External Briefing Document

Taking a Second Look at BSL-2

The Role of BSL-2 Training in Biosecurity

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Overview

- Discuss training gaps created by current approach to biosecurity training
- Discuss a methodology for competency training and proficiency testing in biosecurity
- Demonstrate implementation of suggested methodology using a biosafety training example

Definition

- Biosecurity
  - Measures to address the risk that biological materials may be misused or accidentally or intentionally released.
- Laboratory Biosecurity
  - Measures taken inside a facility containing or working with biological hazards to assure that working practices defend against misuse, accidental or intentional release of a biological hazard.

Laboratory Biorisk Management Standard Training Requirement

- The organization shall ensure that personnel that have responsibilities and/or perform tasks that may impact biorisk management in the workplace are competent to do so…The organization shall define required competency levels ….

AAAS Recommendations

- All BSL-3 and BSL-4 biosafety training should incorporate proficiency (i.e., competency-based) training and testing.
- Programs should include performance-based training standards

Elements Influencing Biosecurity Risk

Training Topics	Type of Threat	Legislative Response	Target BSL	Biosecurity Training Response (BSL)
Biological Material	Personnel and External	Legal	2-4	3-4
Facility and Engineering	Personnel and External	Guidelines	2-4	3-4
Security/ Access Control	Personnel and External	Guidelines	2-4	3-4
Management	Personnel	Guidelines	2-4	3-4
Working Procedures	Personnel	BBP and Guidelines	2-4	2-4

- Targeting legislation and training to BSL-3 and BSL-4 leaves large gaps in personnel training in a biosecurity program.

Safety and Security are a Numbers Game
RISK = FREQUENCY × SEVERITY

- Greatest and Least Facts about Biohazards in BSL-2 Laboratories
  - Largest number of laboratories
  - Largest population of people working with organisms
  - Largest number of organisms including many Select Agent GMOs
  - Least stringent training requirements
  - None - no training programs in biosecurity for BSL-2 laboratories – the training laboratories for BSL-3/4 personnel.

Non Compliance in a Regulated Setting

- Clinical and Emergency Response
  - Outbreaks and Emerging Infectious Disease

    15%-40% transmission to health care workers

    40% positive tuberculin skin test vs. 5% US population

- Non Compliance
  - Compliance with control methods among health care workers is the major obstacle to preventing transmission.

    50% non compliance among health workers with hand washing

    23% of inner city health care workers are not vaccinated for HBV

Sepkowitz, Ann Int Med, Part I and II 1996

Historical Analysis of Laboratory Acquired Infections

1880's	1930-1978	1979-2004	2000-2007
Typhoid	*Brucella spp.*	*Brucella spp.*	*Brucella spp.*
Tetanus	*Coxiella burnetii*	*Coxiella burnetii*	Hepatitis virus
Cholera	Hepatitis B virus	Hepatitis B virus	Hantavirus
Brucella	Herpes B virus	Arbovirus	*B. mallei*
Glanders	*F. tularensis*	Hantavirus	Sabia virus
Diphtheria	*M. Tuberculosis*	*M. Tuberculosis*	SARS virus
	Coccidiodes immitis	*Salmonella spp.*	West Nile Virus
	VEE Virus	*Shigella spp.*	*E. coli* 0157:H7
	Chlamydia psittaci	*N. meningitidis*	*S. aureus*
			Vacinia Virus
			VEE Virus
			AI virus
			Ebola virus

Frontline in the War on Terrorism Bioterrorism in Clinical Laboratories

- First Response
  - First responders to a terrorist attack
    - All clinical labs operate under exemption to the Select Agent Rule
  - Vaccination of health care workers with Small Pox vaccine
- 1990's Case Report
  - Infection of 6 dental patients by HIV + dentist

Problem and Solution

- Problem
  - Current practice of connecting biosecurity program development to BSL-3 – BSL-4 biosafety levels leaves gaps in training and hinders the development of proficiency indicators in biosecurity.
- Challenge
  - Define individual proficiency in biosecurity and measure success in a biosecurity program.
- Suggested Solution
  - Define biosecurity needs by working practices using standardized documents assigning proficiency indicators to the biosecurity task.

Summary and Conclusion

- BSL-2 laboratories are the foundation of a strong biosecurity program.
  - While not as great as the risks posed by biological material handled at BSL-3/4, biological materials handled in BSL-2 laboratories pose significant risks to health, safety and to the environment.
  - Laboratories following BSL-2 criteria account for the majority of research and clinical labs; however, working practices in many of these laboratories are not standardized or well-documented.
  - Establishing guidelines and standards in biosecurity for BSL-2 laboratories will build proficiency in the biosecurity network throughout a facility and establish a culture of biosecurity in all biological research laboratories.

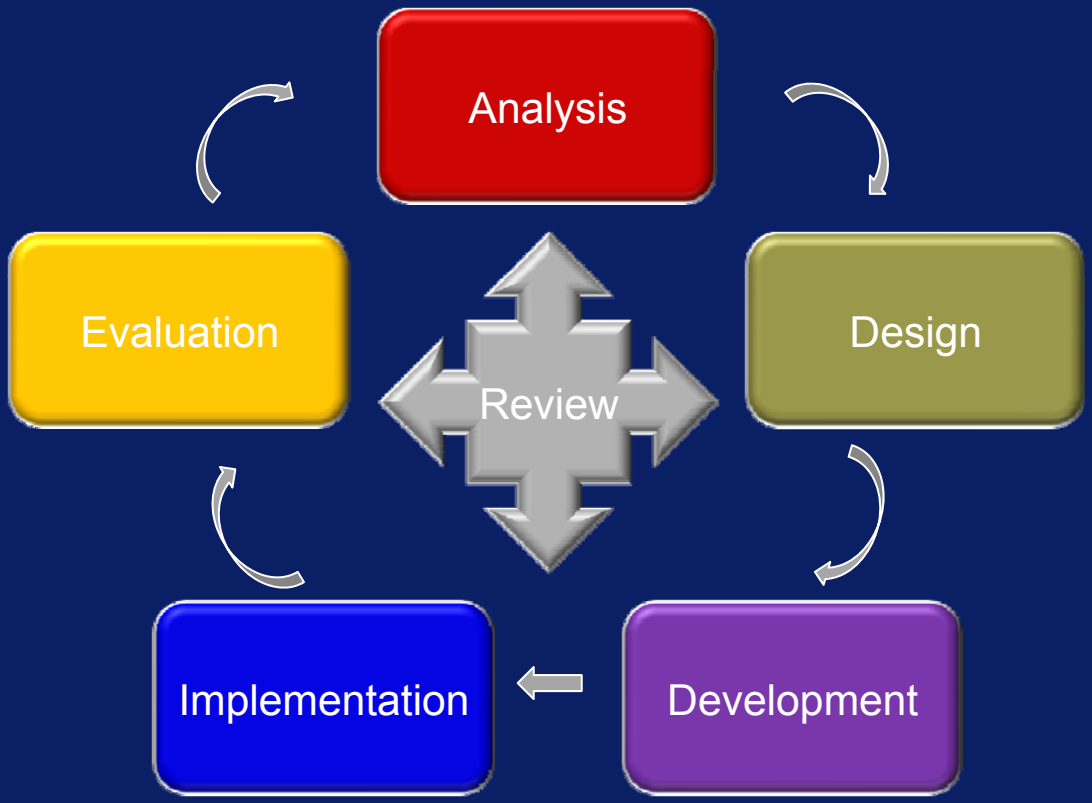
Biosafety Competency Training and Proficiency Testing

- Case Study

Defining Competency and Proficiency

- Competency and proficiency can be assessed using published standards as the basis of the training program.
  - Competency : Capable of completion of a task under specified conditions
  - Proficiency: Expert with knowledge, skill and ability to troubleshoot problems with completion of a task

ADDIE Model


Analysis
Design
Development
Implementation
Evaluation
Review

Training Analysis and Performance Metrics

Skill	Task	Subtask	Performance Metric	Evaluation
ELISA	Perform a series of 1:5 dilutions	Selects the correct pipettor for the volume	Selects 200 µl pipettor	Exam or Demonstration
		Accurately measures 120 µl of liquid	± 2 µl accuracy	Demonstration

Customization of Training to the Facility

- Task Lists
  - Foundation of training materials derived from national and international guidelines and facility SOPs
  - Template Task List
    - List of approximately 400 tasks in biosafety to be completed by all personnel in a research laboratory
    - Based on BMBL but does not include facility-specific SOPs

Expanding the number and type of Biosafety Instructors

Certificate	Training Responsibility
Biosafety Instructor	Proficiency Testing
Laboratory Trainer	Competency Training

Documents Defining Working Practices in a Biosecurity Program

Procedural Documents	Biosafety Bioethics	Quality	Biosecurity	Incident Response
Standard Operating Procedures	BMBL 5th ed	CWA 15793		National Incident Management
Biosafety Manual	WHO Laboratory Biosafety Guidelines	Clinical and Laboratory Standards Institute	WHO/CDS/EPR 2006.6	National Response Framework
Equipment Manuals	OSHA BBP Std 29 CFR 1910.1030	ISO/ETC 17025, 1999	SAR 7 CFR 331	WHO IHR
	CDC Infection Control Guidelines	ISO/ETC 15189, 2003	9 CFR 121	
	NIH Guidelines		42 CFR 73	

Summary

- Most laboratory workers in BSL-2 labs are not subject to stringent training or documentation requirements. This fact is highlighted by the large number of infections resulting from non-compliance with guidelines and regulations.

- Training aimed at improving working practices can decrease biosecurity risks in BSL-2 labs by increasing worker awareness of biosecurity risks and by increasing the transparency of laboratory work will help close gaps in biosecurity programs.

- Worker competency and proficiency are two important components of a biosecurity program, which can be assessed and improved through training that is initiated upon entry into the training or clinical laboratory (BSL-2 programs).

Conclusion – Impact on Biosecurity

- Cooperative culture of safety and security
  - The ISD methodology adapted to biosecurity requires buy-in from laboratory managers and encourages a cooperative interaction between safety and security managers and scientists.

- Performance indicator for personal reliability
  - BSL-2 laboratories “seed” higher containment facilities. This method provides a step-wise path toward proficiency in biosafety and biosecurity in high containment laboratories.

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