This paper describes objective technical results and analysis. Any subjective views or opinions that might be expressed in the paper do not necessarily represent the views of the U.S. Department of Energy or the United States Government.

SAND2015-7344C

Laboratory Biorisk Management

Reynolds M Salerno, PhD

Senior Manager

Biological Sciences and Technologies

Sandia National Laboratories

Albuquerque, NM USA

September 2015

SAND No. SAND2015-3643 PR

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CDC Accidents, 2014

DOD Anthrax Inactivation Failures, 2015

Ebola Outbreak, 2014

Dallas Presbyterian Hospital, 2014

Ebola Patient Arrives in Nebraska

scrippsmedia.com/kmtv

Rick Sacra departing the Nebraska Medical Center

nebraskamed.com

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

- **A scientifically-responsive document that will continue to evolve**
  - **Has undergone multiple revisions since 1976**
  - **Latest version – November 2013**

http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines

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NIH Guidelines – Section II

- **Safety Considerations**
  - **Risk assessments: (Appendix B)**

RG 1	RG 2	RG 3	RG 4
Agents that are not associated with disease in healthy adult humans	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available (high individual risk but low community risk)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available (high individual risk and high community risk)

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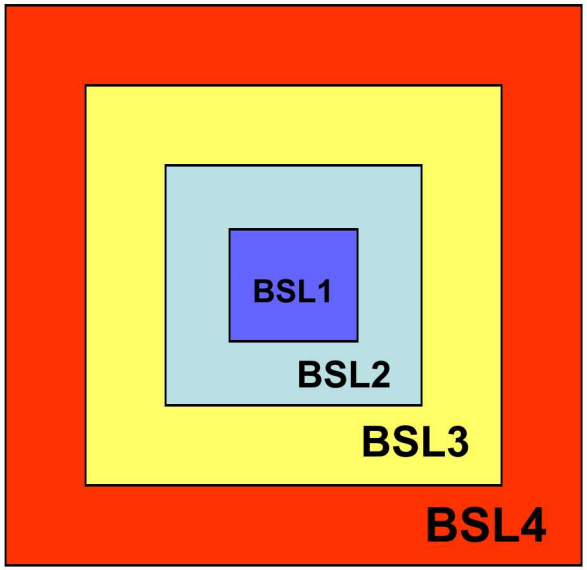
- **Safety Considerations**
  - **Containment**
    - **Physical (Appendix G)**
      - Practices
      - Equipment
      - Facilities
    - **Biological (Appendix I)**
      - Survival
      - Transmission



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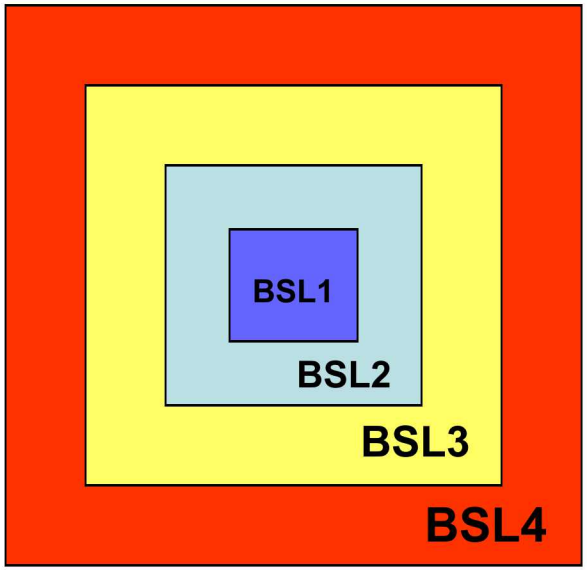
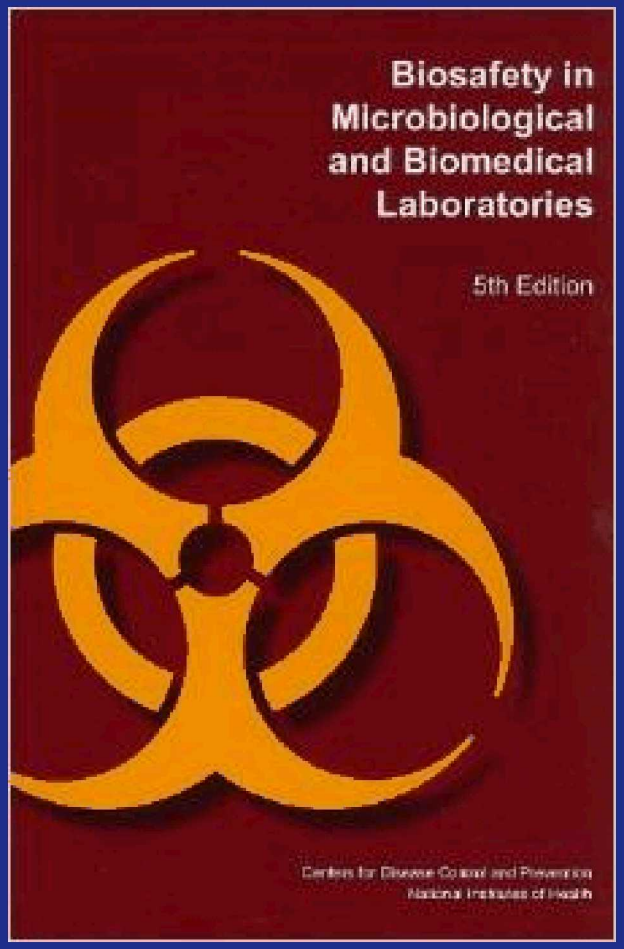


Today's Safety/Security Paradigm



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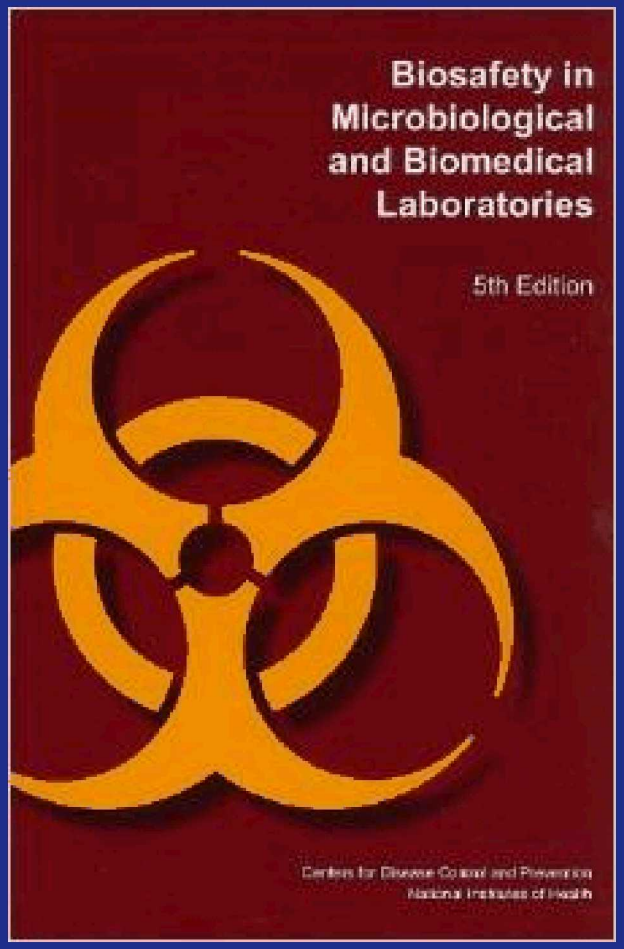

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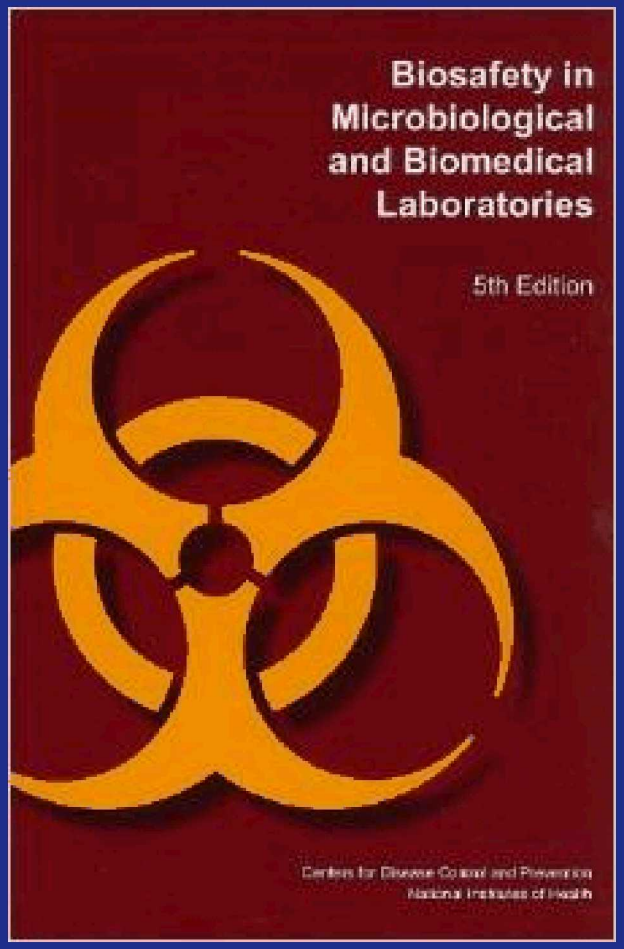
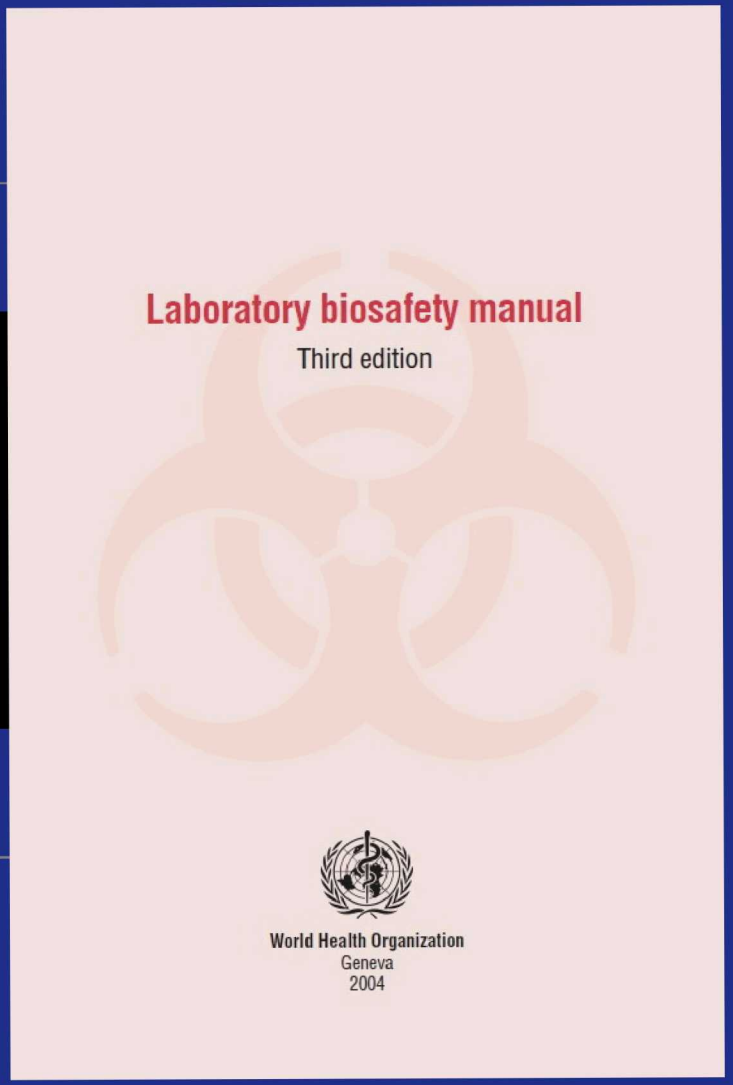


- Select Agents Regulations
  - 7 CFR 331
  - 9 CFR 121
  - 42 CFR 73
- Executive Order 13486—Strengthening Laboratory Biosecurity in the United States, January 2009
- Executive Order 13546—Optimizing the Security of Biological Select Agents and Toxins in the United States, July 2010

US paradigm has become an international paradigm



Result of this paradigm…

- Assumption that all work with the same agent presents the same risk
- For many (perhaps most), a risk assessment is equivalent to the agent's material safety data sheet
- Assumption that achieving the prescribed biosafety level equates to biological safety
- Perception that all the facilities that work with certain select agents should employ the same security measures
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This paradigm was effective…

- …when the field was small and not so complex

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- However, the field began to rapidly expand in the late 1990s and the early 2000s

Synthetic Biology

- Technologies for designing and building biological organisms
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Synthetic Biology

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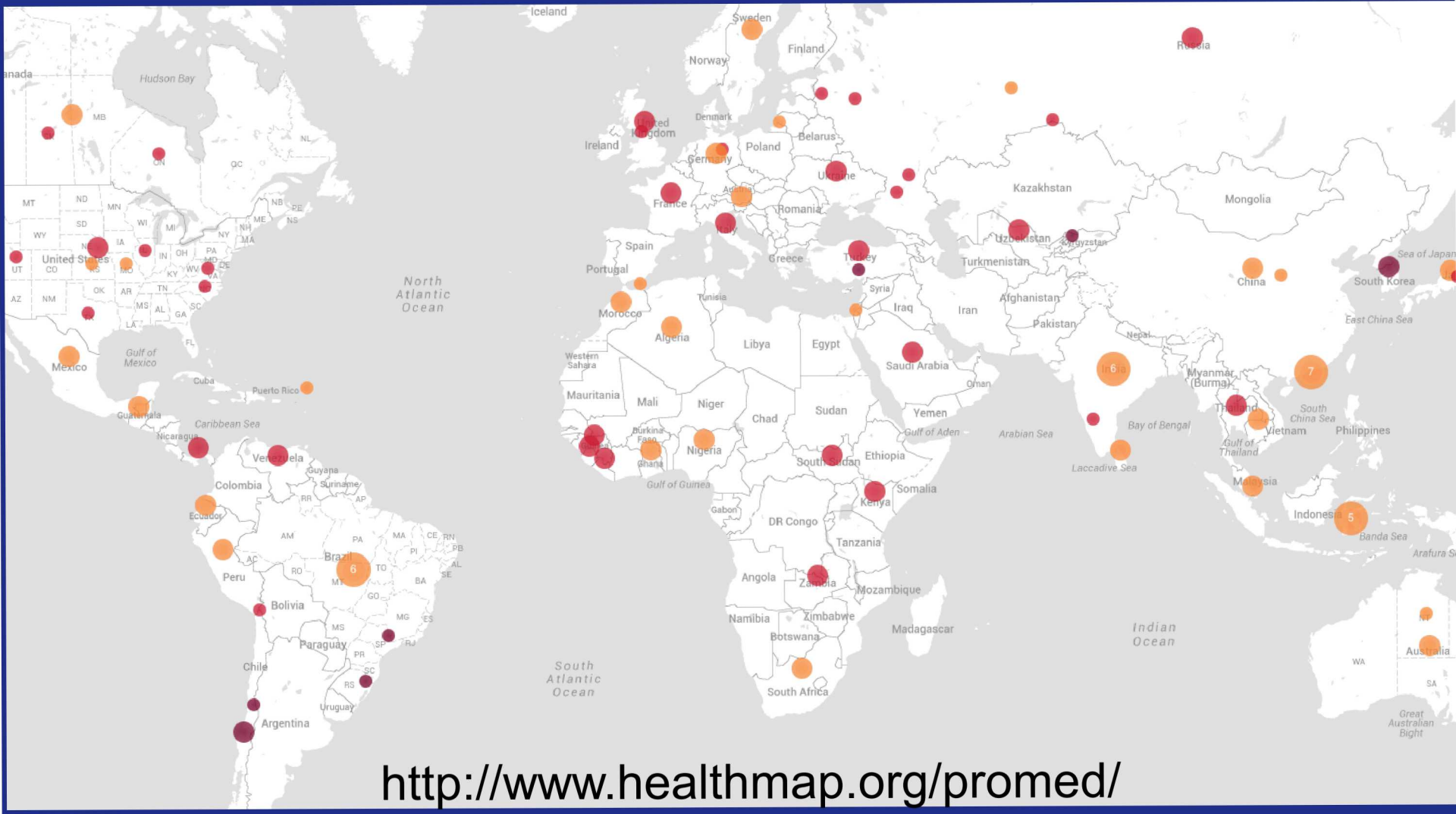
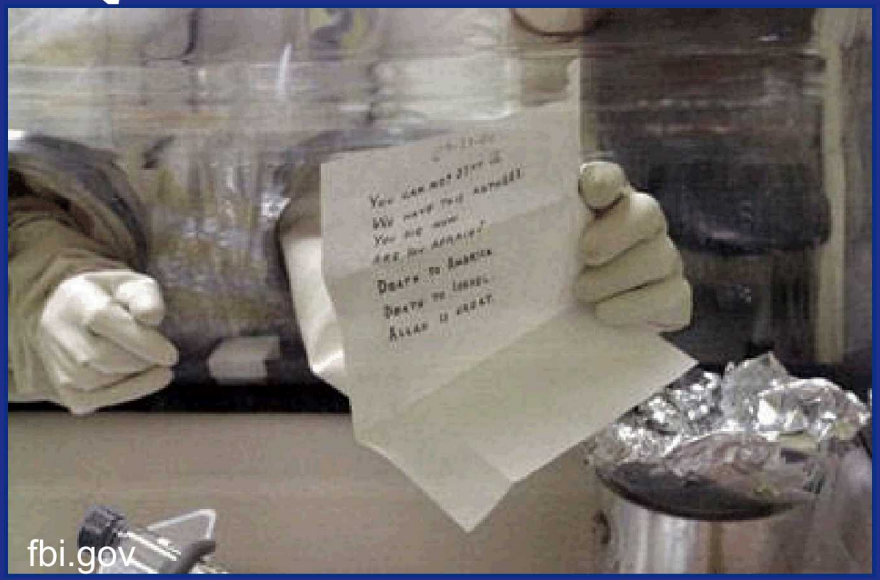
Sophisticated biology is now truly global

ProMED Disease Alerts July 2015



http://www.healthmap.org/promed/

High-profile lab accidents have become commonplace



- 2001 Glanders – USAMRIID
- 2001 Anthrax – USAMRIID
- 2004 Ebola – USAMRIID and VECTOR (Russia)
- 2004 Anthrax – Albuquerque, NM
- 2004 SARS – China, Taiwan, Singapore
- 2006 Brucellosis and Q Fever – Texas A&M
- 2007 FMD – Pirbright, UK
- 2009 Ebola – Hamburg, Germany
- 2009 Plague – Chicago, IL

UCLA Study on Lab Safety, 2013

UCLA Study on Lab Safety, 2013

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

Increasing Skepticism that Bioscience is Safe

- National Emerging Infectious Disease Laboratory in Boston

Increasing Skepticism that Bioscience is Safe

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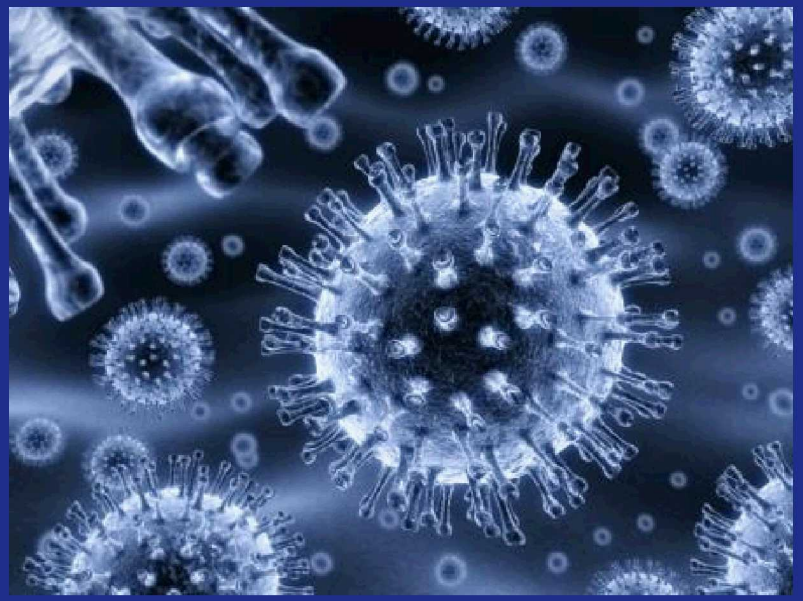
- Gain of function H5N1 avian influenza research



Complexity

Does this approach appreciate the complexity of our system?

…and everything that could potentially go wrong?

Complexity

Do we always know exactly what we're working with?

Complexity

Might the environment in which we're conducting work change over time?

Complexity

Might laboratory procedures drift or change over time?

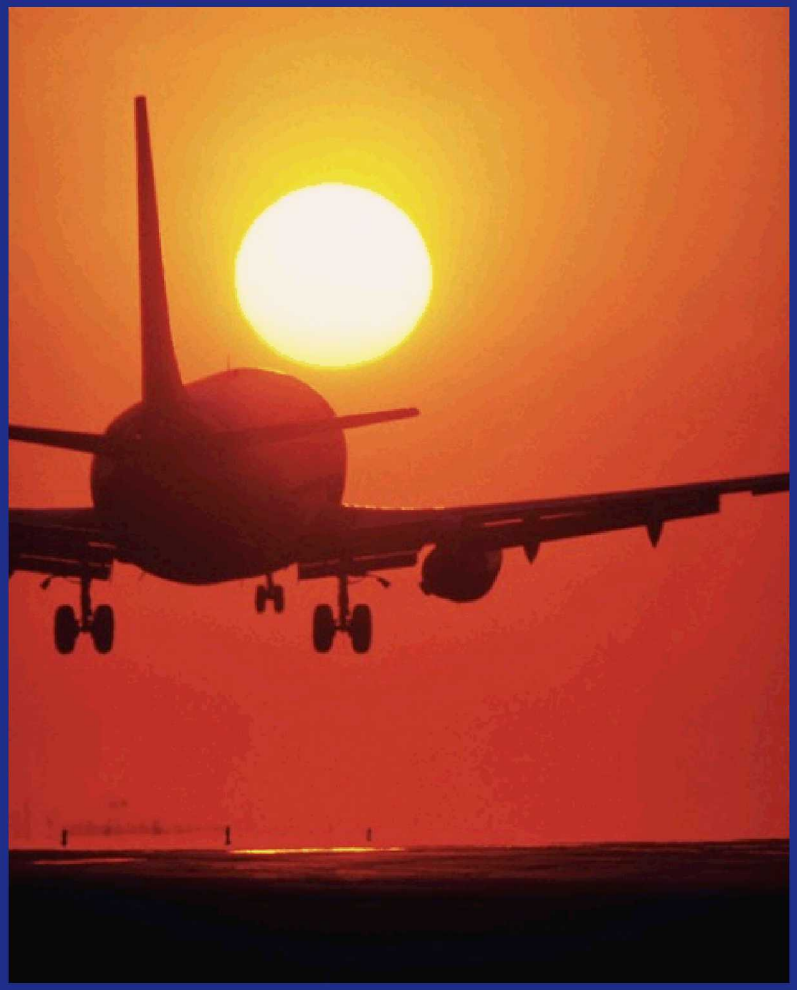
Safety and Security as an Administrative Function

- Safety and security separated into two distinct silos
- Safety and security not perceived as intellectual disciplines
- A “biosafety officer” has responsibility but not authority
- Absence of comprehensive management systems
- Inevitable complacency toward safety and security

Learning Lessons from Other Industries

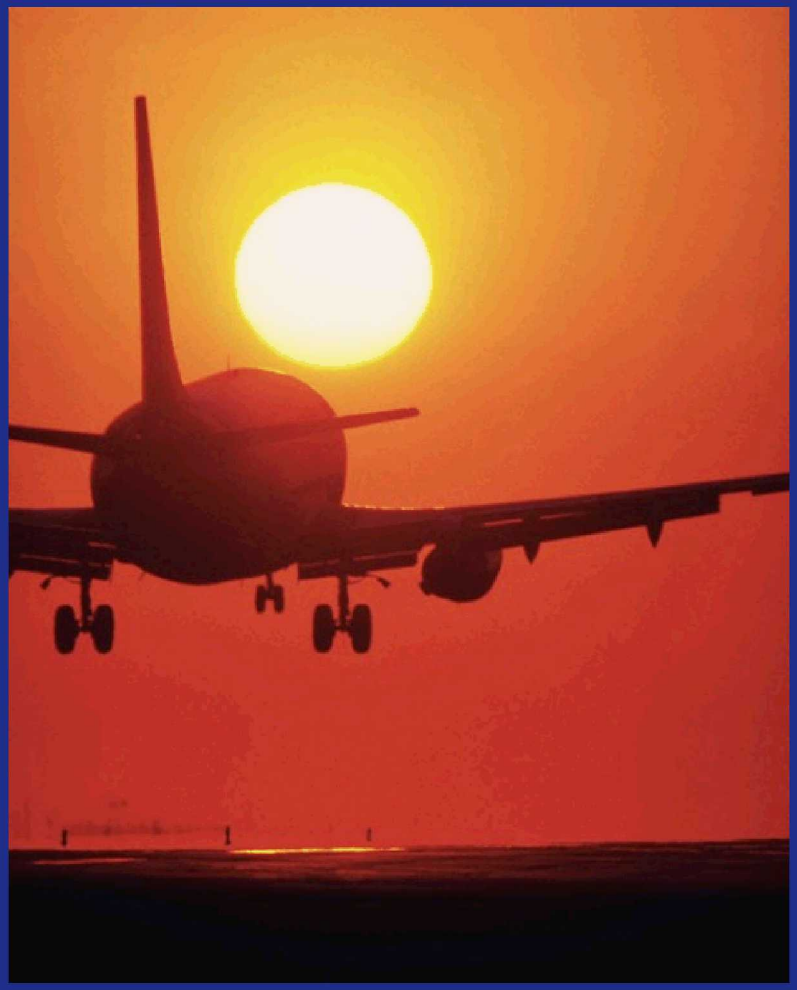
Learning Lessons from Other Industries

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



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**

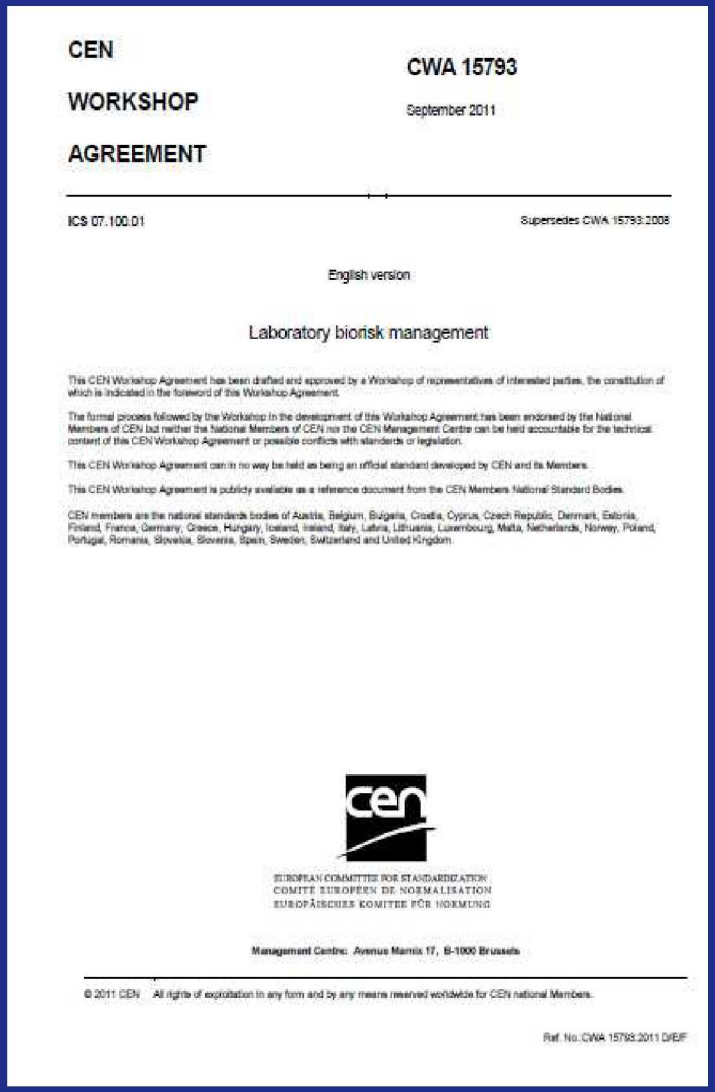


A New System Paradigm

LABORATORY BIORISK MANAGEMENT

Biosafety AND Biosecurity

Origins of Biorisk Management



CEN

WORKSHOP

AGREEMENT

CWA 15793

September 2011

ICS 07.100.01

Supersedes CWA 15793:2008

English version

Laboratory biorisk management

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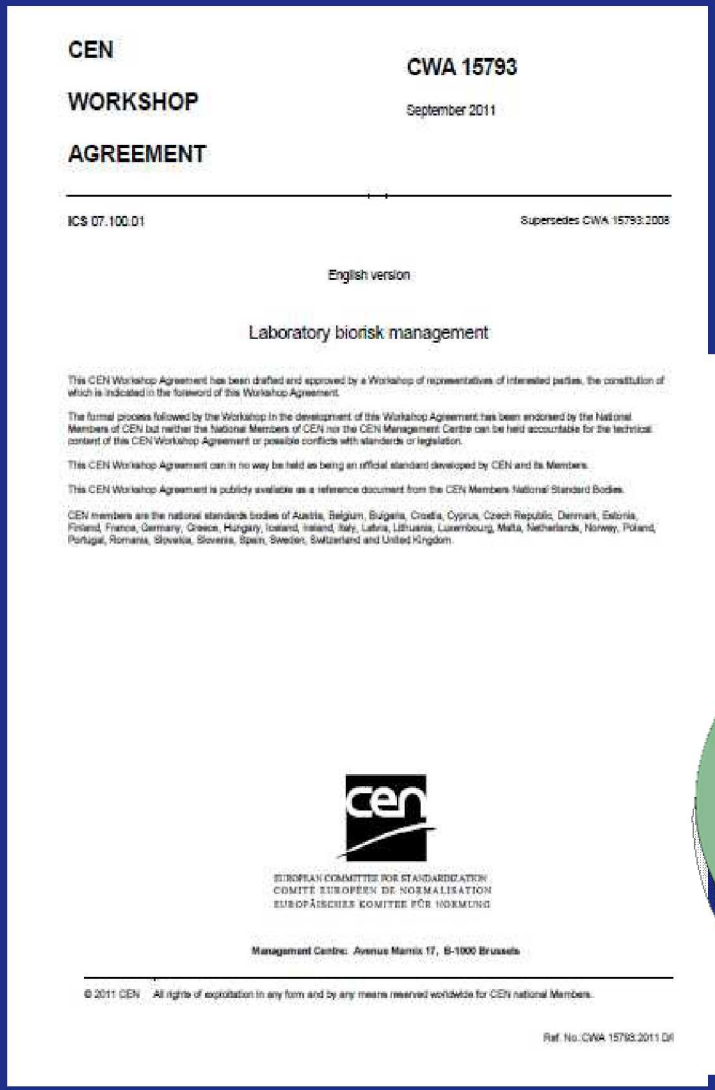
- CWA 15793 (2008, 2011)
- ISO standard now under development

Origins of Biorisk Management



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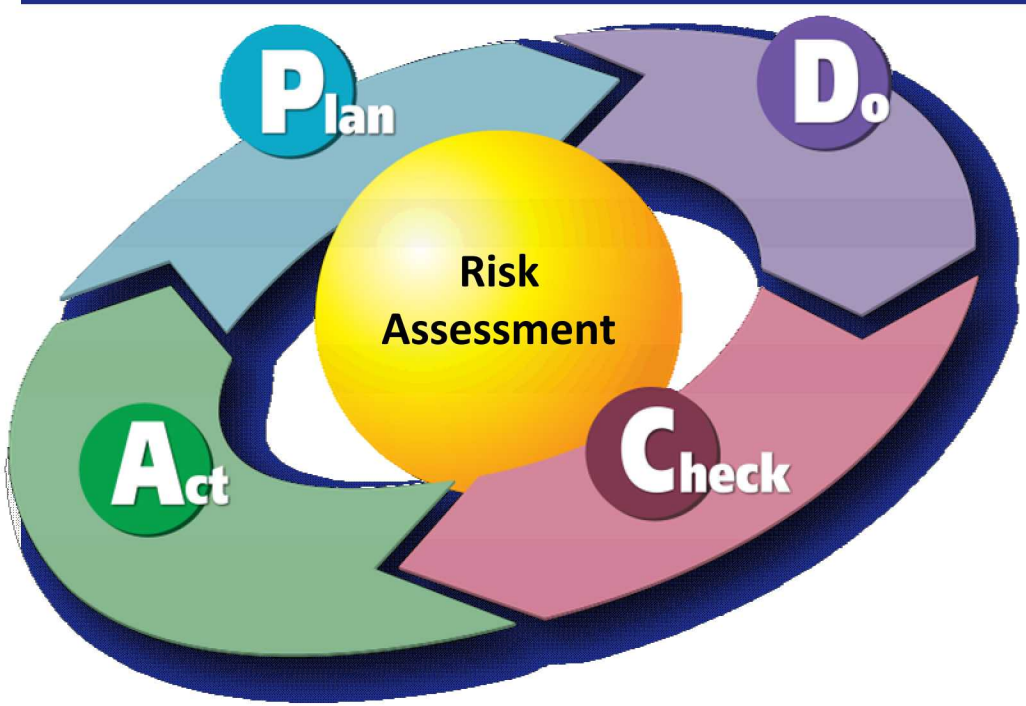
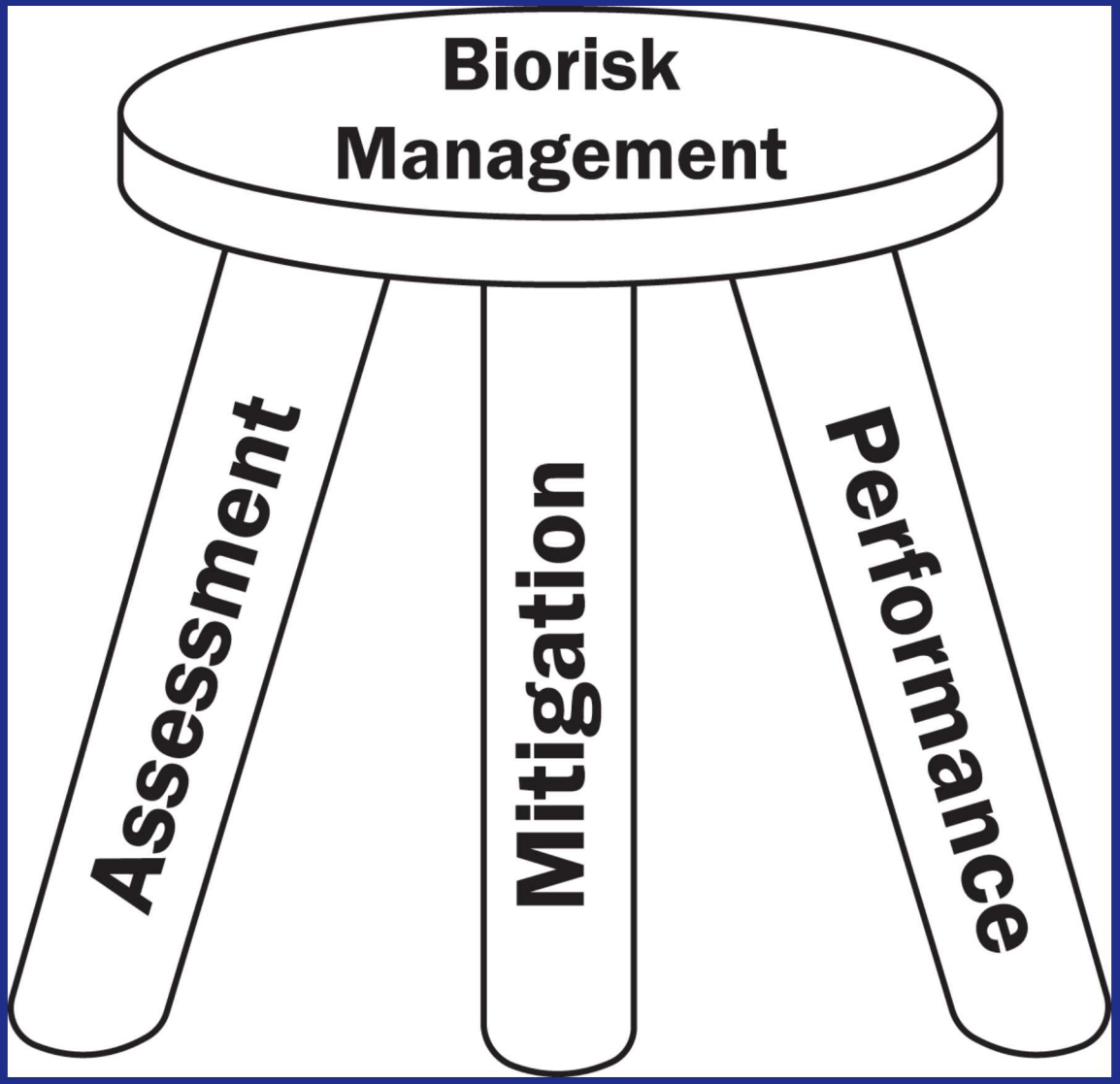


Laboratory Biorisk Management

- Depth of roles and responsibilities
- Intellectually sound, evidence-based decision making
- Substantive risk assessments
- Risk-based control measures
- Constant effectiveness evaluation
- Explicitly scalable

The AMP Model



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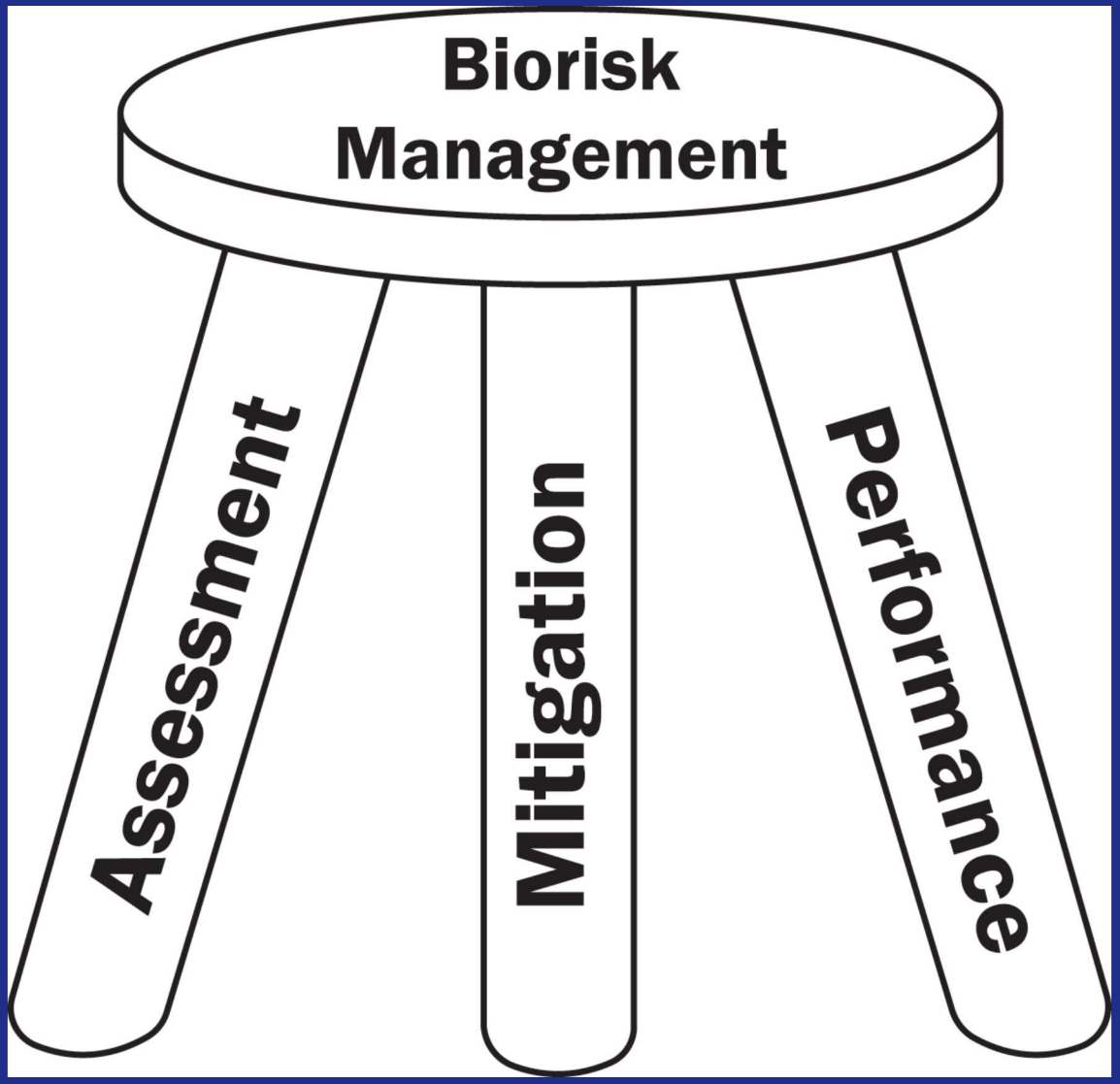

I. Assessment

- **Risks, hazards, threats…**

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Are the Risks the Same?

Should the Mitigation Measures Be the Same?

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A Risk Assessment Tool…

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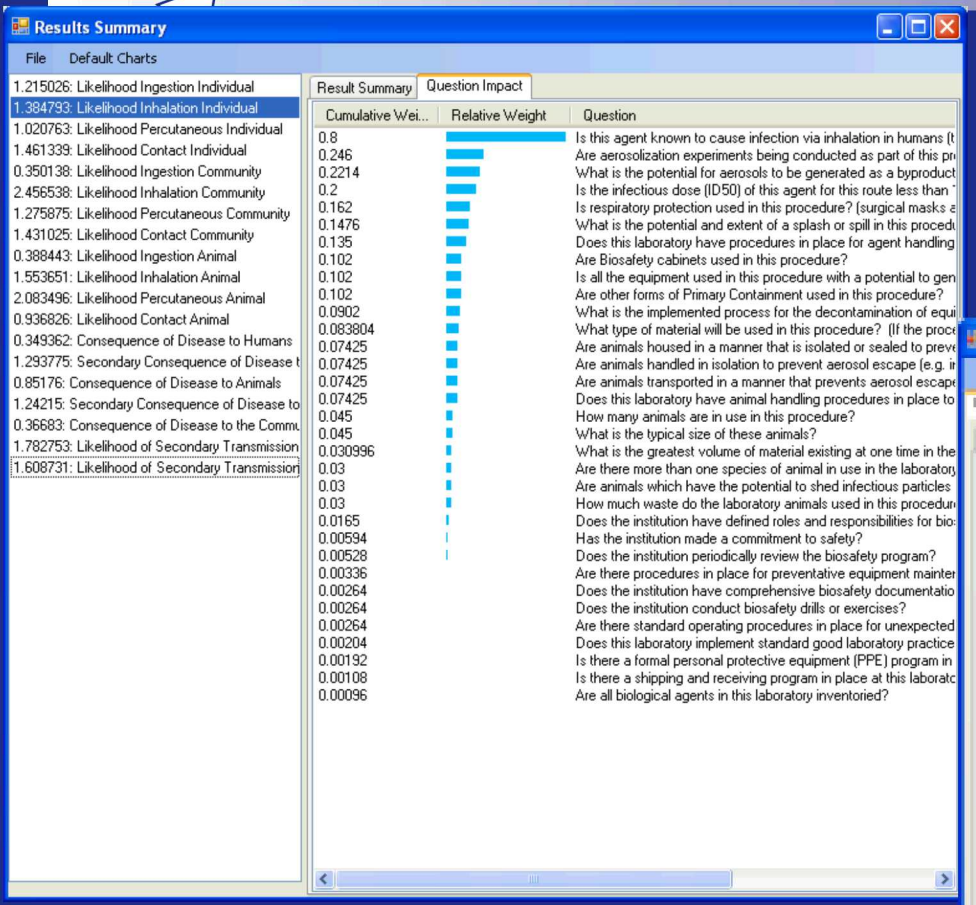

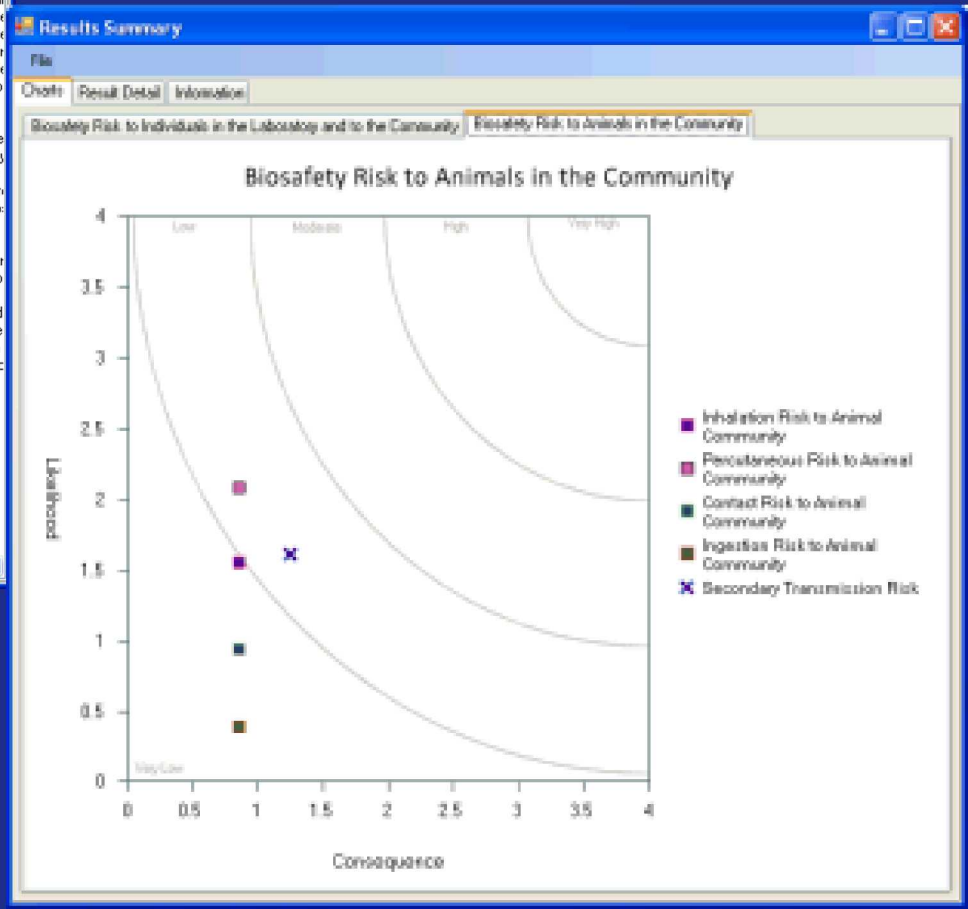

II. Mitigation

- **Mitigation measures should be drawn directly from the risk assessment, and should target the most unacceptable risks**

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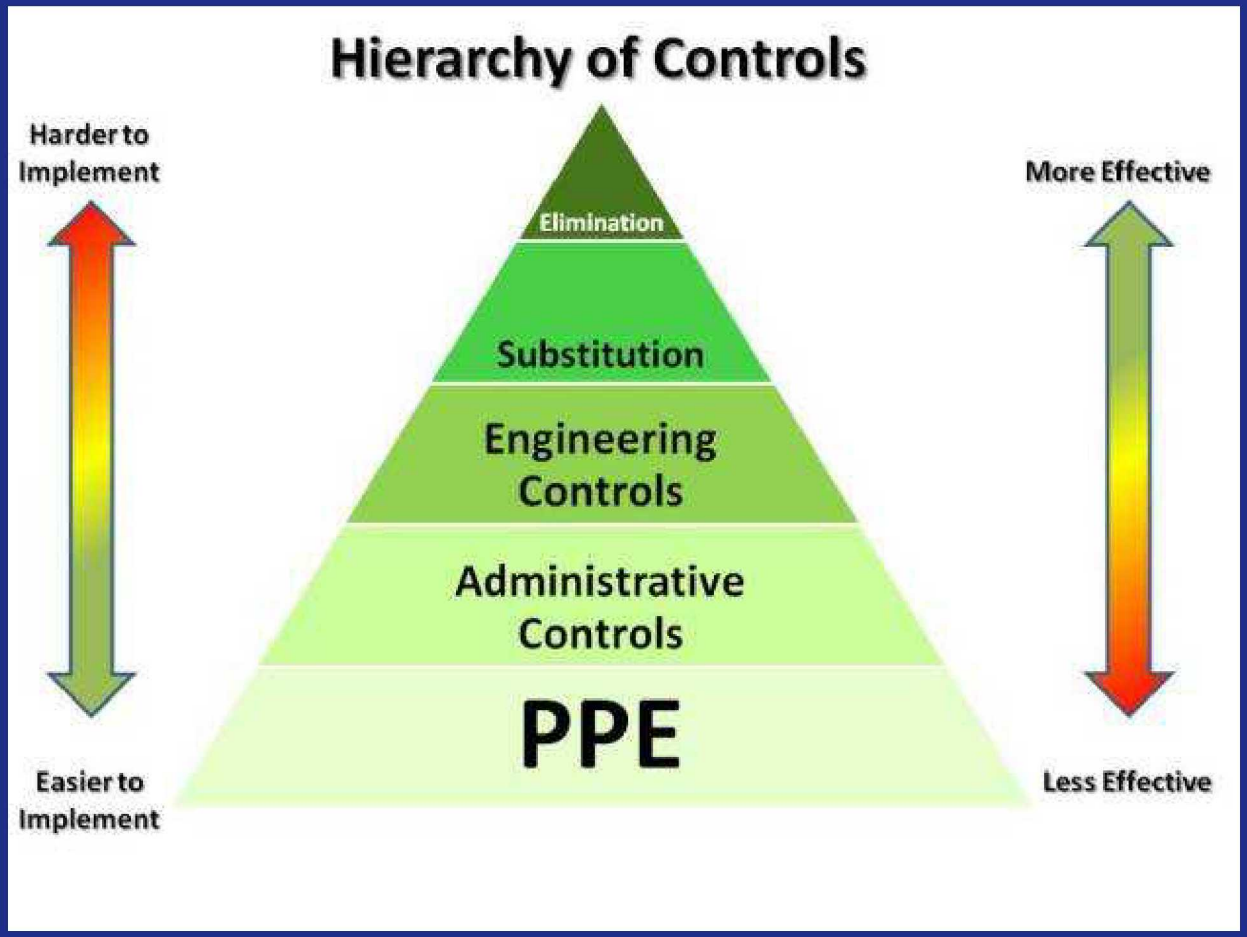

III. Performance

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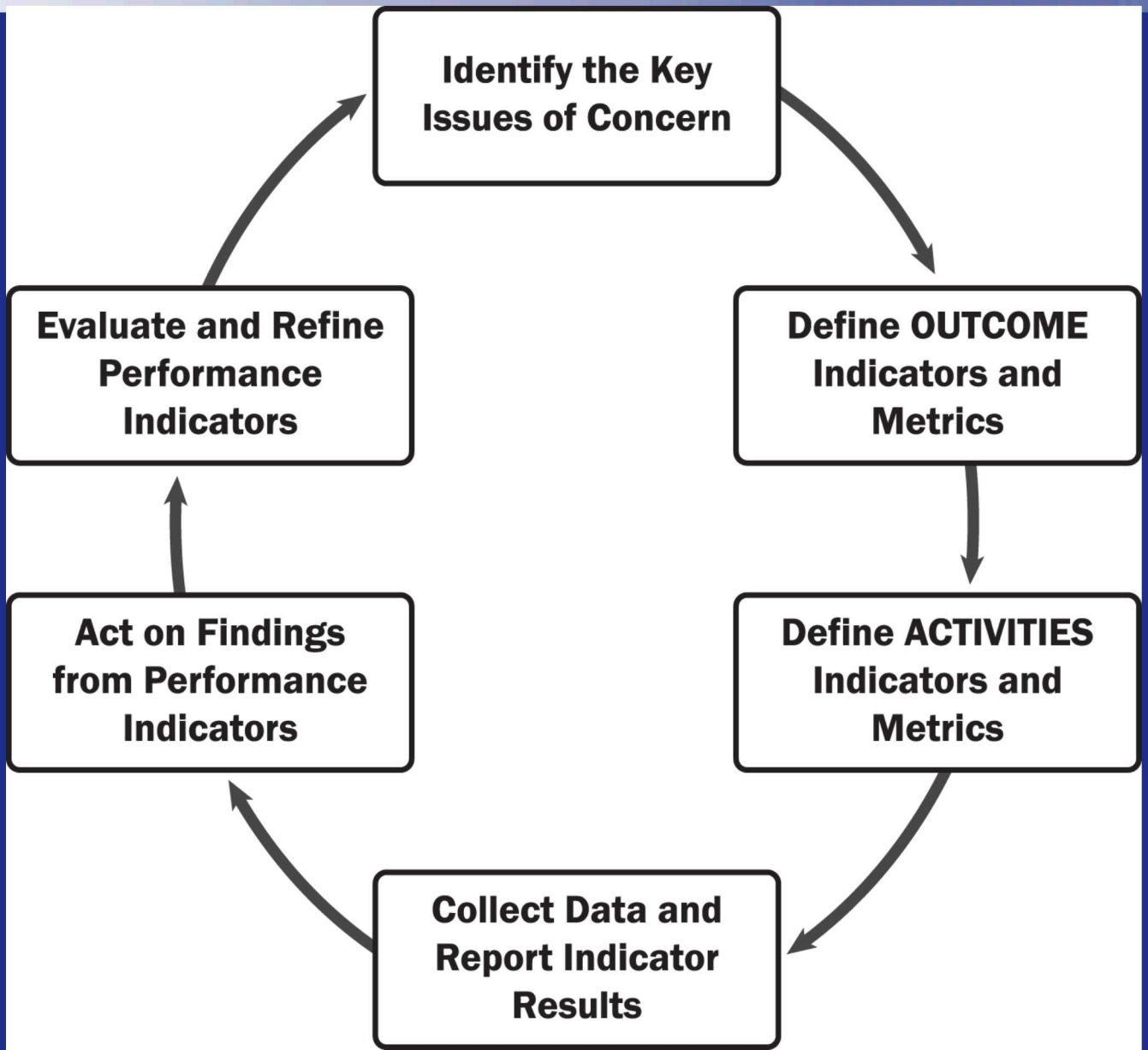

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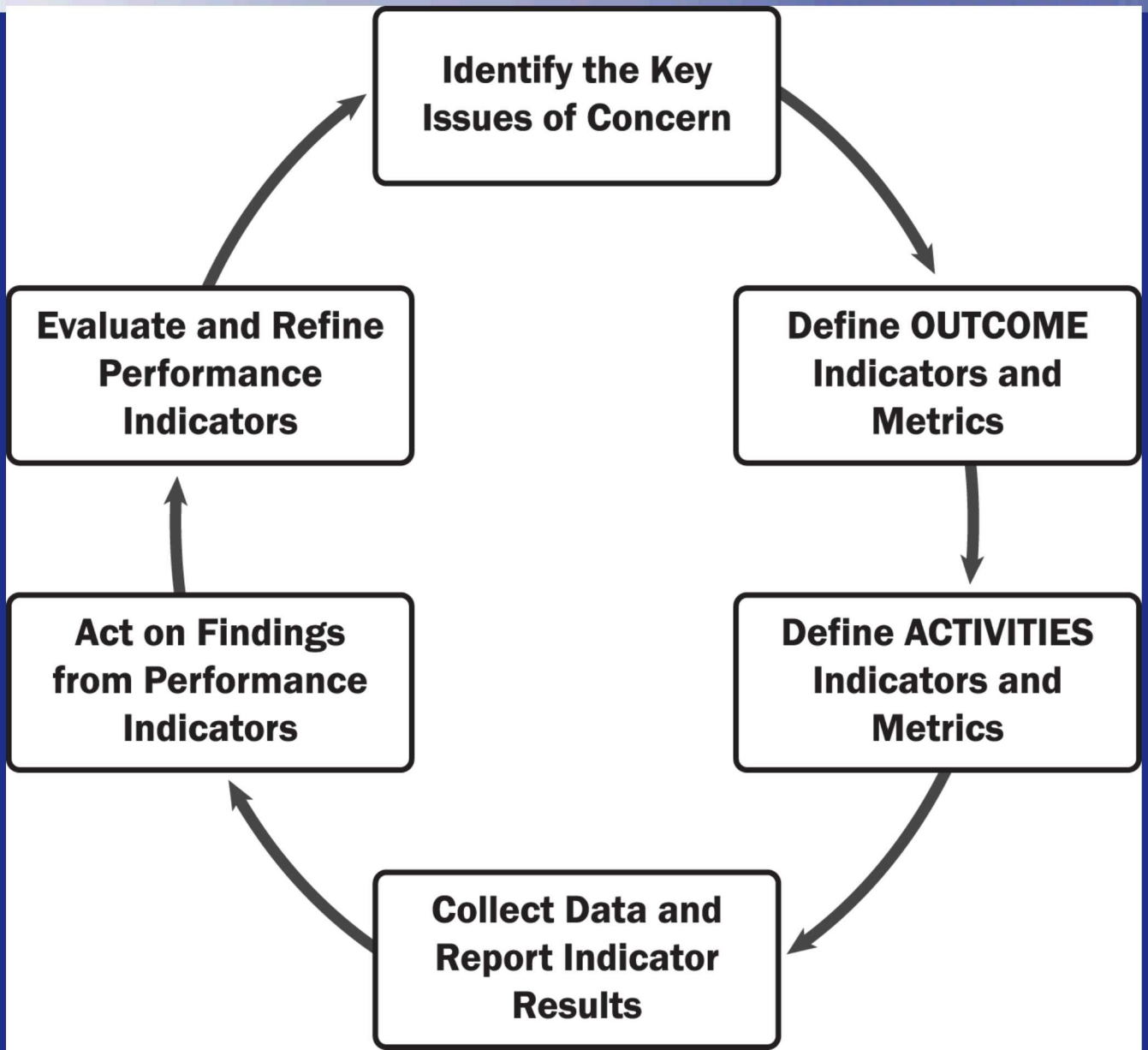
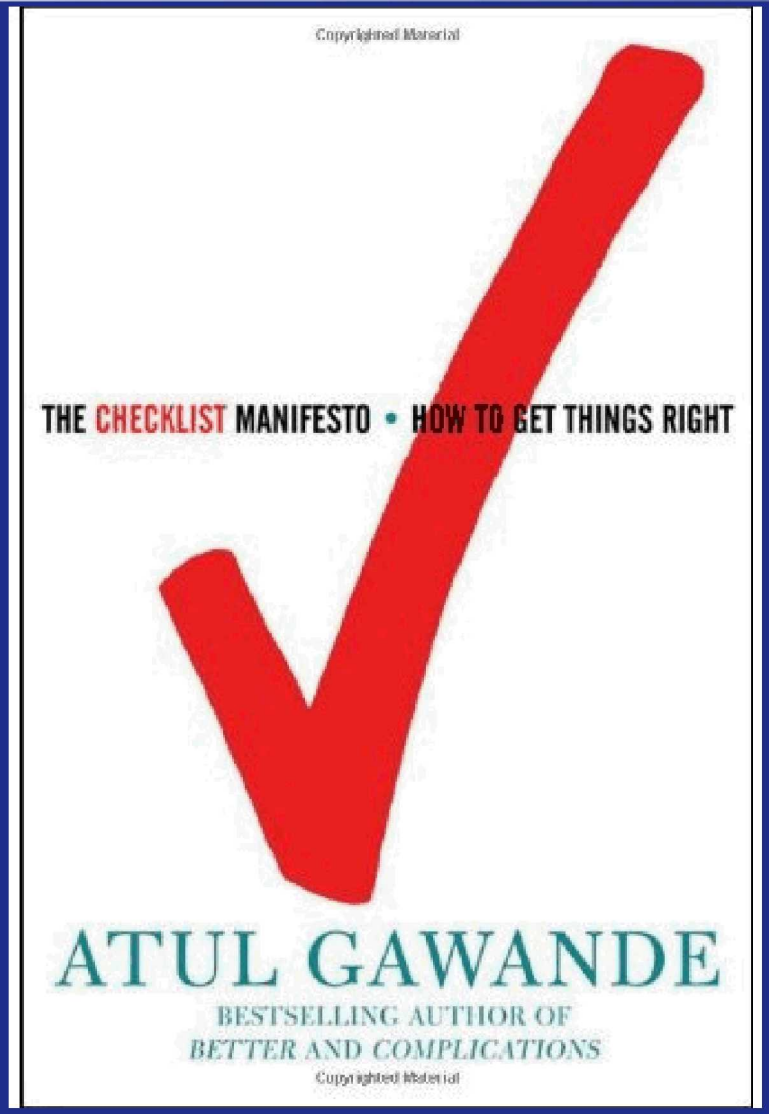


Atul Gawande, Harvard University



Keystone Initiative

uofmhealth.org

Keystone Initiative

uofmhealth.org

Nebraska's Ebola Patient-Specific PPE Checklists

PPE Donning and Doffing

Ebola Patients

These are standard Nebraska Biocontainment Unit Personal Protective Equipment procedures. These are developed to protect against Category A agents. Therefore, they vary slightly from CDC recommendations.

UNMC
UNIVERSITY OF NEBRASKA

Conclusion

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- Need to challenge the biosafety/biosecurity status quo
- Need to adopt the AMP model for biorisk management


Thank you.