EMORY UNIVERSITY | Environmental Health and Safety Office
Research Administration

Initiation of ABSL3 Influenza work based on the Biorisk Management System (CWA 15793:2008)

Kalpana Rengarajan, PhD, MPH, RBP
Emory University
ABSA Conference
October 24, 2012

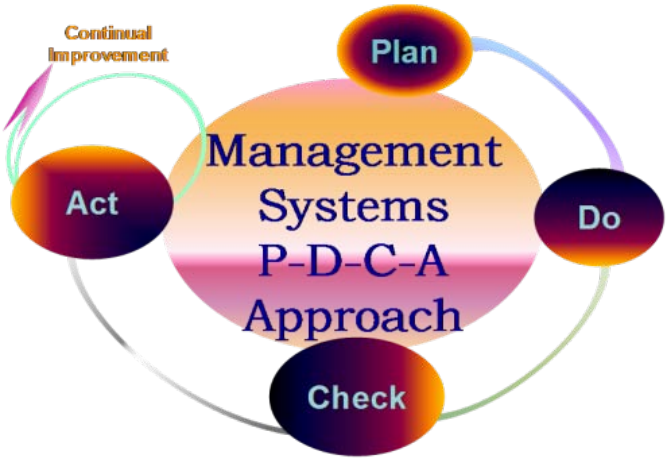
What is the CEN Workshop Agreement (CWA)?

- CEN = The European Committee for Standardization
- CEN Workshop Agreement (CWA 15793:2008):
  - A technical agreement, developed by an open workshop structure through consensus within the framework of CEN
  - Was developed, adopted and published in 2008 with 76 participants from 24 countries
  - A comprehensive and systematic management blueprint to improve Biosafety and Biosecurity (biorisk) performance
  - Is compatible with ISO 14001:2004 and OHSAS 18001:2007
- The recently published CWA 15793:2011 replaces CWA 15793:2008
  - The two versions are identical with no technical changes
  - Only Editorial changes implemented - replacement of the word “standard” in the original document replaced by “CWA” or “Agreement” wherever appropriate based on a request to CEN by the CEN National Members

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

CWA is a Management System Standard

- Management systems are frameworks that integrate best practices and procedures built around the PDCA cycle:
  - *Plan*
  - *Do*
  - *Check*
  - *Act*
- The CWA is voluntary and not intended to replace any national or sub-national regulatory requirements that may apply to a research laboratory or facility



- Compliance with regulatory requirements is mandatory
- The overall objective of the CWA is to support and promote good biorisk practices including self regulation

Purpose of the CWA

- The CWA can be used for:
  - Improving overall laboratory biorisk performance
  - Improving biorisk performance at any level (e.g., institutional level, department level)
  - Effectively managing complex laboratory safety and security processes as they relate to biosafety and biosecurity
  - Improving national and international laboratory collaboration and safety harmonization
  - Building stakeholder confidence

Background of this Study…

- Study specifically based on the initiation of research with recombinant influenza virus strains in an Animal Biosafety Level 3 facility
- Prior to beginning the ABSL-3 research, we worked with all stakeholders to verify and validate:
  - Standard Operating Procedures (SOPs)/ Work Practices
  - Engineering Controls
  - Administrative Controls
  - Personal Protective Equipment
- It offered an opportunity to verify the influenza ABSL3 project based on the CWA
  - By starting with a small program, we are able to take baby steps towards implementing the CWA institution-wide
  - This would facilitate further planning to improve the overall biosafety program campus wide

Objectives of this Study…

- In order to effectively implement the CWA, a gap analysis was conducted to compare and analyze the existing processes and systems

- The gap analysis allowed us to:
  - Determine which requirements are in place and to what degree they are implemented
  - Develop an implementation strategy for future use
  - Provide a framework that may be used as the basis for training and raising awareness of biosafety and biosecurity guidelines and best practices

Predicted Outcomes

- Identifying gaps in the existing program
- Developing an action plan for implementation of the CWA and continuous improvement of the program
- Improvements will address following issues:
  - Effectiveness of process reviews
  - Effectiveness of follow-up activities
  - Documented procedures and instructions
  - Training and awareness programs
  - Risk assessment and management
  - Preventive actions
  - Conformity and compliance

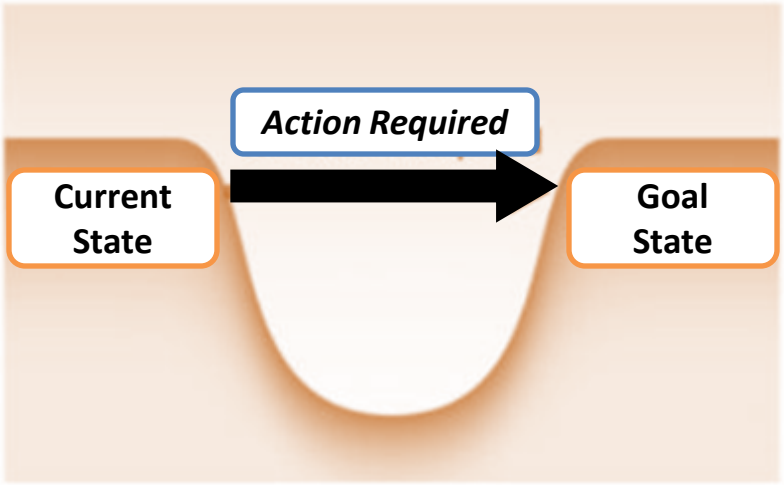
Process to Implement the CWA

Step 1:	Development of a tool to perform systematic gap analysis of the biosafety program
Step 2:	Perform a gap analysis by analyzing the existing program processes and systems
Step 3:	Based on the results obtained from the gap analysis, a process will be defined for the implementation of the CWA

The Gap Analysis Tool

- The Gap Analysis tool was developed based on the CWA 15793:2008 "Laboratory Biorisk Management Standard"
  - *This tool was submitted to the Faculty of the Rollins School of Public Health of Emory University as a thesis project in partial fulfillment of the requirements for the degree of Master of Public Health in Environmental Health*

- The tool consists of a series of questions based on the six major components of the CWA



The Gap Analysis Tool

- *Comprised of six major components and 391 questions*

	Topic	Number of Questions
1	Biorisk Management System	8
2	Policy	11
3	Planning	44
4	Implementation and Operation	245
5	Checking and corrective action	71
6	Review	12

How did we use this Gap Analysis Tool?

- *Methodology*
  - Used the scoring system to the right
  - Scored every line item in the gap analysis tool
  - Calculated the average score for each section and overall

#	Item	Score	Comments
Section 4.1: General Requirements			
1	Has a Laboratory Biorisk Management System that complies with CWA15793 standard been established by the organization?	2	Not specifically pertaining to Biorisk management, but comprehensive EHS management system. The standard has been established.
2	Are the policy and objectives of the institution included in the Biorisk Management system?	2	
3	Are the legal requirements considered prior to establishing the Biorisk Management system?	1	Yes, through the comprehensive gap analysis and the Compliance Register.

Stakeholders Involved in this Gap Analysis

- Biosafety Officer / Environmental Health & Safety Office
- Principal Investigator / Researchers
- Division of Animal Resources Staff
- IBC Members
- Campus Services (HVAC and associated items)
- Occupational Health

Results

Section	Average Score
4.1: General Requirements	1.4
4.2: Policy	1.3
4.3: Planning for Hazard Identification, Risk & Risk Control	1.0
4.4: Implementation and Operation	1.5
4.5: Checking & Corrective Action	1.5
4.6: Review	1.8
Overall Score	1.4

Study Findings

- We have a strong biosafety program but some written policies/procedures need to be further developed to come in line with the CWA requirements
- An institution-wide approach would have been an overwhelming undertaking
- However, by going through this Gap Analysis exercise on a smaller scale we were able to get a snapshot of how the overall biosafety program stands up to the CWA

Taking it Further

- The gap analysis is intended as a living and evolving document
- Thus, it is a good way to determine what the current situation is, where action is critically needed, and gain support from upper management to close discovered gaps
- We plan to:
  - List out the corrective actions needed to fill the gaps
  - Prioritize action items based on program needs and available resources
  - Assign corrective actions to appropriate responsible individuals
  - Document procedures used and time spent to close the gaps

Thank You

- Meagan Fitzpatrick (EHS Professional in Biosafety Program)
- Maria Mendez, MS (Assistant Director, EHSO)
- Patty Olinger, RBP (Director, EHSO)