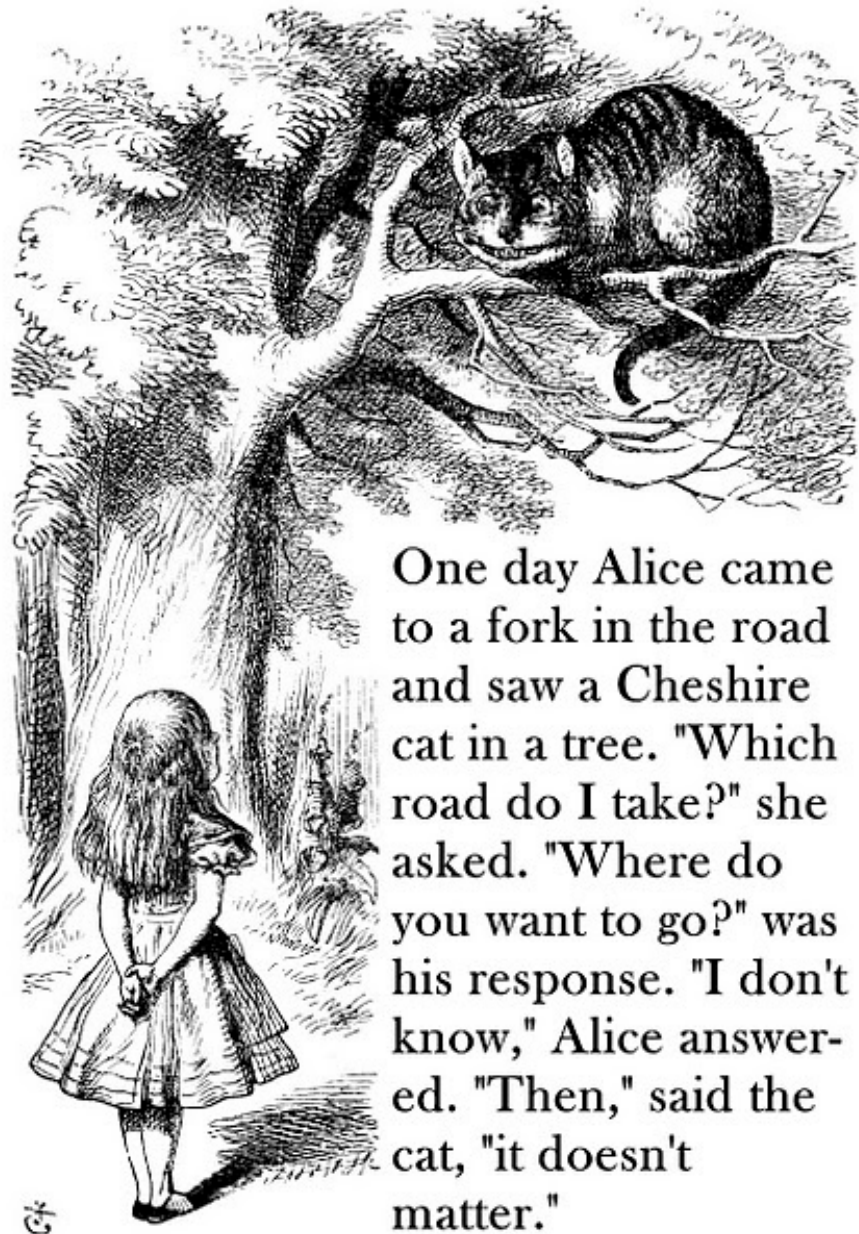


Responsibilities of the Biosafety Professional and Institution



Debra L. Hunt, DrPH, CBSP
Director, Biological Safety; Responsible Official (Select Agents)
Assistant Professor
Duke University / Duke Medicine
Durham, NC





One day Alice came to a fork in the road and saw a Cheshire cat in a tree. "Which road do I take?" she asked. "Where do you want to go?" was his response. "I don't know," Alice answered. "Then," said the cat, "it doesn't matter."

G.K.



Where Do *You* Want to Go?

- What responsibility does the Institution play in Biosafety?
- What is your role as a Biological Safety Professional?
 - Definitions of Biological Safety Professionals
- Where do you NEED to go?
- How do you get there?
- Where can you find HELP?



Goals of a Biosafety Program

- ***To protect employees and their families*** from acquiring work-associated infectious diseases or harm from biological agents/toxins
- ***To prevent contamination of the environment*** and promote environmental quality
- ***To comply with all National, International and Local guidelines and regulations*** for the use of potentially hazardous and/or regulated biological materials



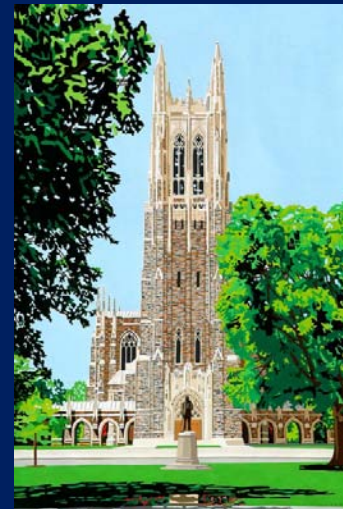
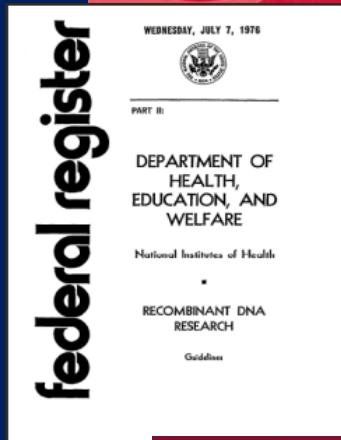
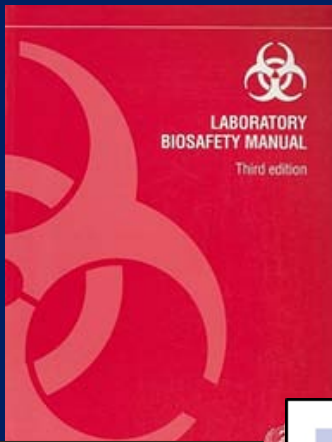
Institutional Responsibility

Develop a *“Culture of Safety”*

Safety is a shared responsibility (shared accountability) among the institution and the workers, and is built upon an atmosphere of trust



References provide a starting point to develop Institutional performance-oriented and risk-based systems



Duke University



NIH Guidelines – Section IV

■ Roles and Responsibilities

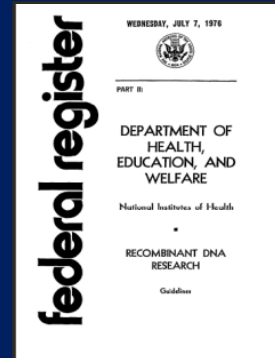
- *Institution*

- *Institutional Biosafety Committee (IBC)*

- **Biological Safety Officer (BSO)**

- **Principal Investigator (PI)**

- **NIH**



International Standards

CEN

CWA 15793

WORKSHOP

February 2008

AGREEMENT

ICS 07.100.01

English version

Laboratory biorisk management standard

This CEN Workshop Agreement has been drafted and approved by a Workshop of representatives of interested parties, the constitution of which is indicated in the foreword of this Workshop Agreement.

The formal process followed by the Workshop in the development of this Workshop Agreement has been endorsed by the National Members of CEN but neither the National Members of CEN nor the CEN Management Centre can be held accountable for the technical content of this CEN Workshop Agreement or possible conflicts with standards or legislation.

This CEN Workshop Agreement can in no way be held as being an official standard developed by CEN and its Members.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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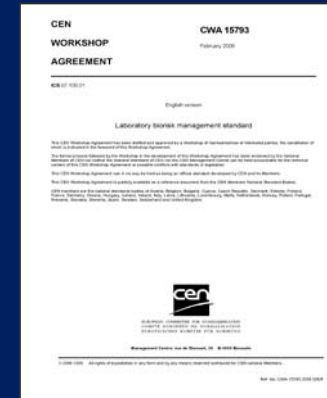
Ref. No.: CWA 15793:2008 D/E/F

International Laboratory Biorisk Management Standard: CWA 15793

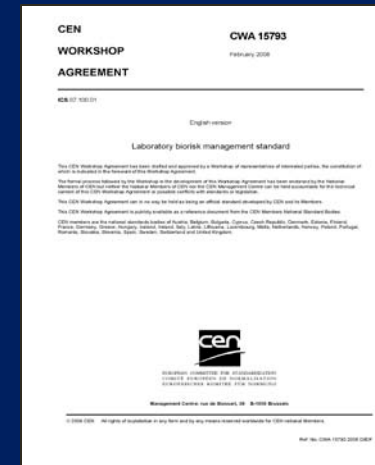


CEN Workshop Agreement: Biosafety Program (Biorisk Management System)

- Institutional oversight & acceptance
 - President, CEO, CFO
- Biosafety Committee (e.g., IBC)
 - peer review, adopt/establish policies
- Biosafety Office / Biosafety Professional
 - inform, administer program, assist
- Faculty, staff, students & visitors
 - merge biosafety into work



Institutional Responsibility: CEN Workshop Agreement



- **4.2.1 Biorisk management policy**

The organization's top management shall develop, authorize, and sign a policy concerning the management of laboratory biorisk (laboratory biosafety and laboratory biosecurity).

The policy shall be appropriate to the nature and scale of the risk associated with the facility and associated activities.



Where Would You Expect a Biological Safety Program?



- Research Laboratories:
 - Universities
 - Pharmaceuticals
 - Government Agencies
- Health Care (Infection Control):
 - Hospitals
 - Clinics
 - Clinical Laboratories
- Manufacturing
- Other



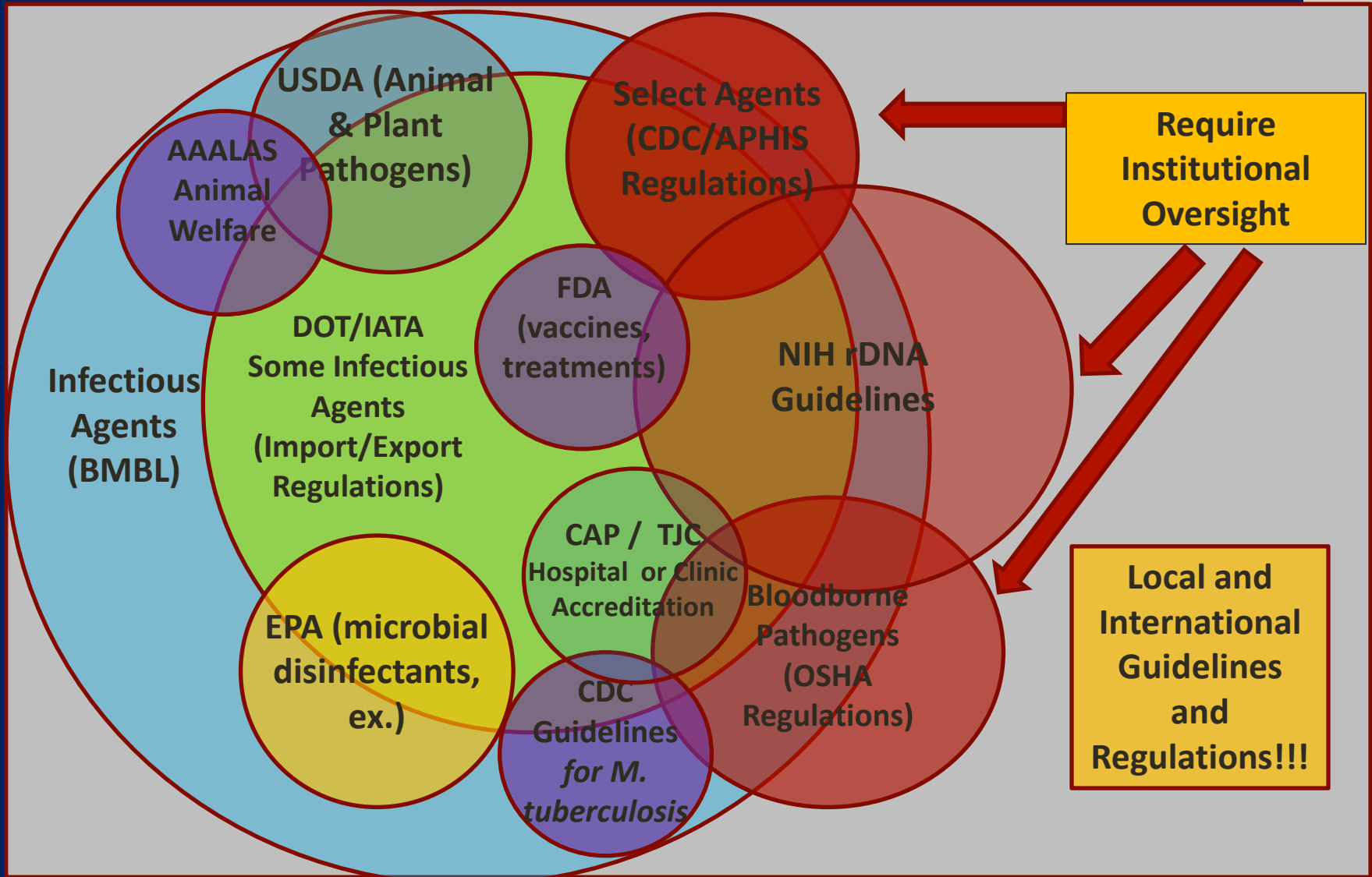


Understand the Scope of Your Institution

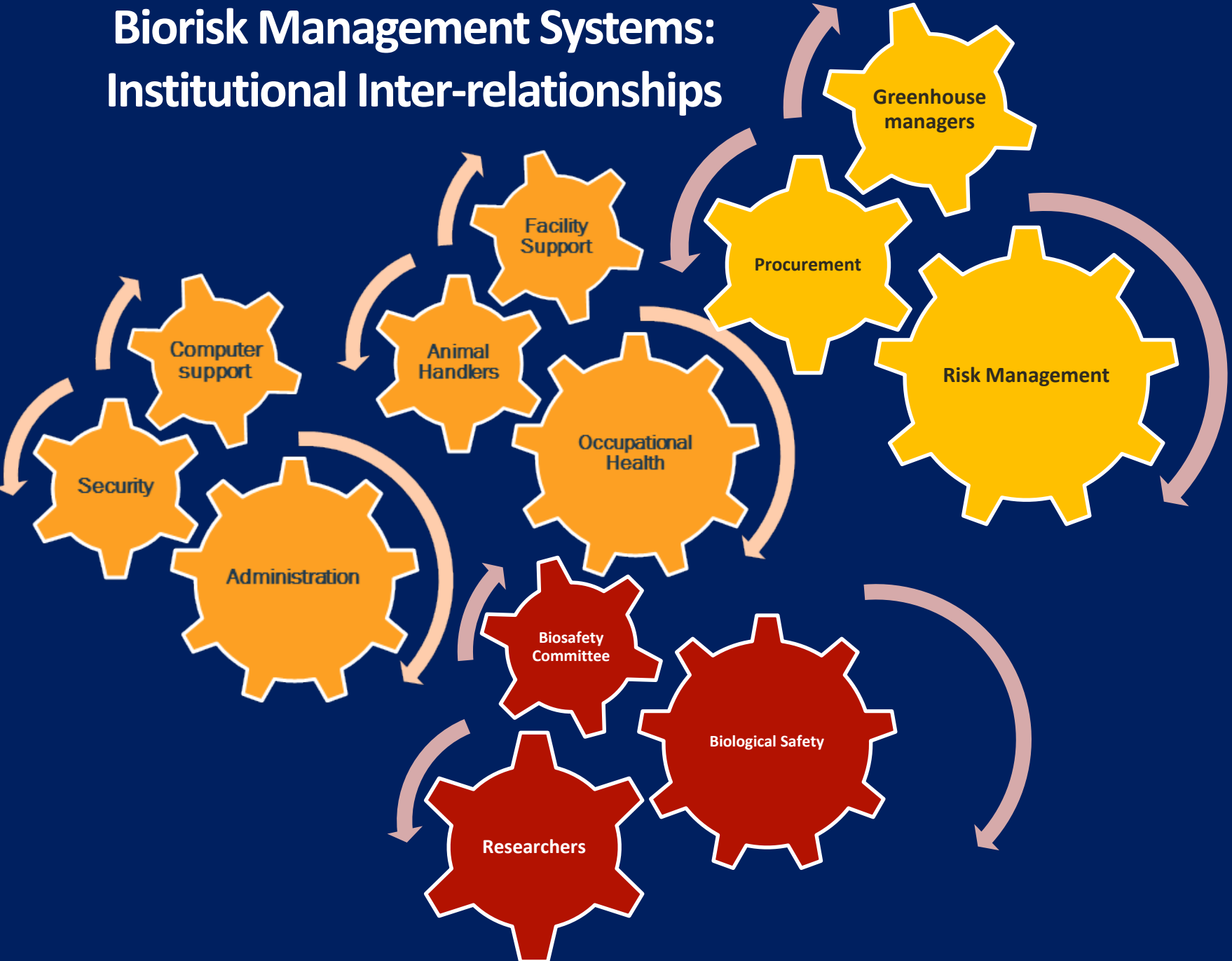
- **How Big is Your Plate????**
 - **Type of Work:**
 - Basic / Biomedical Research
 - Animal (lab/ag)
 - Plant (lab/greenhouse/field)
 - Medical / Patient Care
 - Industrial / Manufacturing
 - **Small vs Large:**
 - Multi-system
 - Local / National / International scope?
 - **Security Needs:**
 - Select Agents
 - High containment



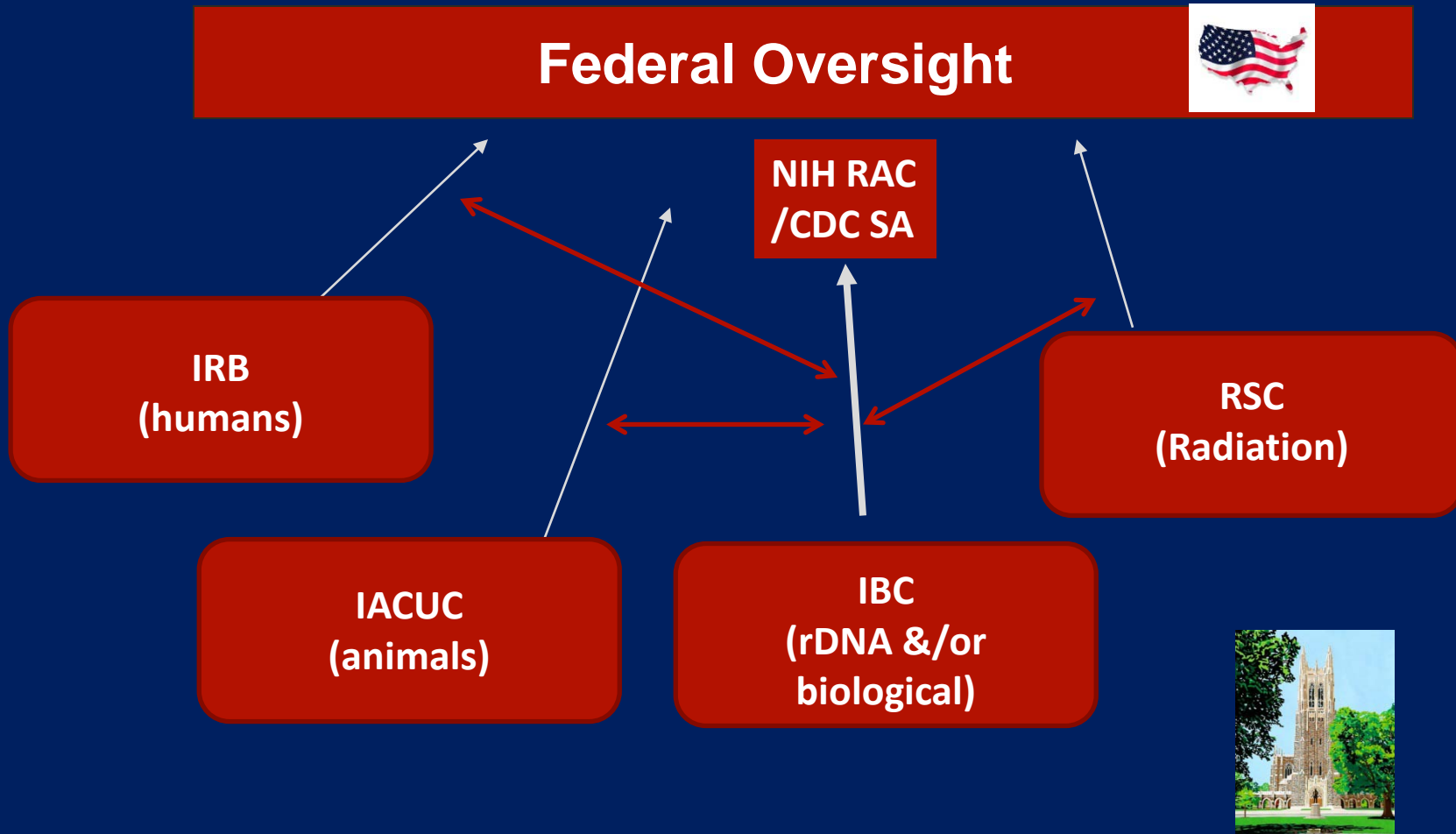
Seek Relevant US Federal Standards for Biological Research/Issues in Your Institution



Biorisk Management Systems: Institutional Inter-relationships



Institutional Research Oversight Committees



What is your role as a Biosafety Professional?





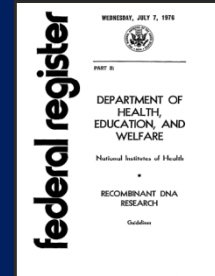
What is a Biosafety Professional?

A biosafety professional *develops and participates* in programs to *promote* safe microbiological practices, procedures, and proper use of containment equipment and facilities; *stimulates* responsible activities among workers; and *provides advice* on laboratory design.



“Biological Safety Officer” Duties

NIH rDNA Guidelines



- Periodic inspections to **ensure** that laboratory standards are rigorously followed;
- **Report** to the IBC and the institution any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses
- **Develop** emergency plans for handling accidental spills / personnel contamination and for investigating lab accidents involving rDNA research;
- **Provide advice** on laboratory security;
- **Provide technical advice** to PIs and the IBC on research safety procedures.



Biorisk Management (CEN Agreement): Responsibilities of the BSP



- Biological Safety Professional (“Biorisk Management Advisor”, “Biosafety Officer”):
 - **Advise** on biorisk management issues within the organization; have **delegated authority** to intervene, if necessary
 - **Verify** that biorisks have been addressed
 - **Review and advise** on investigations of accidents/incidents/exposures
 - **Communicate** current biorisk issues with scientists and other personnel as needed
 - **Develop** biosafety training activities
 - **Ensure compliance** with all biological regulations/guidelines relevant to the institution



National Registry of Certified Microbiologists, ASM

www.absa.org/career/CBSP

Examination Content

National Registry of Certified Microbiologists
SM: Biological Safety Microbiology

*The National Registry of Certified Microbiologists
©2009 American Society for Microbiology*



A list of the tasks tested on the exam is provided below. Questions are classified first by domain and then by task. The examination will have at least one question from each task. The number of questions from each domain is listed below the domain name in the task list.

DISINFECTION, DECONTAMINATION, STERILIZATION (10 questions)

1. Understand the difference between sterilization, decontamination, and disinfection and the applicability and means of monitoring each.
2. Demonstrate knowledge of use, applicability, and potential hazards (explosive, flammable, corrosive, carcinogenic, and irritating) associated with various disinfectants and sterilants.
3. Understand how to use chemicals, steam, dry heat, irradiation, filtration, ultraviolet (UV) sources, gases, or other agents to kill or inactivate microorganisms.

WORK PRACTICES AND PROCEDURES (26 questions)

4. Understand the application of sterile (aseptic) techniques.
5. Develop, evaluate, and document exposure control procedures for biohazardous agents and materials.
6. Develop procedures and practices to prevent release of infectious aerosols from equipment.
7. Perform biosafety audit of work practices and procedures associated with large-scale operations.
8. Understand and apply monitoring techniques and equipment to determine effectiveness of exposure control measures and to investigate environmental problems.
9. Understand use and disposal of sharps.
10. Select and understand use of personal protective equipment.
11. Select and understand use of respiratory equipment.
12. Develop and implement procedures for managing biohazardous spills and releases.
13. Assure documentation of worker exposure to biohazardous materials and preparation of an incident report.
14. Develop comprehensive emergency response plan for biohazard areas.

RISK ASSESSMENT AND HAZARD IDENTIFICATION — INFECTIOUS AGENTS AND RECOMBINANT DNA (33 questions)

15. Demonstrate knowledge of personal risk factors associated with microbial exposure.
16. Assess the risk of occupational exposure and infection associated with handling infectious agents.
17. Demonstrate familiarity with routes of exposure, modes of transmission, and other criteria that determine the hazard category of a microorganism.
18. Assess the risk to the community from various work environments where infectious agents or sensitizing materials may be present.
19. Demonstrate understanding of microbial toxins and their potential to cause work-related illness.
20. Demonstrate the ability to recognize the characteristics of bacteria, viruses, fungi, and parasites.
21. Understand the hazard of exposure of service personnel to biological materials.
22. Understand factors that may affect susceptibility, resistance, or consequences of infection.
23. Understand the difference between risk of infection and consequences of infection.
24. Understand the risk associated with biological aerosols in the workplace, such as ventilation, indoor air quality, recirculation, and cooling towers.
25. Understand the risk associated with point source release of biological aerosols in the workplace, such as from homogenizers, cell scifiers, centrifuges, fermenters, and lasers.
26. Understand the risks associated with recombinant DNA technology.
27. Demonstrate knowledge of unique biosafety conditions associated with naturally or experimentally infected animals, including nonhuman primates.



SM: Biological Safety Microbiology “Domains” Certification Exam for CBSP

- Disinfection, Decontamination, Sterilization
- Risk Assessment and Hazard Identification-
Infectious Agents and Recombinant DNA
- Work Practices and Procedures
- Regulatory Aspects, Standards, and Guidelines
- Program Management and Development
- Equipment Operation and Certification
- Facility Design



SM: Biological Safety Microbiology

“Tasks”

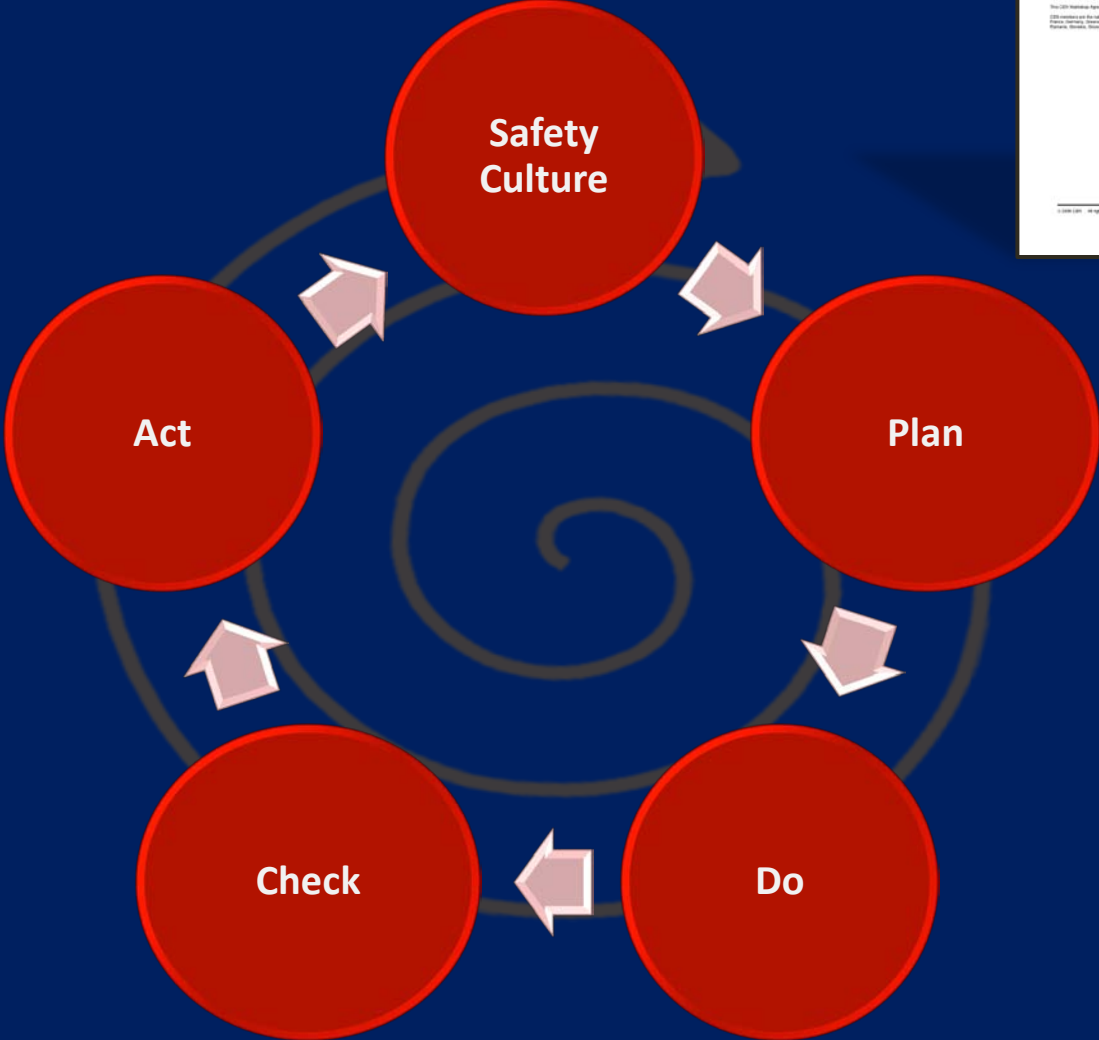
Certification Exam for CBSP

DISINFECTION, DECONTAMINATION, STERILIZATION **(10 questions)**

1. Understand the difference between sterilization, decontamination, and disinfection and the applicability and means of monitoring each.
2. Demonstrate knowledge of use, applicability, and potential hazards (explosive, flammable, corrosive, carcinogenic, and irritating) associated with various disinfectants and sterilants.
3. Understand how to use chemicals, steam, dry heat, irradiation, filtration, ultraviolet (UV) sources, gases, or other agents to kill or inactivate microorganisms.



How do you DO this?



Planning for Biorisk Management

“PLAN”



- Identify the Scope of the Institution
- Identify those Responsible for the Plan
- Identify methods to conduct Risk Assessments (RAs)
- Conduct Risk Assessments
 - Use previous RA results
 - Analyze risk of new hazards
 - MSDSs for infectious agents (Canadian website)
 - Lab-acquired or health-care infections published
 - Current guidelines/regulations
 - Procedures involved with agents
 - Facility appropriateness
 - Identify Security vulnerabilities



Implementing Biorisk Management

“DO”



- **Develop Risk Controls based on the RAs**
- **Develop an Institutional Biosafety Plan (i.e., Manual, Standard Operating Procedures)**
- **Train all relevant personnel based on SOPs, institutional policies**
- **Develop expedient communication methods**
- **Develop and implement Emergency Procedures**



Evaluation/Monitoring of Biorisk Management

“CHECK”



- Conduct audits based on a defined schedule, i.e., annually
- Use monitoring tools to collect safety-related data
 - Training records, accident reports, audit results, etc.
- Develop an Internal Auditing Process of Safety Programs (Office of Compliance, Risk Management, etc.)



Updating and Improving Biorisk Management

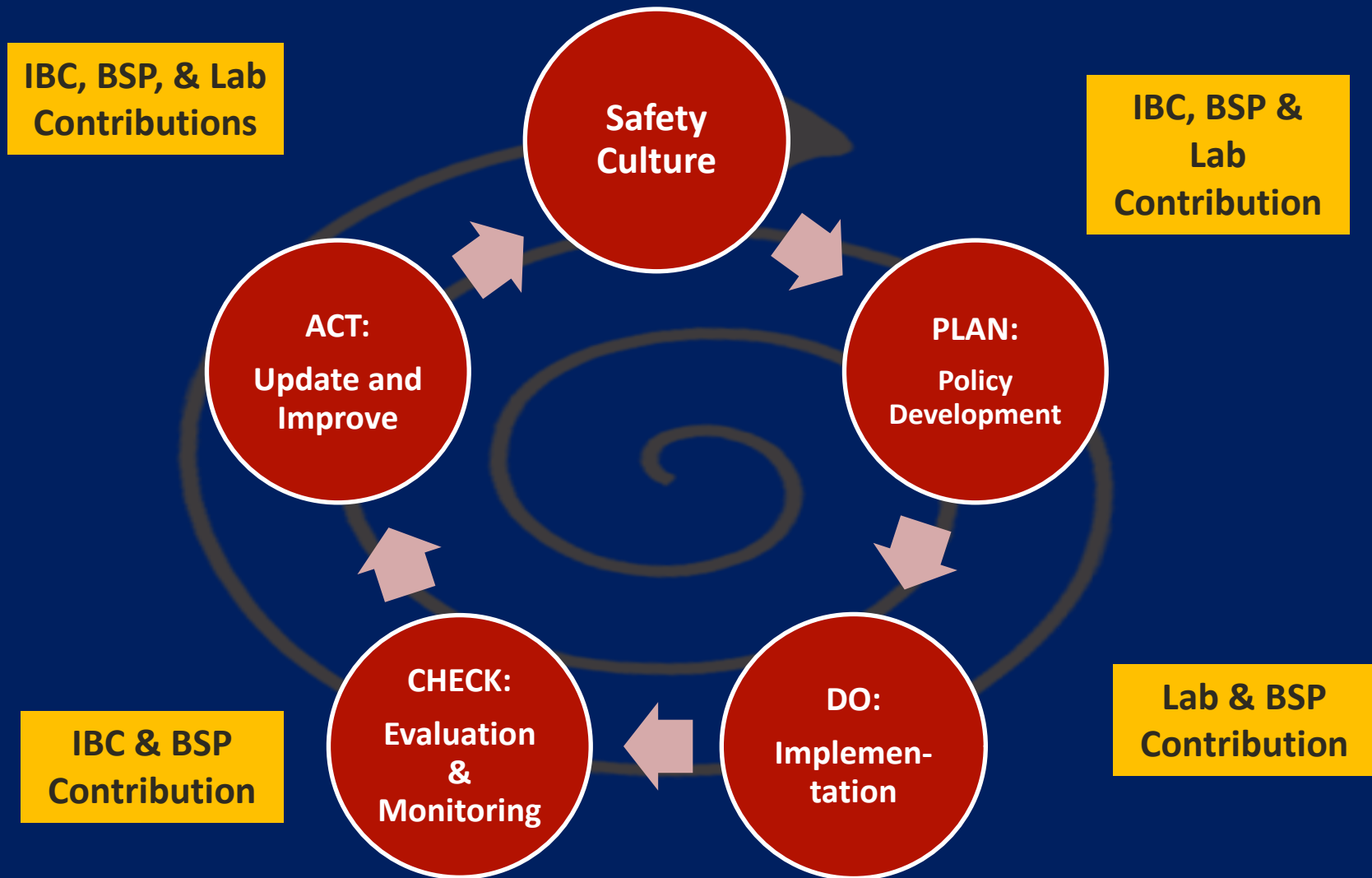
“ACT”



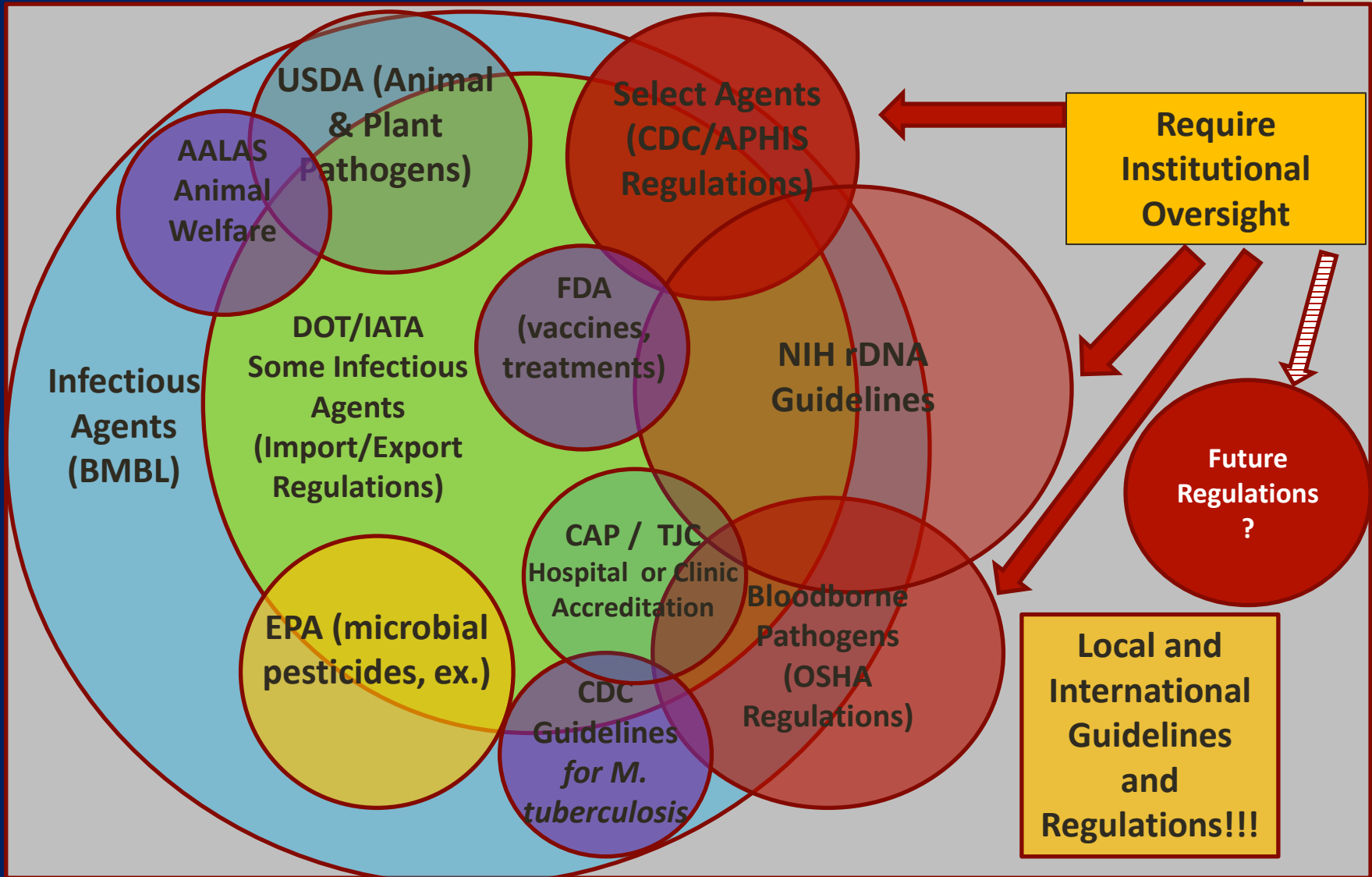
- Review Monitoring Data and implement changes for improvement
- Develop Performance Improvement Projects
- Support Personnel Development (education) and External Networking
- Provide Methods for Institutional Employee Feedback
 - Those in the workforce are able to communicate problems and/or offer improvement suggestions



Sustainability of a Biorisk Management System



Seek Relevant US Federal Standards for Biological Research/Issues in Your Institution



There is help!!



Conferences

Affiliates

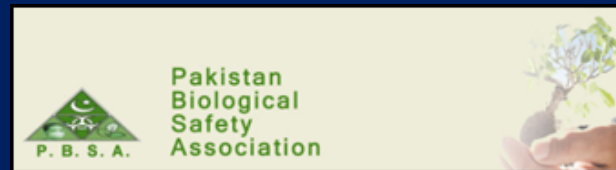
Workshops

Listserve (Biosafety,

Occup. Env Med)

Networking

Webinars



ABSAs - Biosafety Links

have you read... **Anthology of Biosafety X. Animal Biosafety** **Register Now!** **ABSA Orlando** October 19-24 55th Annual Biological Safety Conference

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Biosafety Links

Agencies
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 State Government Web Sites
 International
 Pertinent Government Agency Alerts
 Rumor Management
 ABSA/OSHA Fact Sheets

Agencies
 Department of Health and Human Services
 Center for Disease Control and Prevention
 NIH Office of Biotechnology Activities (OBA)
 Food and Drug Administration (FDA)
 National Institute for Occupational Safety and Health (NIOSH)
 Department of Agriculture (USDA)
 Animal Plant Health Inspection Service (APHIS)
 U.S. Department of Transportation (DOT)
 US Environmental Protection Agency (EPA)

General Regulatory Agency Links
 OSHA Home Page
<http://www.osha.gov/>
 Environmental Protection Agency Home Page
<http://www.epa.gov/>
 Nuclear Regulatory Commission Home Page
<http://www.nrc.gov/>
 Food and Drug Administration Home Page
<http://www.fda.gov/>
 Research and Special Projects Administration (RSPA)
<http://www.rita.dot.gov/>
 Federal Register Search Engine
<http://www.gpoaccess.gov/fr/search.html>
 Code of Federal Regulations Search Engine
<http://www.gpoaccess.gov/cfr/index.html>

Government and Other Technical Agencies
 These are agencies with references to EHS in general and biological safety in particular.
 WHO Home Page
<http://www.who.int/>
 Belgian Biosafety Server (This site has tons of references for all biosafety issues)
<http://www.biosafety.be/>

<http://www.absa.org/resbslinks.html>[9/4/2012 1:56:31 PM]

Rules/Regulations/Guidelines
 Import and Export Permits for Pathogens and Infectious Agents
 Biosafety
 OSHA/NIOSH
 ORDA
 NIH rDNA Guidelines
 CDC
 International Air Transport Association
 National Sanitation Foundation Internal Home Page

Biosecurity
 Bioterrorism
 State Bioterrorism Bills/Laws/Regulations
 ABSA - Biosafety Links
 Health and Safety Executive UK
<http://www.hse.gov.uk/bsehome.htm>
 NIOSH Home Page
<http://www.cdc.gov/niosh/homepage.html>
 ORDA Home Page
<http://www4.od.nih.gov/oba/>
 NIH rDNA Guidelines (new format)
http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
 CDC Home Page
<http://www.cdc.gov/>
 International Air Transport Association
http://www.iata.org/whatwedo/cargo/dangerous_goods/Pages/index.aspx
 National Sanitation Foundation Internal Home Page
<http://www.nsf.org/>

State Government Web Sites
 50 State's Workman's Compensation Web Sites
<http://www.ic.ac.gov/ncic/pages/all50.htm>
 50 State's Regulatory Agencies Web Sites
<http://www.clay.net/statag.html>
 State and Local Government on the Net
<http://www.piperinfo.com/state/index.cfm>

International
 CEN Laboratory Biorisk Management Standard
 Belgian Biosafety Server (European Biosafety Topics) >
 Office of Biosafety, LCDC (Canada) >
 OHASIS, Office of Health and Safety Information Systems (CDC) >
 Select Agent Website >
 International Veterinary Biosafety Workgroup >
 European Biosafety Association >

Rules / Regulations / Guidelines
 NAFPO APPROVED RSPM 22 "Guidelines for Construction and Operation of a Containment Facility for Insect and Mite Biological Control Agents"

Swine Influenza A (H1N1) Virus Biosafety Guidelines for Laboratory Workers
 HHS security guidelines for synthetic DNA manufacturers
 Bloodborne Pathogens
 29 CFR 1910.1030 (OSHA)
 Bloodborne Pathogens Compliance Directive (PDF)
 Hazardous Materials Regulations (49 CFR 100-185)
 HazMat Safety
 Select Agent Final Rule
 Department of Health and Human Services (DHHS) (PDF 247KB) >
 CDC Correspondence to ABSA regarding Final Rule (MSWord 48k) >
 Select Agent Final Rule
 US Department of Agriculture (USDA) (PDF 333KB) >
 Hazardous Waste (EPA)
 NIH Guidelines on Recombinant DNA Molecules (PDF) >
 April 2002
 IBC Resources
 Microbiology (EPA)
 IAQ (EPA)
 Needlestick Standard (OSHA)

<http://www.absa.org/resbslinks.html>[9/4/2012 1:56:31 PM]

Principles of Good Mice
 Sheet (PDF 1359KB)

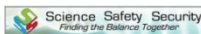
Principles of Biosafety
 For best results print face legal-sized paper with a

Biosafety Guidelines

Guidelines for Human and Animal Laboratories
 concerned, Biosafety, Morbidity and Mortality (MMWR), January 15, 2011

Guidelines for Competency
 Morbidity and Mortality (MMWR), January 15, 2011
 CDC/NIH: Biosafety Manual, 5th Edition, 2009
<http://www.absa.org/niatcg.html>[9/4/2012 1:54:02 PM]

International Biosafety Working Group (IBWG)



SS: Science, Safety, and Security >
 Biosafety, Biosecurity, Biocontainment, and Biorisk management

ABSAs - Legislative Issues

have you read... **Anthology of Biosafety IX** Exploring the Performance Envelope for BSL-3 and BSL-4 Labs **Register Now!** **Effective Biosafety Training** August 21 and September 11, 2012 **ABSA Webinar**

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Legislative Issues

ABSA Domestic and Global Biosafety Training Support Letter(PDF 75KB)
 Open Letter from the **ABSA Legislative Committee**(PDF 100KB)

Select Agent
 S.485(PDF 100KB) To reauthorize the Select Agent Program by amending the Public Health Service Act and the Agricultural Bioterrorism Protection Act of 2002 and to improve oversight of high containment laboratories.
 H. R. 1225(PDF 180KB) To reauthorize the Select Agent Program by amending the Public Health Service Act and the Agricultural Bioterrorism Protection Act of 2002 and to improve oversight of high containment laboratories.

Center for Biosecurity of the University of Pittsburgh Medical Center (UPMC) letter of support for H.R. 6671, The Select Agent Program and Biosafety Improvement Act of 2008(PDF 80KB)
 The National Science Advisory Board for Biosecurity (NSABB) report on **Enhancing Personnel Reliability Among Individuals with Access to Select Agents**(PDF 364KB)

WMD
 The World at Risk: The Report of the Commission on the Prevention of WMD Proliferation and Terrorism(PDF 2MB)
 August 11, 2009 - **WMD Prevention and Preparedness Act**(PDF 193KB)
 Section by Section Description (MS Word 43KB)
 One Page Description (MS Word 40KB)

BioSecurity
 Report of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight(PDF 1.1MB)
 GAO - HIGH-CONTAINMENT LABORATORIES: National Strategy for Oversight Is Needed(PDF 2.1MB)
 Executive Order 13486(PDF 4KB) of January 9, 2009 Strengthening Laboratory Biosecurity in the United States
 Oversight of High-Containment Biological Laboratories: Issues for Congress(PDF 356KB)
 Biological Safety Training Programs as a Component of Personnel Reliability (PDF 300KB)

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 Phone: 1-866-425-1385 (toll free) or 847-949-1517 Fax: 847-566-4580 E-mail: info@absa.org

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trust
yourself.
you know
more than you
think you do.

(dr. spock)

