Implementing Biorisk Management Practices

Reynolds M Salerno, PhD
Director, Division of Laboratory Systems
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Occupation Safety and Health Act of 1970

- General Duties Clause (section 5)

"Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."

UCLA study on lab safety, 2013

- Almost half had experienced injuries in the laboratory
- 30% of respondents had witnessed a major injury
- UK respondents: 66% regularly execute risk assessments
- US respondents: 25% conduct formal risk assessments, 50% assessed risk only “informally”

Challenges in implementing biosafety…

- Historically, the scientific community has not seen safety as part of the intellectual process of conducting laboratory science
- Rigorous risk assessment methodologies are not well integrated into traditional education and training for laboratory life scientists
- Failure data is the yardstick by which safety effectiveness is measured
- Often safety accidents are blamed on laboratory workers

Learning lessons from other industries

- Airline safety has improved by a factor of more than 130 times over the past 60 years

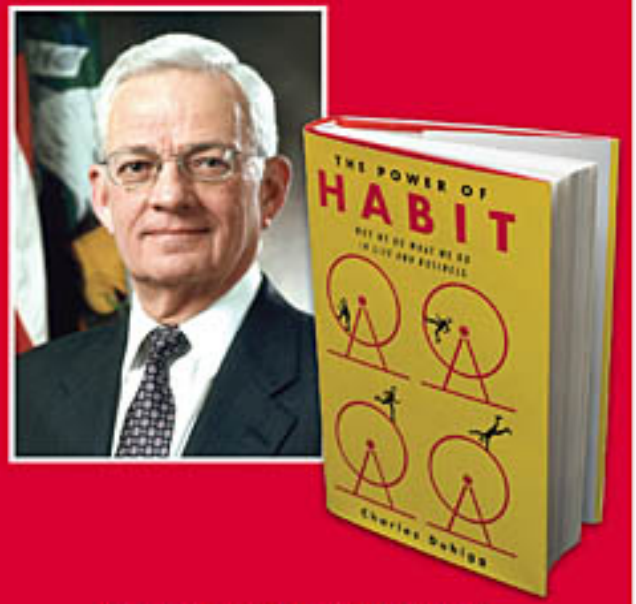
- ICAO Safety Management Manual
  - First edition 2003
  - Third edition 2013

- Organizational accident

Professor, Aeronautics, Astronautics, and Engineering Systems, MIT

THE POWER OF SAFETY

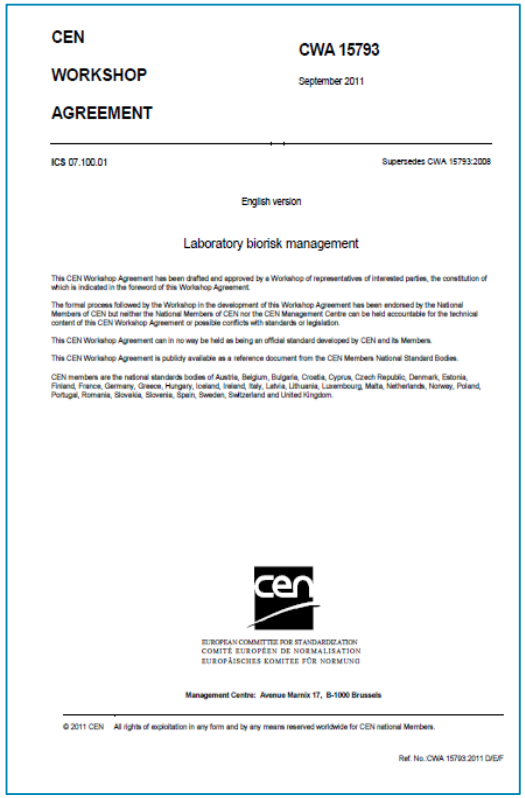
The story of Alcoa's CEO, Paul O'Neill,
and how he achieved incredible
business success by focusing on *safety*



An excerpt from *The Power of Habit* used
with permission from the author, Charles Duhigg

**Paul O'Neill,
CEO, Alcoa,
1987-2000**

Origins of biorisk management



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WORKSHOP

AGREEMENT

CWA 15793

September 2011

ICS 07.100.01

Supersedes CWA 15793:2008

English version

Laboratory biorisk management

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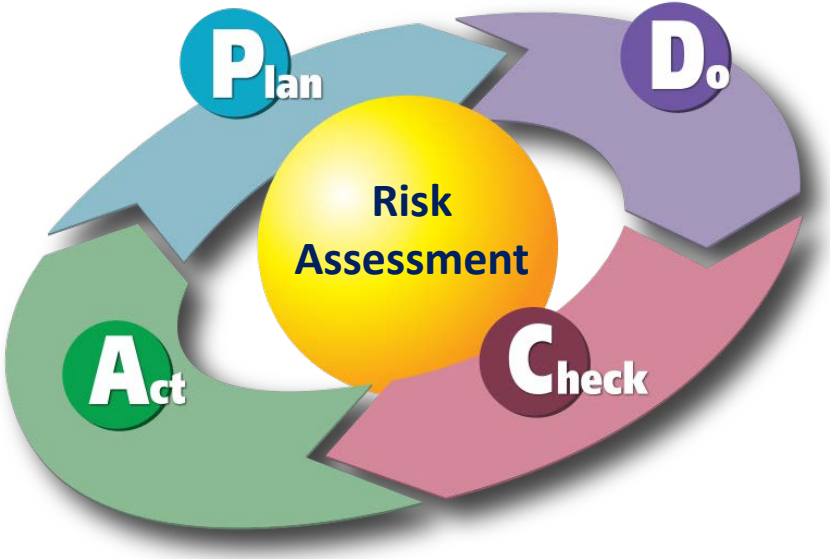
- CWA 15793 (2008, 2011)
- ISO Standard 35001 now under development



Laboratory biorisk management

- Depth of roles and responsibilities
- Intellectually sound, evidence-based decision making
- Substantive risk assessments
- Risk-based control measures
- Effectiveness evaluation routinely integrated into the workflow
- Explicitly scalable

The AMP model

- A management systems approach to safety that is analogous to a quality management system

Risk assessments are not static exercises but constantly iterative analyses

- What could go wrong today? Location, situation, and activity specific
- What are the likelihood and consequences of each of those risks?
- What data do we lack to make these evaluations more reliable?
- How should we prioritize those risks?

A risk assessment tool…

Zika testing process step	What could go wrong? (Specimen, reagents, equipment, procedures, personnel, environment)	Mitigations already in place	Probability (1-5)	Severity (1-5)	Risk Total	Proposed Mitigation (if Risk Total ≥6)	New Prob (1-5)	New Sev (1-5)	New Risk Total
Package receipt and transfer of packages to testing area	Leaking Package	• Protocols and best practices for handling leaking packages include placing in leak-proof secondary container and opening in BSC and PPE: gloves, lab coat, safety glasses	3	2	5				
	Unexpected delivery	• Samples are shipped with Category B packaging safety measures • All received packages are opened in BSC with proper PPE	3	2	5				
Transport of Specimens between testing areas	Breakage of the specimen container	• Protocols require specimens to be transported in a clearly labeled, durable, shatter and leak-proof transport container directly to the specimen handling area of the laboratory.	2	2	4				
	Contaminated transport container	• Protocols require decontamination of transport container surfaces before and after each use.	2	2	4				

Implementing controls extends beyond pre-determined, generic guidance

- Can we show how our control measures reduce each of the identified risks?
- Are we confident that our control measures concentrate more on mitigating the highest risks than the lower risks?
- What measures will we use to evaluate the effectiveness of our control measures on a routine basis?

Adopt a performance evaluation system that is dynamic and inclusive

- Checklists based on the results of a risk assessment can be used to assess the biosafety control measures

- Routine hot washes with the laboratory staff can
  - discuss the utility and value of all of the control measures, and
  - reveal data that can augment revisions of the risk assessment

- Incentives/rewards for those laboratory staff who identify safety issues and improvements

Keystone Initiative

uofmhealth.org

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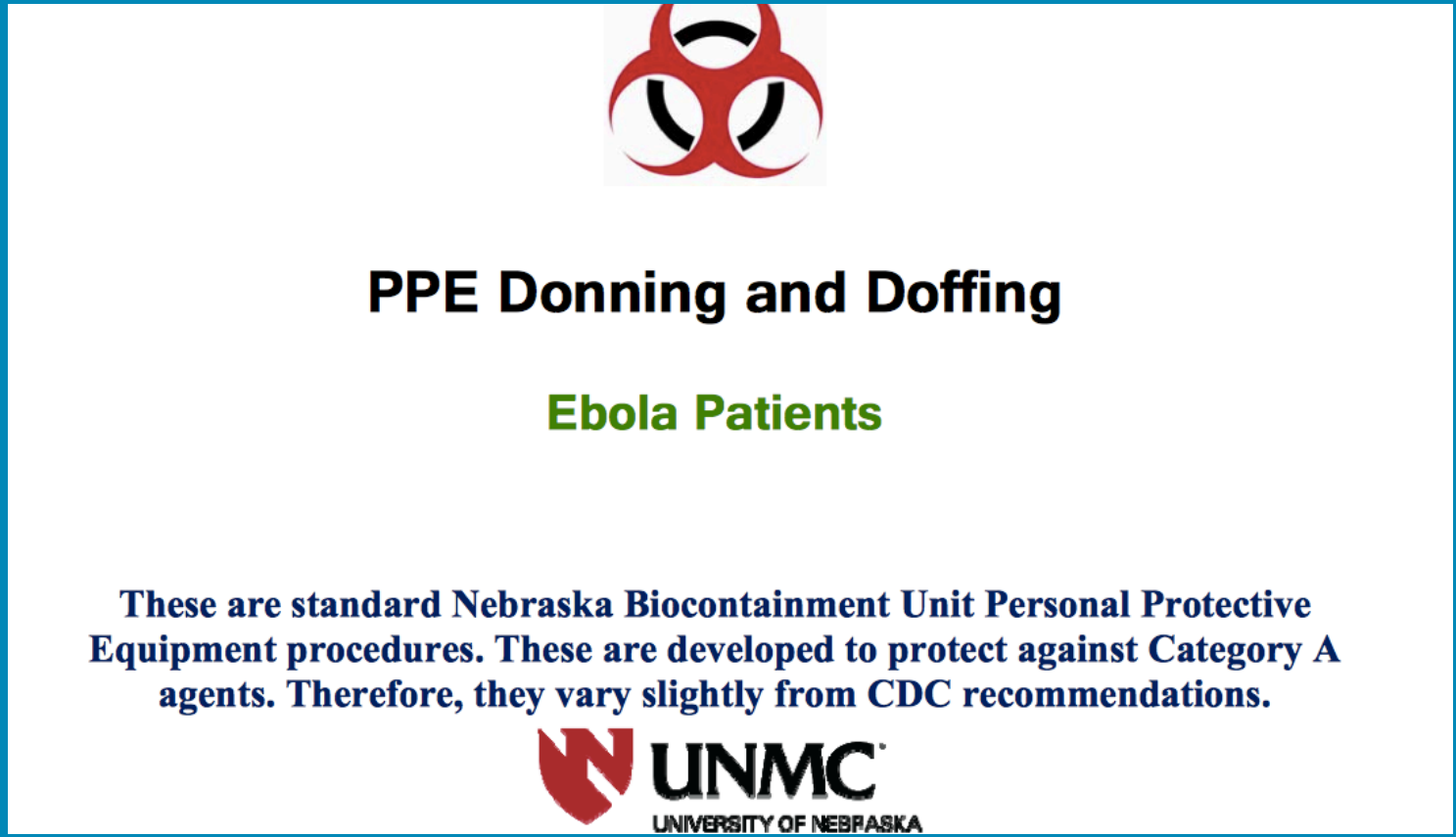
uofmhealth.org

Nebraska's Ebola patient-specific PPE checklist



Conclusion

- Embrace risk assessments as iterative scientific exercises that can always benefit from more/better data
- Measure the effectiveness of safety systems on a routine basis
- Incentivize and normalize discussions about safety problems and concerns
- Envision biosafety as a critical part of the scientific endeavor

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