The Implementation of a Biorisk Management System (CWA 15793:2008) and Process Improvement using an ABSL-3 Research Project as a Model System

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What is the CEN Workshop Agreement (CWA)?

- CEN = The European Committee for Standardization
- CEN Workshop Agreement (CWA 15793:2008):
  - The first internationally recognized management systems standard to address biological risks and improve Biosafety and Biosecurity performance
  - Developed by an open workshop structure through consensus within the framework of CEN
  - Adopted and published in 2008 with 76 participants from 24 countries
  - Compatible with other management systems standards such as: ISO 14001:2004 and OHSAS 18001:2007

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

CWA 15793:2011

- CWA 15793:2011 replaces CWA 15793:2008
  - Only editorial changes implemented - 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
  - In 2012 CEN Workshop 55 published CWA 16393:2012 – Guidelines for the implementation of the CWA 15793:2008
  - Both documents are available for free download through the CEN website

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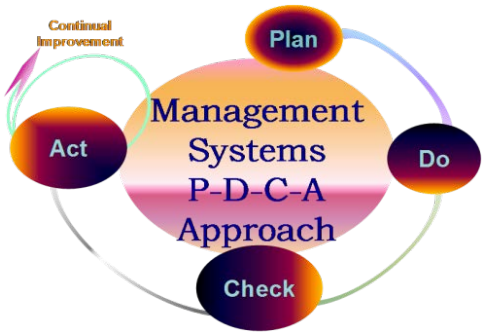
Purpose of the CWA

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

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

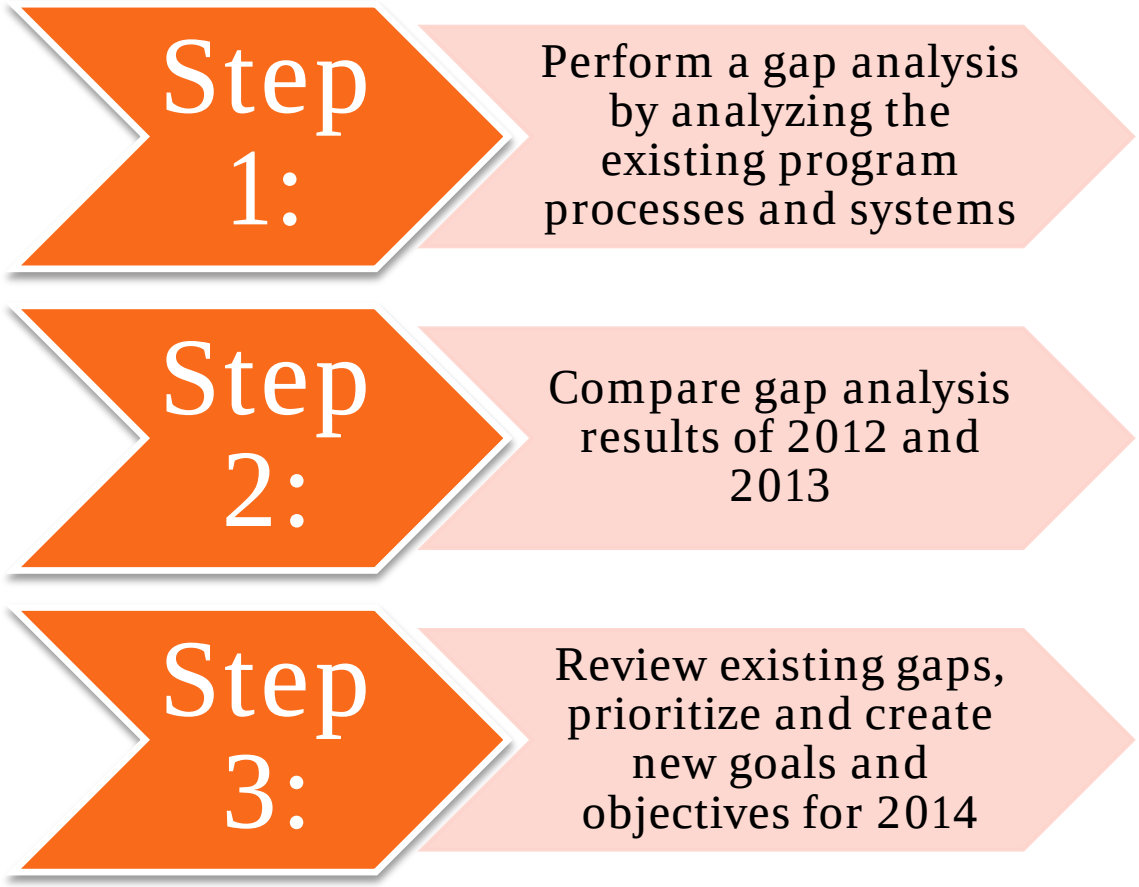
Background

- In 2012, initiated implementation of CWA at a program level
- Validated a ABSL-3 facility to conduct research with recombinant influenza viruses and West Nile Virus in guinea pigs and mice
  - Prior to validation, conducted a gap analysis (based on CWA 15793) and gave a score of 1,2 0r 3.
- The gap analysis allowed us to:
  - Determine which requirements are in place and to what degree they were 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

Objectives of this Study

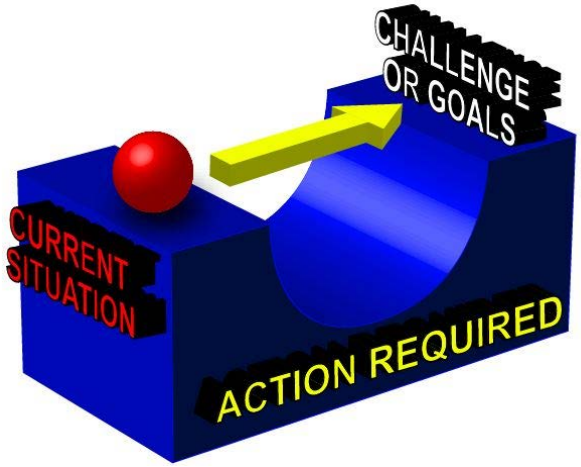
- One year later, our aims were to conduct another gap analysis on the research performed in the same facility
- Goals:
  - To see if items that scored 1, 2 or 3 in 2012, remained the same
  - To see if the prioritized gaps from previous year were closed
    - Example: installation of redundant exhaust fan
  - To continually improve the implementation of the CWA in the ABSL-3 facility

Methods to Implement the CWA



The Gap Analysis Tool

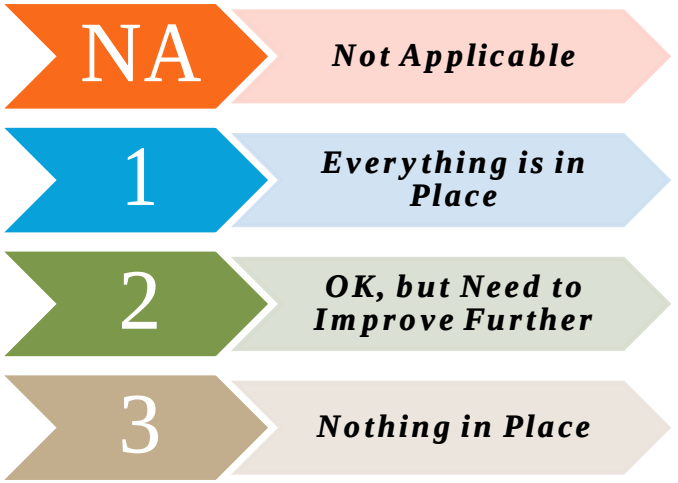
- Developed based on the CWA 15793:2008 “Laboratory Biorisk Management Standard”
- Comprised of six major components and 391 questions



	Topic	# 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

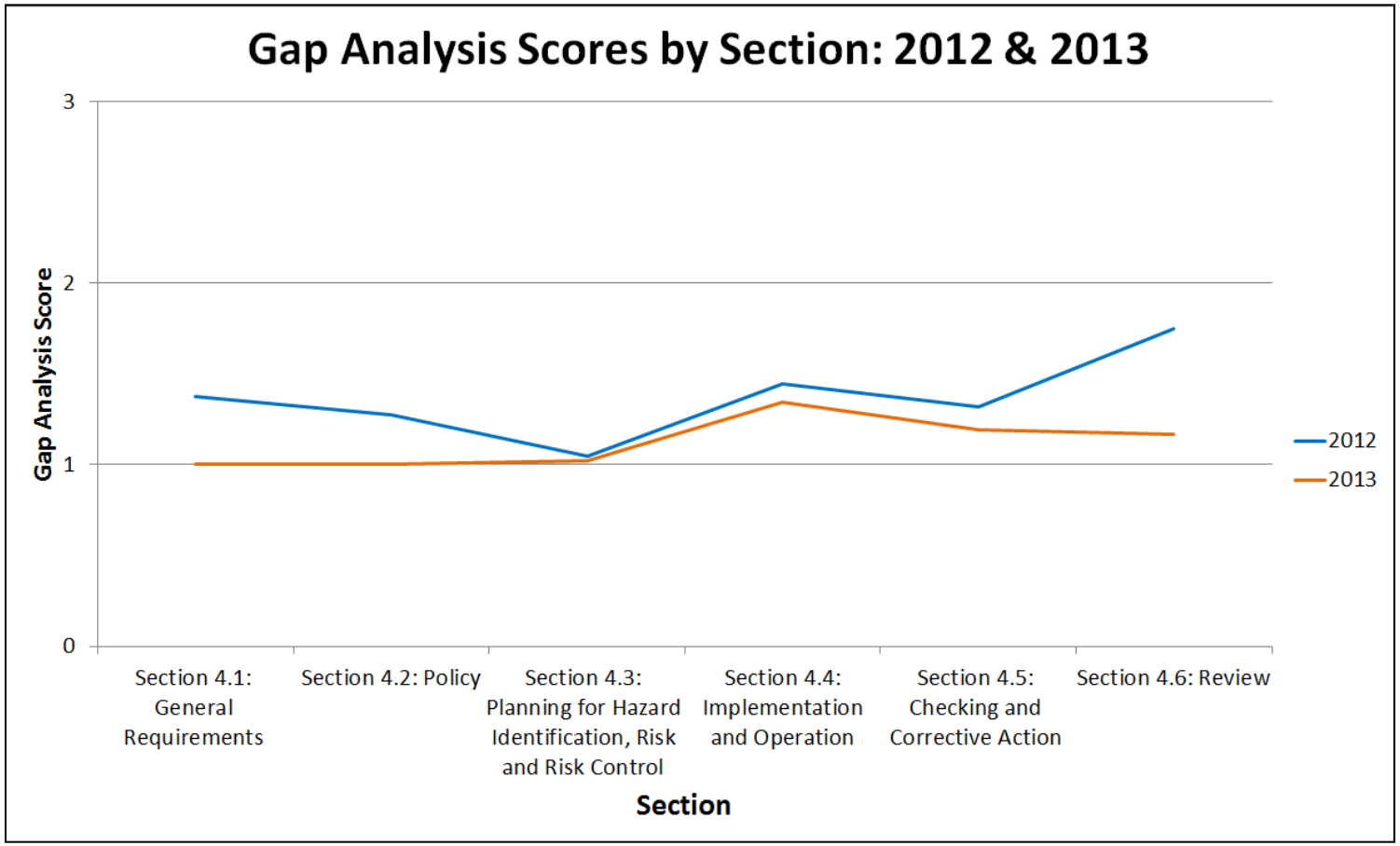


#	Item	Score	Comments
Section 4.1: General Requirements			
1	Has a Laboratory Biorisk Management System that complies with CWA15793 standard been established by the organization?	2	Not specifically pertaining to Biorisk management, but comprehensive EHS management system. The standard has been established.
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.

Results – Scores by Section

Section	Average Score 2012	Average Score 2013
4.1: General Requirements	1.38	1.00
4.2: Policy	1.27	1.00
4.3: Planning for Hazard Identification, Risk & Risk Control	1.05	1.02
4.4: Implementation and Operation	1.45	1.34
4.5: Checking & Corrective Action	1.32	1.21
4.6: Review	1.75	1.17
Overall Score	**1.38**	**1.26**

Results – Scores by Section



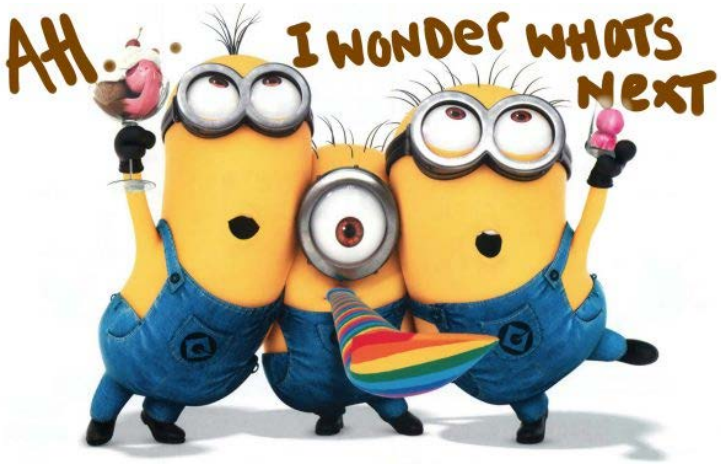
Results – Changes in Scoring

	Scoring 2012 → 2013	Number of Items
Positive change	3 → 2	8
	3 → 1	4
	2 → 1	26
No change	3 → 3	35
	2 → 2	19
	X → N/A*	35

* N/A questions were removed from the scoring

Study Findings

- Overall improvement in all six components
- At Emory, we are establishing a comprehensive EHS-MS, which integrates biorisk management systems along with environmental, general safety, occupational management systems.
  - Integrated approach has improved our scoring in the first two components: general requirements and policy
- The CWA is a performance based initiative
  - During facility inspections by interviewing lab and animal care personnel we have evaluated their understanding of policies, SOPs, etc.
- One major gap (lack of a redundant exhaust fan) was corrected through active involvement of relevant stakeholders
- Items pertinent to select agents were marked as N/A



- The gap analysis is intended to be used as a living and evolving document
- Is a tool to determine what the current situation is, where action is critically needed, and gain support from upper management to close discovered gaps
- We will continue to:
  - 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
- Gaps targeted for the next year:
  - ABSL-3 contingency planning , emergency drills

Thank You

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