorisk management and a variety of related technical disciplines. The program is structured in compliance with the policies and procedures of ISO/IEC 17024: 2012 Conformity assessment – General Requirements for Bodies Operating Certification of Persons. Read more at:
https://internationalbiosafety.org/certification/certification/

The IFBA Global Mentorship Program is a worldwide initiative to support and sustain the international biosafety and biosecurity community. Mentor and Mentee pairs are matched based on region and professional discipline to encourage locally relevant professional guidance in any and all IFBA Professional Certification domains. Read more at:
https://internationalbiosafety.org/program-activities/mentoring/ifba-global-mentorship-program/

American Association for Laboratory Animal Science

Online Courses | AALAS Learning Library https://aalaslearninglibrary.org

Biosafety Training courses include:

- **Animal Biosafety Training Program. 16 courses that orient researchers, animal care technicians, and other personnel to the biosafety principles, guidelines, safety equipment, and facility safeguards that enable the safe conduct of infectious disease research using laboratory animals at Animal Biosafety Level (ABSL) -2 and -3. Courses can be taken separately, or the Animal Biosafety Training Certificate can be earned if the learner completes the required courses and passes each exam.**
- **Biosafety in Microbiological and Biomedical Laboratories: 6th edition**
- **NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)**
- **Bloodborne Pathogens Training for Animal Research**
- **Occupational Health and Safety in the Care and Use of Research Animals**

Video Training – Working Safely with Nonhuman Primates
https://www.aalas.org/education/educational-resources/working-safely-primates

Training Manuals | https://www.aalas.org/store

- **Assistant Laboratory Animal Technician Training Manual**
- **Laboratory Animal Technician Training Manual**
- **Laboratory Animal Technologist Training Manual**

AALAS Technician and Manager Certification

Technician & Manager Certification | https://www.aalas.org/certification

- **Assistant Laboratory Animal Technician (ALAT)**
- **Laboratory Animal Technician (LAT)**
- **Laboratory Animal Technologist (LATG)**
- **Certified Manager of Animal Resources (CMAR)**

The technician certification designations of ALAT, LAT, and LATG are well known and widely used throughout the varied fields of laboratory animal care. These certifications have come to be a common requirement for a lab animal care position.

The Certified Manager of Animal Resources (CMAR) program raises competency and professionalism in the field of laboratory animal resources management.

Association of Public Health Laboratories

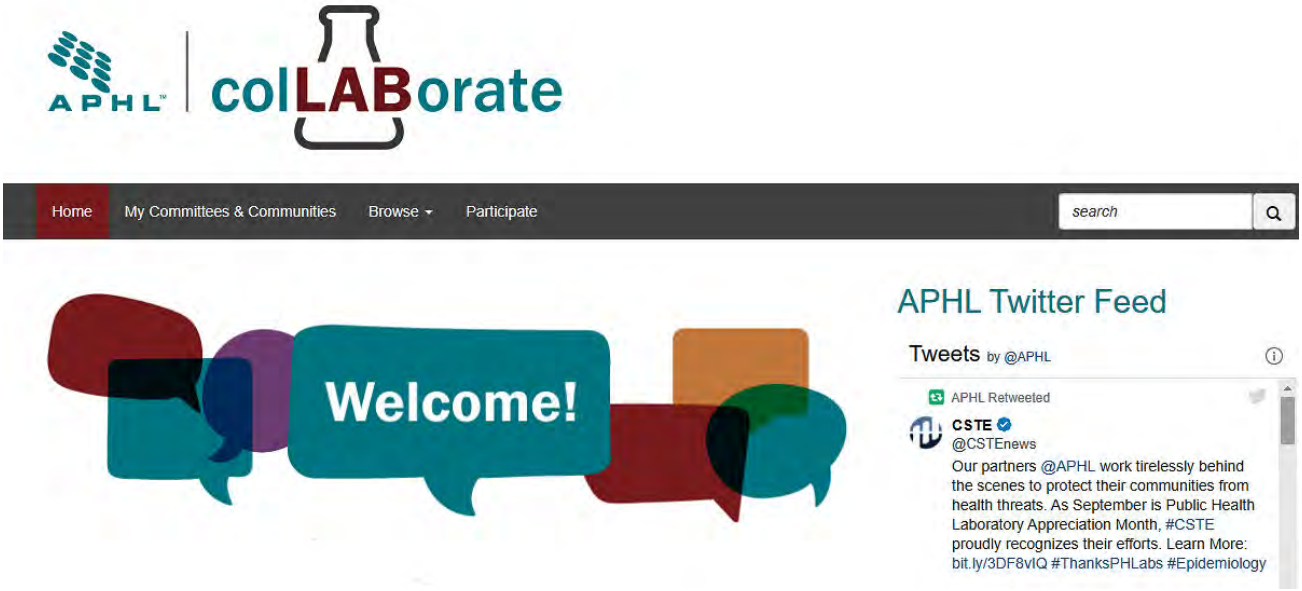
Laboratory Biosafety and Biosecurity Resources:

APHL, working in partnership with the US Centers for Disease Control and Prevention (CDC), offers tools and resources to strengthen biosafety and biosecurity practices in public health and clinical laboratories. Read more at:
https://www.aphl.org/programs/preparedness/Pages/Biosafety-Biosecurity-Resources.aspx

- **Biosafety and Biosecurity Resources**
  - **APHL Risk Assessment Best Practices**
  - **APHL Biosafety Checklist**
  - **Clinical Laboratory Biosafety Risk Management Program Assessment Checklist**
  - **Biorisk Management for Clinical and Public Health Laboratories**
  - **Competency Based Position Description for Biosafety Officials**
  - **APHL Biothreat Identification Bench Cards**
  - **APHL Biothreat Identification Poster**
- **Biosafety Community of Practice**
  - **Laboratory Safety ColLABorate Community (anyone can join the free community if interested)**
- **COVID-19 Biosafety/Biosecurity Resources**
  - **APHL Potential Hazards and Recommended Mitigation Procedures for COVID-19**
  - **COVID-19 Antigen Testing Biosafety Guidance**

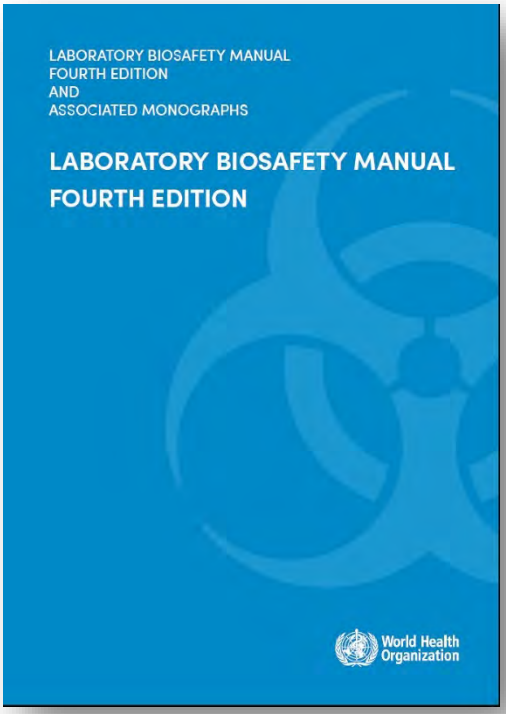
Archived APHL Biosafety and Biosecurity Webinars:
https://www.aphl.org/training/Pages/ondemand-laboratory-training-search.aspx

Participate in discussions with your peers, update your profile/add your picture, find and contact other community members, share your documents/presentations and enjoy exploring [APHL ColLABorate!]



OpenWHO is WHO's interactive, web-based, knowledge-transfer platform offering online courses to improve the response to health emergencies. OpenWHO enables the Organization and its key partners to transfer life-saving knowledge to large numbers of frontline responders. Read more and browse the OpenWHO course catalogues at: https://openwho.org/pages/catalogues

https://www.who.int/publications/i/item/9789240011311



https://www.who.int/publications/i/item/who-guidance-on-implementing-regulatory-requirements-for-biosafety-and-biosecurity-in-biomedical-laboratories--a-stepwise-approach

Additional WHO training resources:

Safeguarding biosafety and biosecurity in laboratories

WHO Guidance on Establishing a Strong Biosafety Culture

"This edition of the manual aims to guide sustainable developments in biosafety, including a national oversight system, training, best working practices and a risk assessment framework to promote a responsible safety culture that builds country capacity and complies with the International Health Regulations."

"This culture is crucial for the success of a biosafety programme, and is built from mutual trust and the active engagement of all personnel across the organization, with a clear commitment from the organization's management."

WHO-recommended best practices:

Demonstrated commitment of senior management

Demonstrated commitment to biosafety throughout the organization

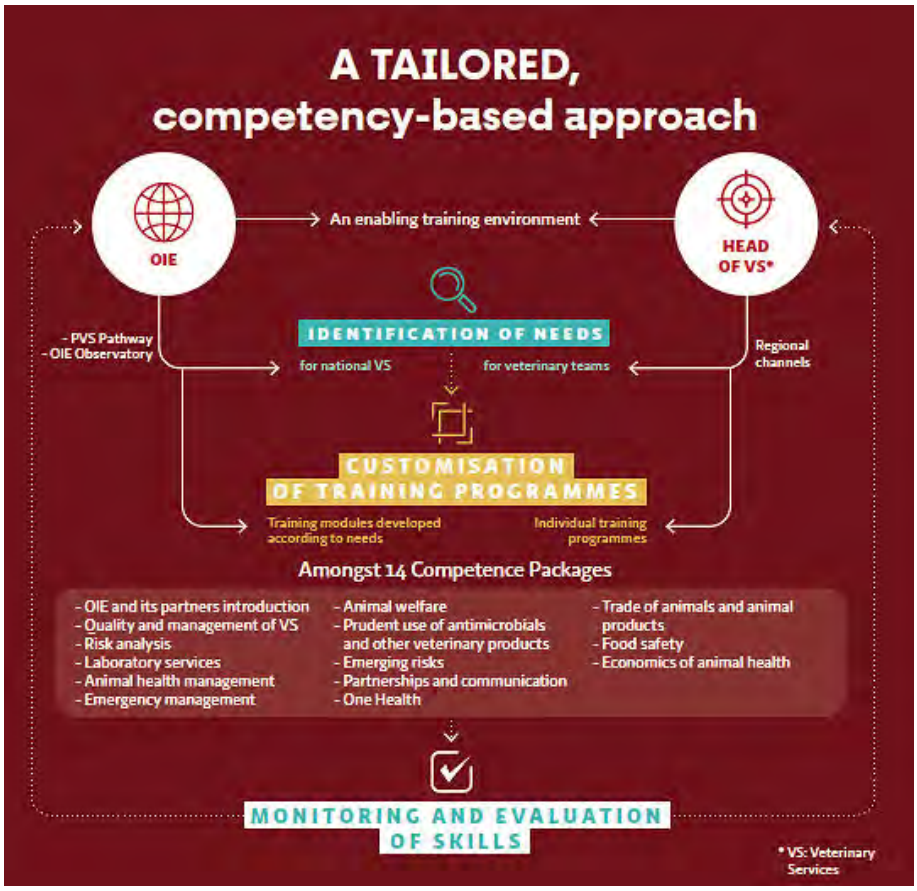
Active engagement of laboratory personnel and support personnel

Ongoing communication and promotion of biosafety

World Organisation for Animal Health

:0 to assist with the delivery of training, whether

https://training.oie.int/pluginfile.php/1636/course/section/757/EN_LR_Brochure%20formation.pdf



"The OIE is re-envisioning its educational activities and making its Lyon-based platform a global centre of excellence for the training of Veterinary Services. By combining the scientific, technical and pedagogical expertise of our international network of Reference Centres and partners, we are aiming to provide an innovative training offer to better equip countries to meet the health, climate and societal challenges of tomorrow. The countdown to a new era of training has begun!"

Dr. Monique Éloit, OIE Director General

GLLP Global Laboratory Leadership Programme

Strong leaders for health security

The Global Laboratory Leadership Program (GLLP) is a unique workforce development initiative led by six organizations (the GLLP Partners) working globally in the human, animal, and environmental health sectors. The goal of the GLLP is to foster and mentor current and emerging laboratory leaders to build, strengthen, and sustain national laboratory systems. The GLLP combines didactic learning with mentorship, practical experience, and a community of practice to support individual learning and laboratory systems strengthening. The GLLP partners are:

- **Association of Public Health Laboratories (APHL)**
- **Centers for Disease Control and Prevention (CDC)**
- **European Centre for Disease Prevention and Control (ECDC)**
- **Food and Agriculture Organization of the United Nations (FAO)**
- **World Organization for Animal Health (OIE)**
- **World Health Organization (WHO)**

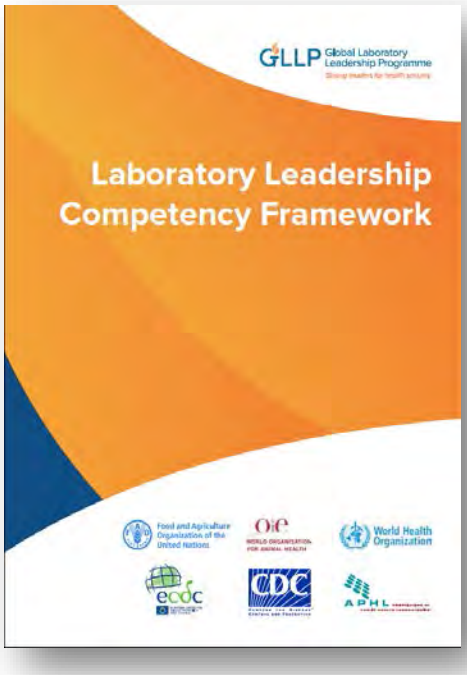
Laboratory Leadership Competency Framework

The purpose of the Laboratory Leadership Competency Framework is to outline the essential competencies needed for laboratory leaders to build sustainable national laboratory systems that improve disease detection, control and prevention efforts in health systems around the world.

The Framework consists of nine competencies:

- **Laboratory system**
- **Leadership**
- **Management**
- **Communication**
- **Quality management system**
- **Biosafety and biosecurity**
- **Disease surveillance and outbreak investigation**
- **Emergency preparedness, response and recovery**
- **Research**

The GLLP encapsulates the nine core competencies outlined in the Laboratory Leadership Competency Framework.



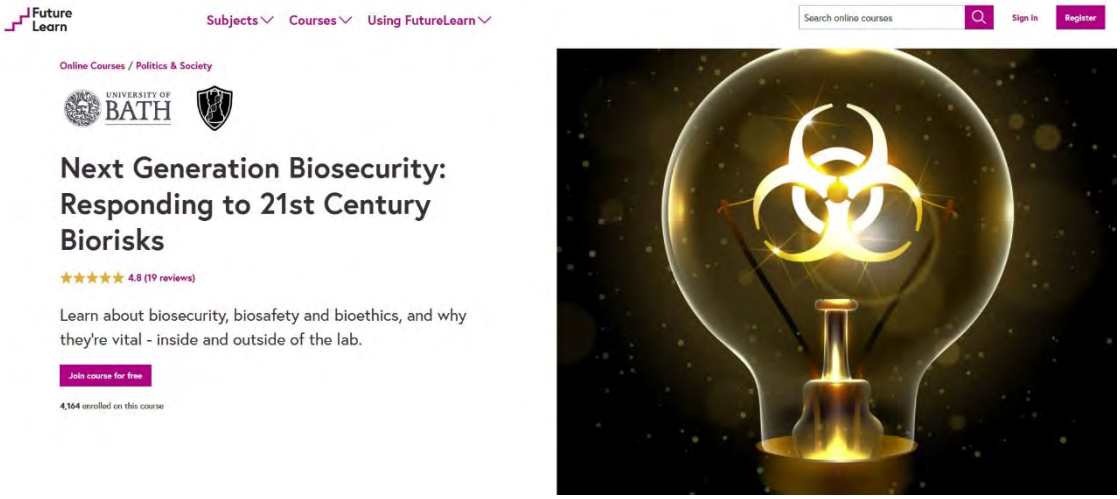
Championing Biosafety and Biosecurity

Next Generation Biosecurity: Responding to 21st Century Biorisks

This free, online course developed by Biosecure and the University of Bath, UK, covers topics such as:

- **Introduction to biosecurity**
- **Biological threats and challenges**
- **Responding to biological challenges: what you can do inside the lab**
- **Responding to biological challenges: what is done outside the lab**
- **Responsible conduct of science: learning to critically examine security issues arising with the lab and formulate responses**

Read more about the course and start at your own pace, at:
https://www.futurelearn.com/courses/biosecurity

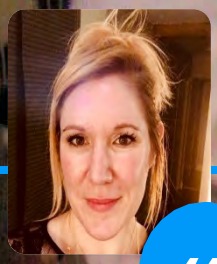


Safer Behaviors, LLC

Safer Behaviors offers a variety of training, consulting, and coaching services including on biological risk assessment and mitigation; behavioral-based safety methodologies; team and safety culture development, and many more.

Check out the BioSafe360 Laboratory Safety Culture Program, at: https://www.youtube.com/watch?v=1pY4ZjN-BJc and subscribe to Safer Behaviors You Tube Channel at: https://www.youtube.com/channel/UCQIKdRb621AWDpBBtRD6myw featuring Sean G. Kaufman.

Safer Behaviors
Connecting plans and outcomes



Laboratory leadership is fundamental. Without a focus on people and building a community of practice of One Health laboratory leaders, laboratory system sustainability, quality, safety, and security will remain challenging.

— Jennifer Lasley, MPH, Preparedness and Resilience Department, World Organization for Animal Health (OIE)

Biosecurity and certainly dual use aspects of research do not always occur to researchers.

— Rik Bleijs, PhD, Head Netherland Biosecurity Office, National Institute for Public Health and the Environment (RIVM)

CDC Learning Connection helps public health and healthcare professionals stay informed about quality trainings from CDC, other federal agencies, and federally funded partners.

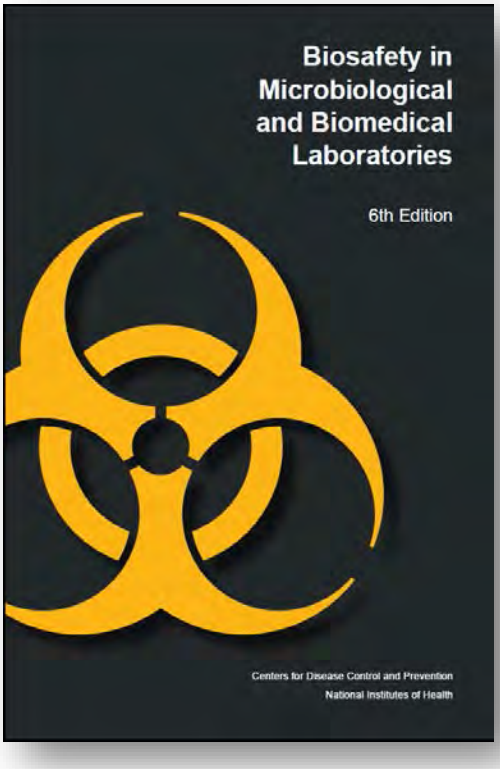
Are you interested in developing training? CDC is offering Tools and Resources to help you develop quality training.

CDC Laboratory Training

CDC Laboratory Safety Portal

Biosafety Resources and Tools

https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf




INTERNATIONAL STANDARD

ISO 35001

First edition
2019-11

Biorisk management for laboratories and other related organisations

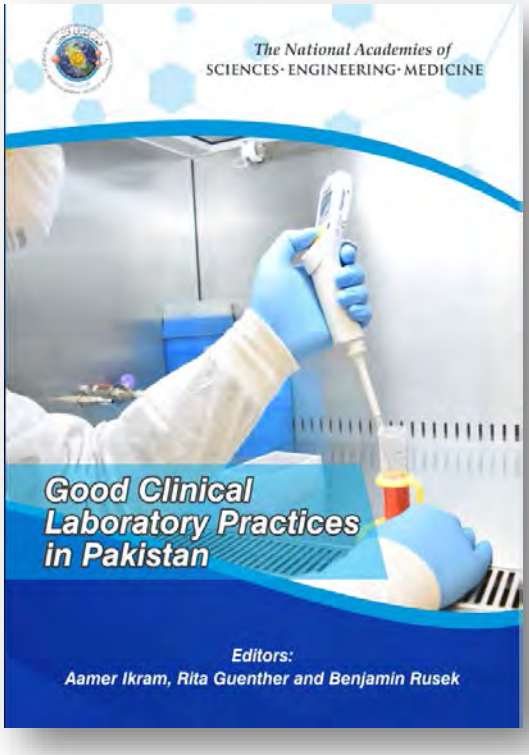
Système de management des biorisques en laboratoires et autres organismes associés

ISO

ISO 35001:2019 ***Biorisk management for laboratories and other related organizations*** **defines a process to identify, assess, control, and monitor the risks associated with hazardous biological materials and it is intended to complement existing International Standards for laboratories.**

ISO 15189:2012 ***Medical laboratories — Requirements for quality and competence*** **can be used by medical laboratories in developing their quality management systems and assessing their own competence.**

https://www.nih.org.pk/wp-content/uploads/2019/04/HANDBOOK-for-Good-Clinical-Lab.pdf



This handbook is a joint initiative of the Pakistan Academy of Sciences (PAS) and National Academies of Sciences, Engineering and Medicine (NASEM), USA, and is has sections on laboratory management, biosafety, laboratory operations and quality management systems. It is intended to serve as an informational guide for clinical laboratories in Pakistan in line with the concept of 'One Health'.

The Biosecurity Office of The Netherlands is the national information center for the Dutch Government and for organizations that work with high-risk biological material.

The website offers a Biosecurity Self-Scan Toolkit in the form of an online questionnaire covering the eight pillars of biosecurity listed below, that is designed to give you an indication of the current level of biosecurity in your organization. A Vulnerability Scan is also available online.

- **Awareness**
- **Personnel Reliability**
- **Transport Security**
- **Information Security**
- **Materials Accountability**
- **Response Management**
- **Physical Measures**

Additional toolkits and resources (including the postcard above) are available on the website at:

https://www.bureaubiosecurity.nl/en/toolkit

CENTRE FOR BIOSECURITY AND BIOPREPAREDNESS

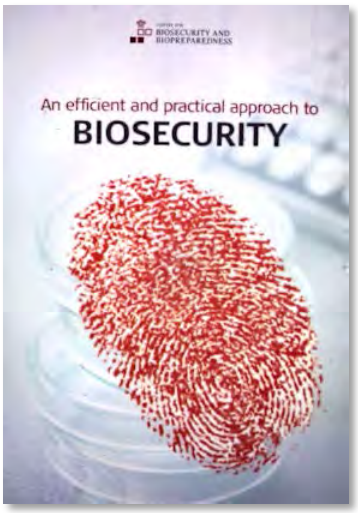
Denmark's Center for Biosecurity and Biopreparedness (CBB)

offers an international course in biosecurity system implementation.

Additional educational materials:

An Efficient and Practical Approach to BIOSECURITY

and the Biosecurity Insight Newsletter



The Laboratory Biosafety and Biosecurity e-learning portal of The Public Health Agency of Canada offers a variety of courses and resources, including the *Principles of Laboratory Biosafety e-Learning Course,* Health Emergency Management Training, and instructional videos on biosafety which can be viewed for free online:

- **Biosafety 101**
- **Containment Level 2 Laboratory: Operational Practices**
- **Containment Level 3 Laboratories: Operational Practices**

An Analytical Approach for the Development of a National Biosafety and Biosecurity System

The *Analytical Approach* is a tool developed to assist countries or regions build, modernize, or strengthen their national or regional biosafety and biosecurity systems to mitigate the risks of a natural, accidental or deliberate release of biological agents. A complete biosafety and biosecurity system encompasses a legal structure that provides a mandate for an oversight program, along with a policy framework, education and training, and a culture of responsible conduct.

The International Experts Groups of Biosafety and Biosecurity Regulators (IEGBBR) is made up of biosafety and/or biosecurity regulatory authorities from 11 member countries that have strong regulatory oversight systems in place for biosafety and biosecurity. WHO and OIE are non-member observers. The IEGBBR developed a Compendium of International Biosafety and Biosecurity Oversight Systems for Human and Animal Pathogens and Toxins, which provides detailed descriptions of the national regulatory oversight approaches among the 11 member countries. The Compendium was launched as a publicly available, searchable mobile application in English and French at the Google Play store in December 2019. Users can search and contrast desired aspects of the biosafety and biosecurity oversight systems for any or all of the 11 IEGBBR members.

Dual Use and Gain-of-Function Research of Concern

The Biosecurity Office of The Netherlands developed a Dual-Use Quick Scan toolkit to help researchers identify potential dual use issues and increase awareness of the related issues. The survey is based on 15 questions in the areas below and results are stored only on the user's computer:

- **High-risk biological agents**
- **Host range and tropism**
- **Virulence**
- **Stability**
- **Transmissibility**
- **Absorption and toxicokinetcs**
- **Drug resistance**
- **Population immunity**
- **Detection methodology and diagnostics**
- **Reconstruction**
- **Harmful effects**
- **Knowledge and technology**
- **Economic consequences**
- **Consequences for society**

The Public Health Agency of Canada offers an online course on Introduction to Dual-Use in Life Sciences Research

The Introductory Course on Dual-Use in Life Science Research has been developed to increase awareness on dual-use and to promote the responsible conduct of research among scientists, educators, institutional administrators, biological safety and security professionals, funding organizations, policy and decision makers, and the public.

A free online course on *Engineering Life: Synbio, Bioethics & Public Policy* also covers gain of function research. Content is presented in many forms, including not only reading and lectures, but also recorded and live interviews and discussions with scientists, ethicists and policy makers.

Why gain of function research matters

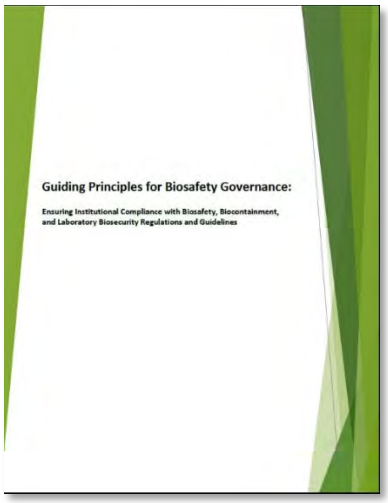
National Institutes of Health
Office of Science Policy

Dual Use Research of Concern

Tools for the Identification, Assessment, Management, and Responsible Communication of Dual Use Research of Concern

A Companion Guide to the United States Government Policies for Oversight of Life Sciences Dual Use Research of Concern

Guiding Principles for Biosafety Governance: Ensuring Institutional Compliance with Biosafety, Biocontainment, and Laboratory Biosecurity Regulations and Guidelines



Emerging Threats of Synthetic Biology and Biotechnology is an open access book that presents discussions on risks and mitigation strategies for these technologies including biosecurity, or the potential of synthetic biology technologies and processes to be deliberately misused for nefarious purposes. The book presents strategies to prevent, mitigate, and recover from 'dual-use concern' biosecurity challenges that may be raised by individuals, rogue states, or non-state actors. Several key topics are explored including opportunities to develop more coherent and scalable approaches to govern biosecurity from a laboratory perspective up to the international scale and strategies to prevent potential health and environmental hazards posed by deliberate misuse of synthetic biology without stifling innovation. Read more and download the book at: https://link.springer.com/book/10.1007/978-94-024-2086-9

Checking iGEM projects for safety issues is sort of like getting to do an annual synthetic biology horizon scan. We need to develop policies to govern the work that teams do, often sooner than local or international policies are available.

— **Tessa Alexanian, Safety and Security Program, iGEM**

Ethics and Codes of Conduct

The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists

"The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists focus on the prevention of intentional misuse of bioscience research, as per the articles and norms of the BWC, though the prevention of unintentional harm is equally important and closely intertwined. With the inclusion and implementation of elements from the Tianjin Biosecurity Guidelines for Codes of Conduct for scientists, institutions, professional organizations, and all scientists can increase biosecurity and minimize risks of misuse and harm".

"To promote a culture of responsibility and guard against such misuse, all scientists, research institutions, and governments are encouraged to incorporate elements from the Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists in their national and institutional practices, protocols, and regulations."

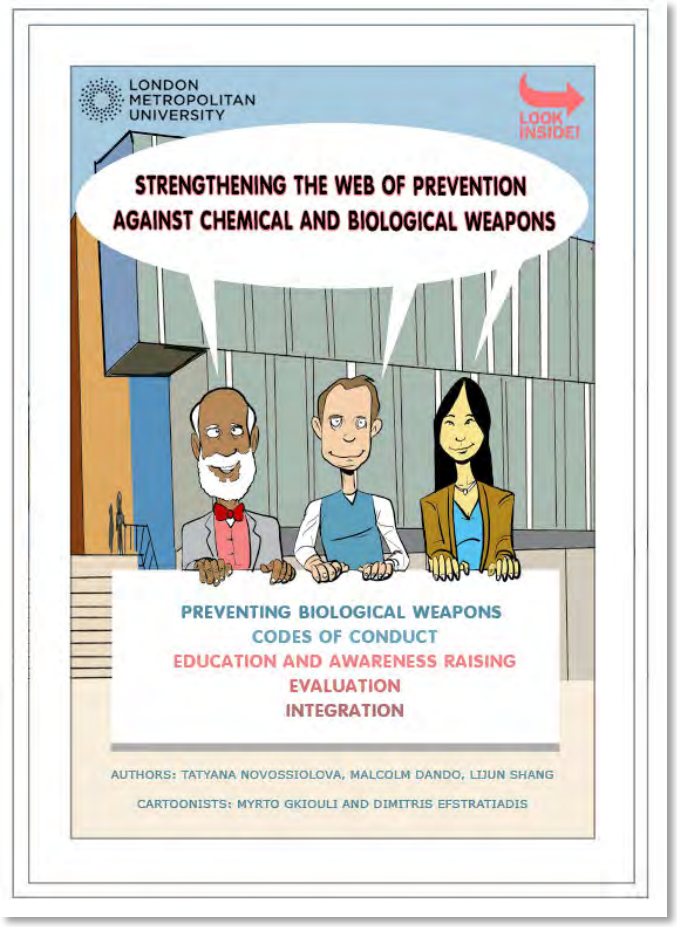
The Guidelines have been endorsed by the Inter-Academy Panel. China and Pakistan submitted a Working Paper at the Meeting of Experts on Review of developments in the field of science and technology related to the Convention Geneva, 1-2 September 2021 proposing that the Ninth Review Conference of States Parties of the Biological and Toxin Weapons Convention: "*a) Endorse the Tianjin Guidelines and encourage all stakeholders to voluntarily incorporate elements from the Guidelines in their practices, protocols, and regulations, and to disseminate the Guidelines, as appropriate; and (b) Task the intersessional process to exchange information, experiences and good practices about the dissemination of the Tianjin Guidelines and report the outcomes of these exchanges and dissemination to the Tenth Review Conference.* "

Excerpt from the Working Paper on Managing Biosafety and Biosecurity Risks: The Importance of Codes of Conduct and a BTWC Science and Technology Advisory Process submitted by Switzerland at the **Meeting of Experts on Review of developments in the field of science and technology related to the Convention Geneva, 1-2 September 2021:**

"Endorsement of the Tianjin Biosecurity Guidelines by States Parties at the Ninth Review Conference would further promote the impact and usefulness of such guidelines. The Tianjin Biosecurity Guidelines in the field of the life sciences would constructively complement the Hague Ethical Guidelines (https://bit.ly/3xV9TUF) in the field of chemistry and support the role of biorisk management standards like the recently established ISO 35001:2019 "Biorisk management for laboratories and other related organisations" (https://bit.ly/37nlhf7)."

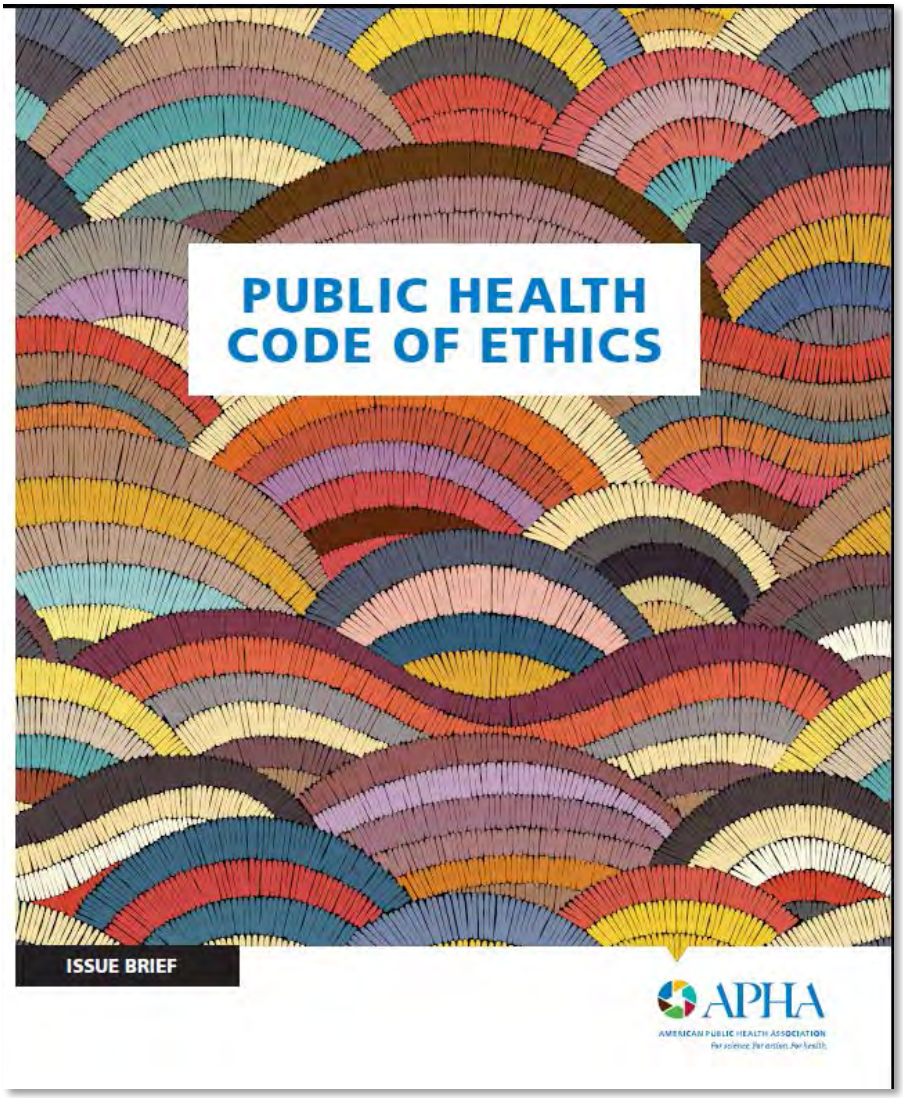
LONDON METROPOLITAN UNIVERSITY

An innovative way to educate the science and policy communities about the risks of scientific research being misused for nefarious purposes is through a series of cartoons. Each cartoon consists of two pages and successively addresses Preventing Biological Weapons, Codes of Conduct, Education and Awareness, Evaluation and Integration.



Learn about the history of biological and chemical warfare in the Poisons and Pestilence Podcast

In 2019, the American Public Health Association released the Public Health Code of Ethics to serve as an update of to the Principles of Ethical Practice of Public Health.



Public Health Ethics Training Materials

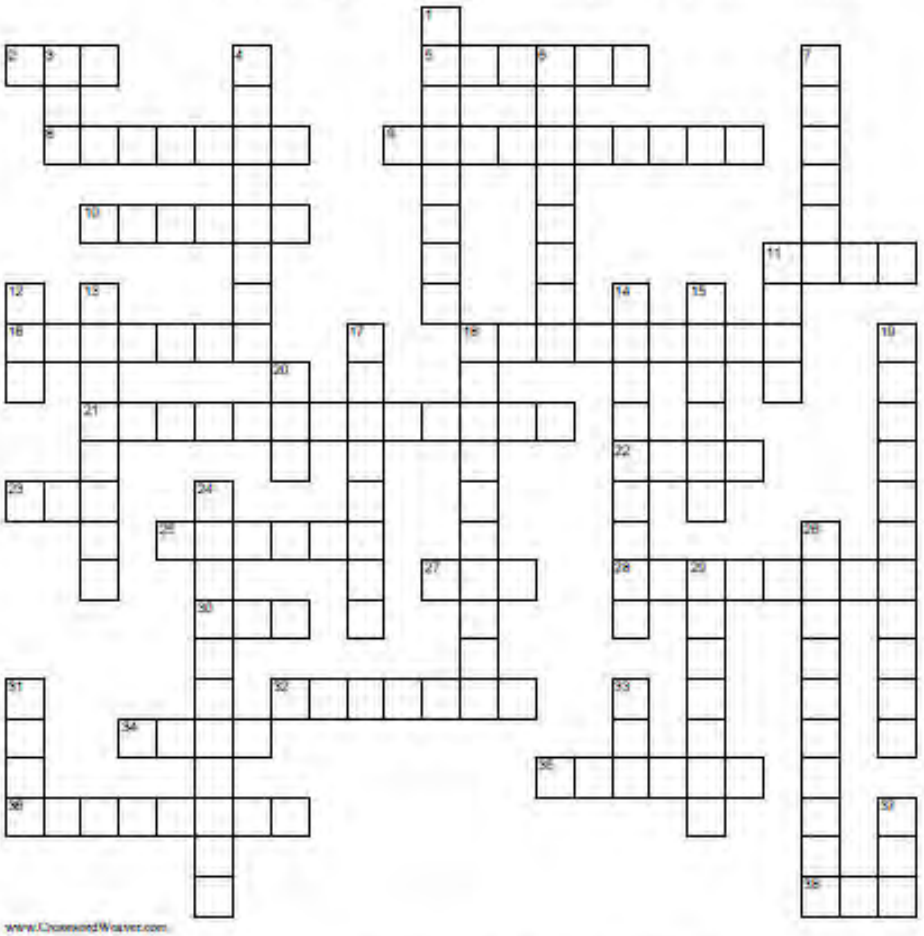
The Public Health Case Repository includes materials on Ensuring Biosafety/Biosecurity during a Public Health Emergency and a link to download free of charge the book *Public Health Ethics: Cases Spanning the Globe* (2016). DH Barrett, LW Ortmann, A Dawson, C Saenz, A Reis, G Bolan (Eds.). Springer Open

Culture is the collective understanding that everyone within the organization – no matter their role – shares common risks which require a specific set of rules, which when followed produces common rituals throughout the organization.

. — **Sean Kaufman, CEO and Founding Partner of Safer Behaviors, LLC**

http://www.MyCrosswords.com/327/DanaPerkins/BiosafetyAndBiosecurity-CultureSmart.html

Biosafety and Biosecurity - Culture Smart



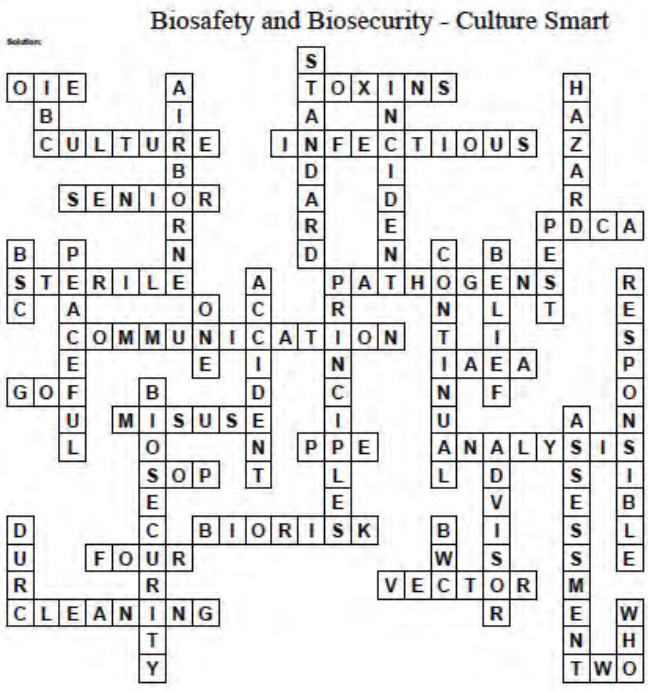
ACROSS

2 World Organization for Animal Health
6 Biological agents produced by living organisms, are unable to replicate, and do not result in communicable diseases
8 An assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations
9 A type of material or substance which contains biological agents capable of causing infection in either humans, animals or both
10 The WHO Laboratory Biosafety Manual 4th edition states that ____ management is ultimately responsible for the safety of all personnel, contractors and visitors to the organization
11 ISO 35001:2019 refers to this model and how it relates to its requirements
16 Completely free of all forms of living microorganisms, including spores and viruses
18 Microorganisms and other agents such as prions which can cause disease in humans, animals, or plants
21 The WHO Laboratory Biosafety Manual 4th edition mentions that this process builds trust between senior management, the institutional biosafety committee, the biosafety officer(s) and personnel.
22 The International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences was inspired by the work of this organization
23 Research that increases the ability of infectious agents to cause disease by enhancing its pathogenicity or by increasing its transmissibility among mammals by respiratory droplets.
26 The Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists state that scientists should guard against this when referring to science
27 Equipment equipment worn by a laboratorian to provide protection against infectious agents or toxins
28 Root cause ____ describes the range of approaches, tools, and techniques used to uncover causes of problems
30 The "cook book" of laboratory procedures
32 A combination of the likelihood and consequences of an event related to a specific biological hazard.
34 For a pathogen in this Risk Group, effective treatment and preventive measures are not usually available
35 Delivers genetic material into cells
36 Removal of gross contamination from a surface
38 A pathogen in this Risk Group can cause human or animal disease but is unlikely to be a serious hazard to laboratory personnel, the community, livestock or the environment

DOWN

1 35001:2019 is a _____
3 Institutional Biosafety Committee
4 Transmission of disease through infectious droplet nuclei suspended in air
6 An occurrence that has the potential to, or results in, the exposure of laboratorians to biological agents
7 Anything that has the potential to cause harm
11 An organism living and growing where their presence is undesired or unintentional.
12 Biological Safety Cabinet
13 The type of uses of biological science and technology encouraged and protected under ARticle X of the Biological Weapons Convention
14 ISO 35001:2019 promotes a culture that refers to this type of improvement
15 Acceptance or assent toward a proposition without the full intellectual knowledge required to guarantee its truth
17 It results in infection, illness, injury or contamination of the environment
18 The International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences calls this element of culture "___for Guiding Decisions and Behaviors"
19 Such a conduct involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research
20 This Risk Group has no or low individual and community risk
24 Measures designed to prevent loss, theft, or deliberate misuse of biological material, technology, or research-related information
25 The evaluation or estimation of organizational culture
29 According to ISO 35001:2019 this position is filled by a competent individual who provides advice, guidance, and assurance on biorisk management issues
31 Research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.
33 This Convention has 15 Articles
37 World Health Organization

Crossword Puzzle Solution



Women in Biosafety and Biosecurity

An organizational culture fostering responsible conduct of science is built on a foundation of diversity, equity, and inclusion, with everyone part of the team, empowered in their daily work and career development, and recognized for their unique contributions. Check out the resources below.

The International Federation of Biosafety Associations' Equity-Focused Coordinating Committee (IFBA ECC) serves to identify and implement objectives aimed towards sustainable equitable practice within global biosafety and biosecurity, and intends to promote a global professional culture of accountability and inclusivity. Read more at: https://internationalbiosafety.org/program-activities/ifba-equity-focused-coordinating-committee/

– Diversity, Equity, and Inclusion in Global Biosafety and Biosecurity

GHSA APP3 Community Corner Newsletter

Working Paper on Enhancing Gender Equality and Women's Empowerment as an Integral Part of the Institutional Strengthening of the Biological Weapons Convention (BWC), submitted by Panama to the Meeting of Experts on Institutional strengthening of the Convention Geneva, 8 September 2021:

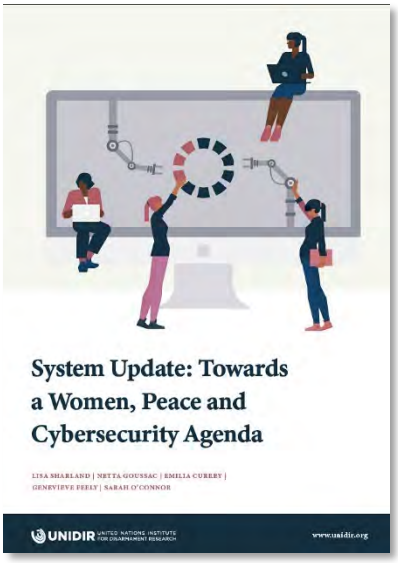
> *"In order to promote a real change, States Parties need to integrate gender perspectives into BWC meeting discussions and promote gender equality in the BWC's machinery and processes in a sustainable manner… The Review Conference constitutes the only authority to make substantive and procedural decisions, and the upcoming Ninth Review Conference will provide the opportunity for States Parties to make recommendations in this regard."*

G7 Health Ministers' Communique, 4 June 2021:

> *"The pandemic has particularly affected women and girls in a number of ways because of existing and persistent gender inequalities and unequal power relationships in societies: it has seen an intensification of gender based violence (GBV), including violence against women and girls globally that we all need to act to tackle; particular impacts of reduced access to services; as well as disproportionate impacts on women as informal, including unpaid, caregivers and income providers for their families. Women also constitute the majority of the health and social care workforce, particularly in nursing and midwifery. We should maintain a strong focus on gender equality and the empowerment of all women and girls to achieve the goals of the UN Agenda 2030 and Sustainable Development Goal 5 as we continue to combat this pandemic and through our recovery, promoting their important role as agents of change and leaders in our societies, including in the health sector."*

UNIDIR
UNITED NATIONS INSTITUTE FOR DISARMAMENT RESEARCH

Gender & Disarmament Resource Pack



Systems Update: Towards a Women, Peace, and Cybersecurity Agenda

For more resources, visit the UNIDIR Gender and Disarmament Hub at:
https://www.unidir.org/gender

CYBERSECURITY & INFRASTRUCTURE SECURITY AGENCY

Cybersecurity Resources for COVID-19

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1. **Perkins D, Danskin K, Rowe AE, Livinski AA. 2018. The Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences: A Comprehensive Literature Review, in Applied Biosafety Journal, online at: http://journals.sagepub.com/doi/abs/10.1177/1535676018778538**

2. **International Atomic Energy Agency. Nuclear Security Culture: Implementing Guide. Vienna, Austria: International Atomic Energy Agency; 2008. https://www-pub.iaea.org/MTCD/publications/PDF/Pub1347_web.pdf**

3. **International Atomic Energy Agency. Nuclear Safety and Security Programme: Safety Culture. Vienna, Austria: International Atomic Energy Agency; 2015. https://www-ns.iaea.org/downloads/ni/safety-culture/safety-culture-leaflet.pdf**

4. **Guiding Principles for Biosafety Governance: Ensuring Institutional Compliance with Biosafety, Biocontainment, and Laboratory Biosecurity Regulations and Guidelines: https://www.phe.gov/s3/Documents/FESAP-guiding-principles.pdf**

Contact Information

For more information please contact the Co-Chairs of the International Working Group on Strengthening the Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences (IWG):

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