SAND2011-0011P

Course Introduction

Introduction to Biorisk Management
Sana'a Yemen

January 15 – 17, 2011

BIOSECURITY ENGAGEMENT PROGRAM

SAND No. 2008-0480P, 2008-0480P, 2008-1138 C
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
for the United States Department of Energy's National Nuclear Security Administration
under contract DE-AC04-94AL85000.

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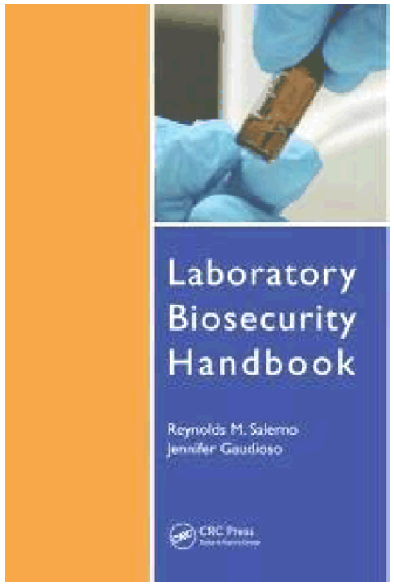
Sandia IBTR Mission and Goals

- **Mission: To enhance United States and international security by reducing biological threats worldwide**

- **IBTR's highest goals**
  - Promote the responsible use of biological agents, equipment, and expertise at bioscience facilities
  - Strengthen capacities to detect and control dangerous biological agents
  - Improve understanding and mitigation of accidental and deliberate biological risks



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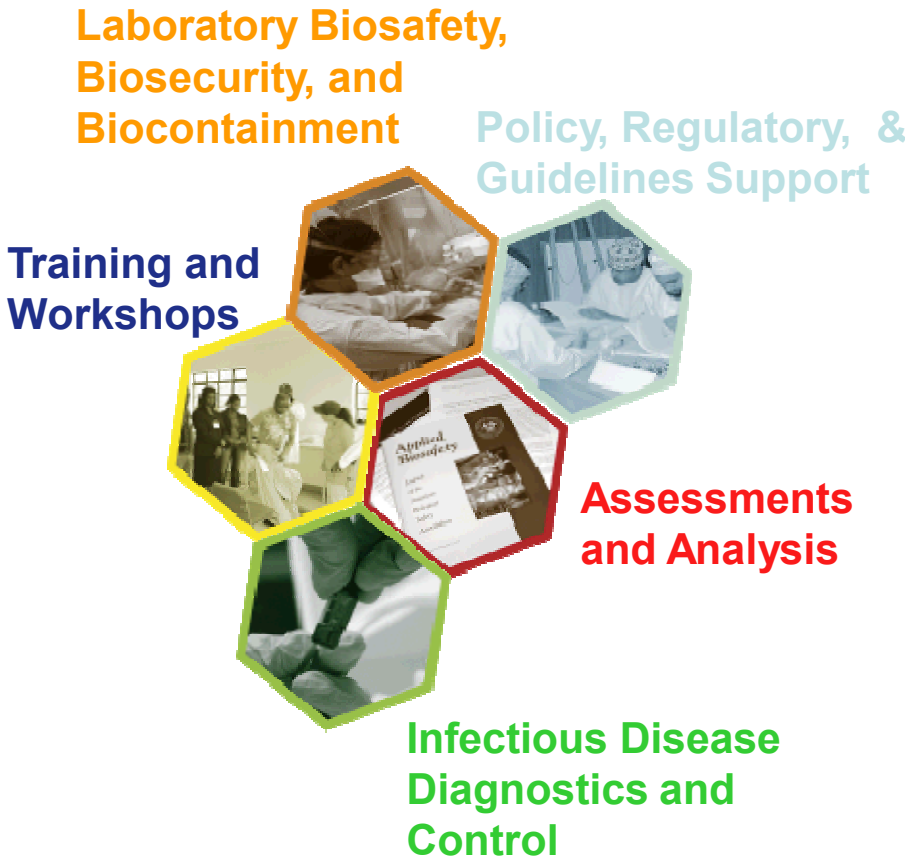
IBTR Program and Unique Technical Capabilities

- **Lab biorisk assessments**
  - Biosafety
  - Biosecurity
- **Biosecurity implementation**
- **Biorisk systems implementation**
- **Biorisk management training for labs**
- **Integrated systems approach to biothreat identification, prevention, and response**
- **Structured decision analysis tools**
  - Global/regional
  - National
  - Agent-specific



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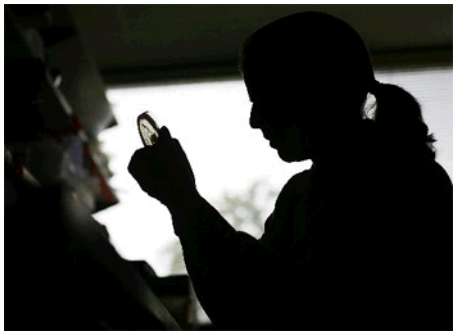
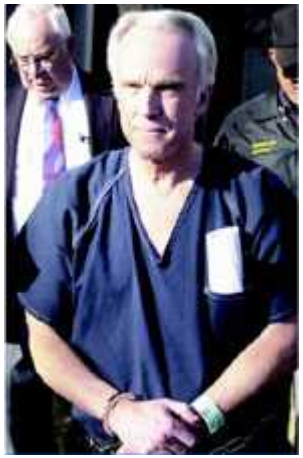
Examples of Safety and Security Issues Arising from Problems in Biorisk Management

- **Texas A&M University, United States, 2006 – 2007**
  - U.S. federal officials suspend all Select Agent research due to failures to report two incidents
- **Pirbright Laboratory, Institute of Animal Health, United Kingdom, 2007**
  - Leaks from pipes in the effluent system caused Foot and Mouth Disease outbreak
  - Pipes were known to need maintenance
- **Professor Thomas Butler, United States, 2003**
  - 30 vials of *Yesinia pestis* missing from lab (never recovered); Butler served 19 months in jail
- **Laboratory-acquired outbreaks of SARS, 2003 – 2004**
  - Singapore—September 2003
  - Taiwan (China)—December 2003
  - Beijing and Anhui (China)—March 2004



TAMU Select Agent researcher – Dallas Morning News



Thomas Butler

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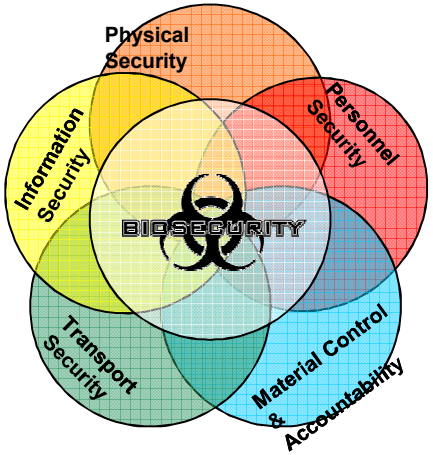
How Do You Avoid Similar Problems at Your Institution?

- **Laboratory biorisk management programs need:**
  - Appropriate resources
  - Institutional guidelines and operating procedures
  - Training
  - Oversight
- **But:**
  - How do you decide to allocate your scare resources?
  - How do you determine what needs to be addressed in operating procedures?
  - How do you determine which training is required for whom?
  - How do you determine what level of oversight is appropriate?

Biorisk Management Systems Approach

- **Need a cohesive framework for implementing a program to control biorisks**
  - Many elements to integrate
- **Example management systems used in labs**
  - ISO 9001:2000 – a quality management system
  - ISO 14001:2004 – an environmental management system
  - OHSAS 18001:2007 – an occupational health &safety management system
- **CEN Workshop Agreement, 2008 – laboratory biorisk management system**
  - Risk-based approach
- **All rely on a "Plan-Do-Check-Act" approach with the goal of continuous improvement**



Strengthening Biological Risk Management

Vision for Integrated BioRisk Management:

- ✓ Increased focus on "awareness" to change current culture
- ✓ Clarify terminology
- ✓ Development of targeted "training strategies"
- ✓ Securing "commitment" from key stakeholders, including government officials, who must be on board
- ✓ Continue increasing "capacity" based on Regional/Country needs and establish accountability through development of Country "report cards"

Course Outline

Course will include lecture, discussion, and activities

- **Key Modules include:**
  - Introduction to Biorisk management
  - Introduction to Risk **Assessment**
  - Introduction to Biorisk **Mitigation**
  - Discussions on diseases and laboratory needs in Yemen
  - Introduction to Biorisk Management **Performance**
- **This course is an introduction and summary of the key concepts**

Course Materials

- **The materials developed for this course are based on those currently owned and used by the WHO for its *Biorisk Management Advanced Training Programme*, and used here with permission of the WHO**
  - WHO Programme initiated in 2010
  - WHO Point of Contact: Nicoletta Previsani
- **Sandia/IBTR: co-developer of the programme and one of the principal trainers**

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Biorisk Management

Group exercise 1

Split into groups:

In your group, take 10 minutes to discuss and answer the following question:

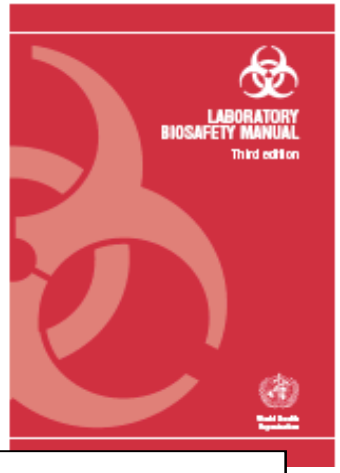
What are the risks of working in a laboratory with biological materials?

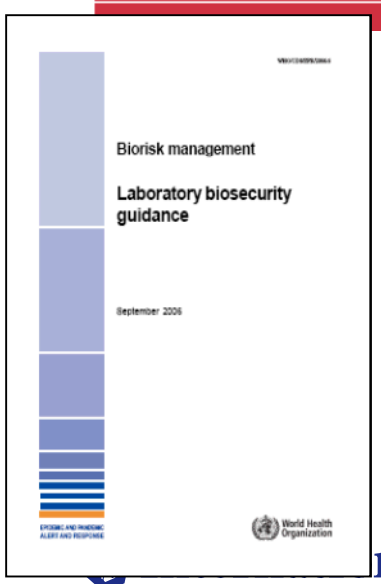
Write down your answers and be prepared to report to the class

Definitions[1]

- **Laboratory biosafety**: containment principles, technologies, and practices implemented to prevent **unintentional** exposure to pathogens and toxins, or their unintentional release

- **Laboratory biosecurity**: institutional and personal security measures designed to prevent the loss, theft, misuse, diversion, or **intentional** release of pathogens and toxins



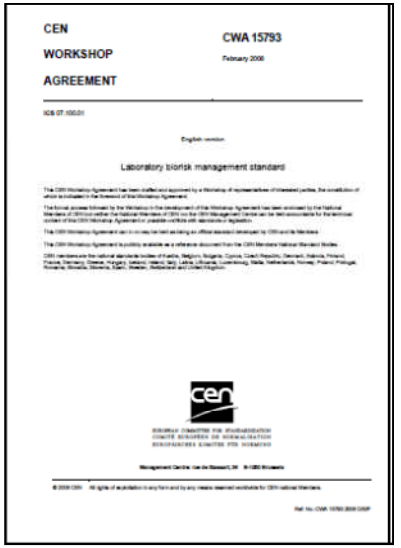


[1] *Laboratory biosafety manual, Third edition* (World Health Organization, 2004)

Laboratory Biorisk Management

- System or process to control **safety** and **security** risks associated with the handling or storage and disposal of biological agents and toxins in laboratories and facilities

- CWA 15793:2008


CEN
WORKSHOP
AGREEMENT

CWA 15793

February 2008

Laboratory biorisk management standard

Biorisk

- The risk associated with biological materials in the laboratory hasa safety and a security component

- Biorisk encompasses biosafety and biosecurity

Group exercise 2

In your group, take 10 min to discuss and answer the following three questions:

How do you identify these risks?

What are some things you can do to manage these risks?

How do you know that your risk management is working, and will continue to work?

Use *post-it notes* to write down your answers, one idea per note

Biorisk Management: the AMP Model

Biorisk Management =
Assessment, Mitigation, Performance

Key Components of Biorisk Management

- Biorisk **Assessment**

  Process of identifying the hazards and evaluating the risks associated with biological agents and toxins, taking into account the adequacy of any existing controls, and deciding whether or not the risks are acceptable

Key Components of Biorisk Management

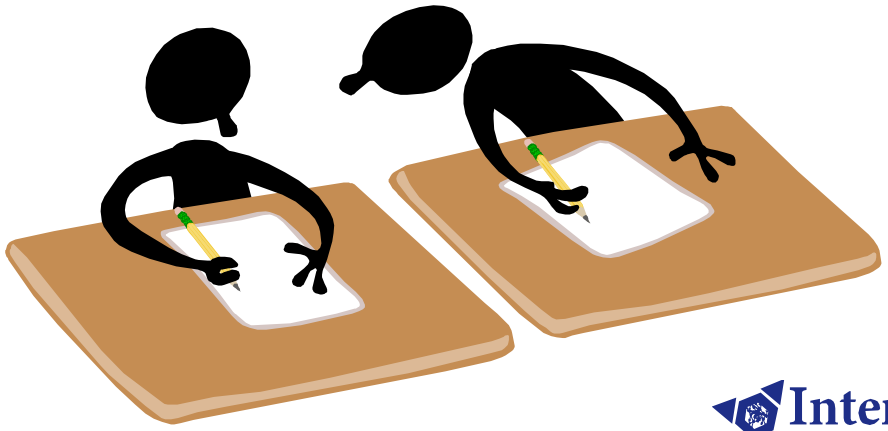
- Biorisk **Mitigation**

  Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins

Key Components of Biorisk Management

Performance

The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.



Group exercise 3

Let's get organized:

Take the *post-it notes*, and place them under one of the following columns:

Assessment	Mitigation	Performance

Key Components of Biorisk Management

- During the next sessions, we will always refer back to the AMP model and individually address the three components

Biorisk Management =
Assessment, Mitigation, Performance

Biorisk Assessment – Session 2

Biorisk Management =
Assessment, Mitigation, Performance

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Group Exercise 3, Step 1

Consider this scenario:

A young child is left alone in a kitchen while there is pot of water heating on the stove

- What could go wrong? List all the possibilities
- Choose the single most important risk for this scenario
- Identify the hazard for that risk
- 10 Minutes. Be prepared to report to the rest of the class

What is a hazard?

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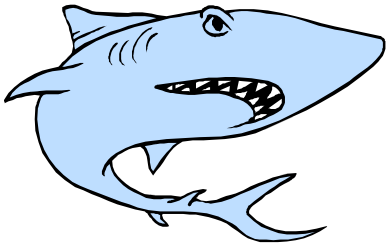
Hazard

- **Hazard** is a source that has a potential for causing harm



- **Hazard** is not a risk without a specific environment or situation

What is risk?

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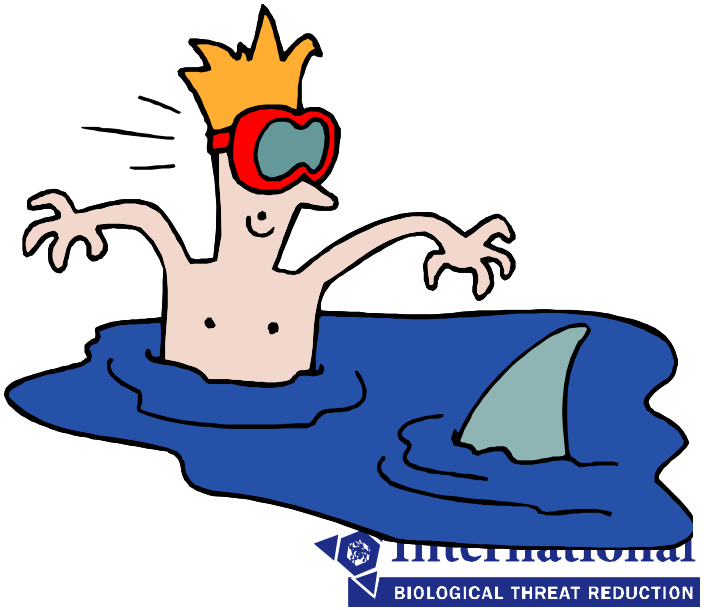
Risk

- Risk is the **likelihood** of an undesirable event, involving a specific hazard, that has **consequences**



Small Group Exercise 3, Step 2

Consider again the young child in the kitchen scenario:

Risk: child being burned by the boiling water

Hazard: pot of water heating on the stove

- Identify the factors that influence the likelihood and consequences of the risk.
- Write one factor per post-it note
- Evaluate the risk (low, moderate, high)
- Report your results to the class

Slide 28

bhb1 Can we give an allotted time on this slide?
Ben Brodsky, 12/1/2010

What would be different if the risk were the child being injured by an older brother, whose toy had just been broken by the younger brother?

What is the hazard (threat) now?

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What is the difference between a hazard and a threat?

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Hazard, Threat, and Risk

- A **hazard** is an inanimate object that can cause harm
- A **threat** is a person who has intent and/or ability to cause harm to other people, animals, or the institution
- A **risk** can be based on either a hazard and/or a hazard and a threat

Review: define risk, likelihood, and consequences?

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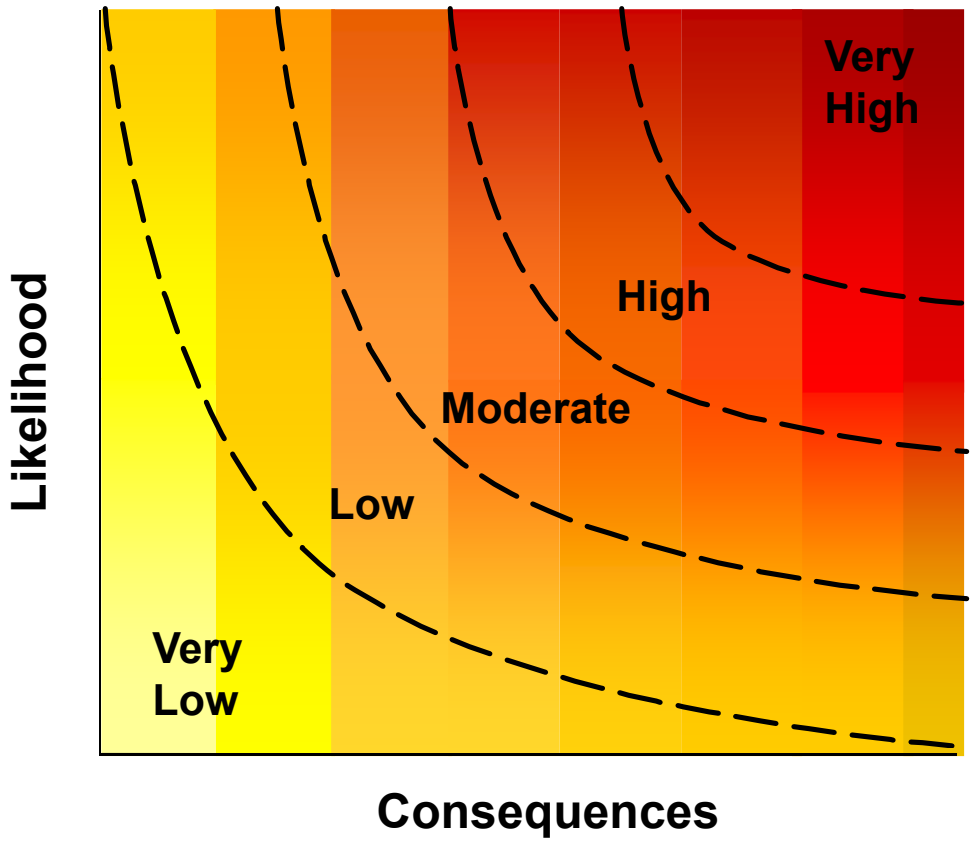
Risk, Likelihood, and Consequences

- **Risk** is the likelihood of an undesirable event, involving a specific hazard (or hazard and threat), that has consequences

- **Likelihood** is the probability an event occurring

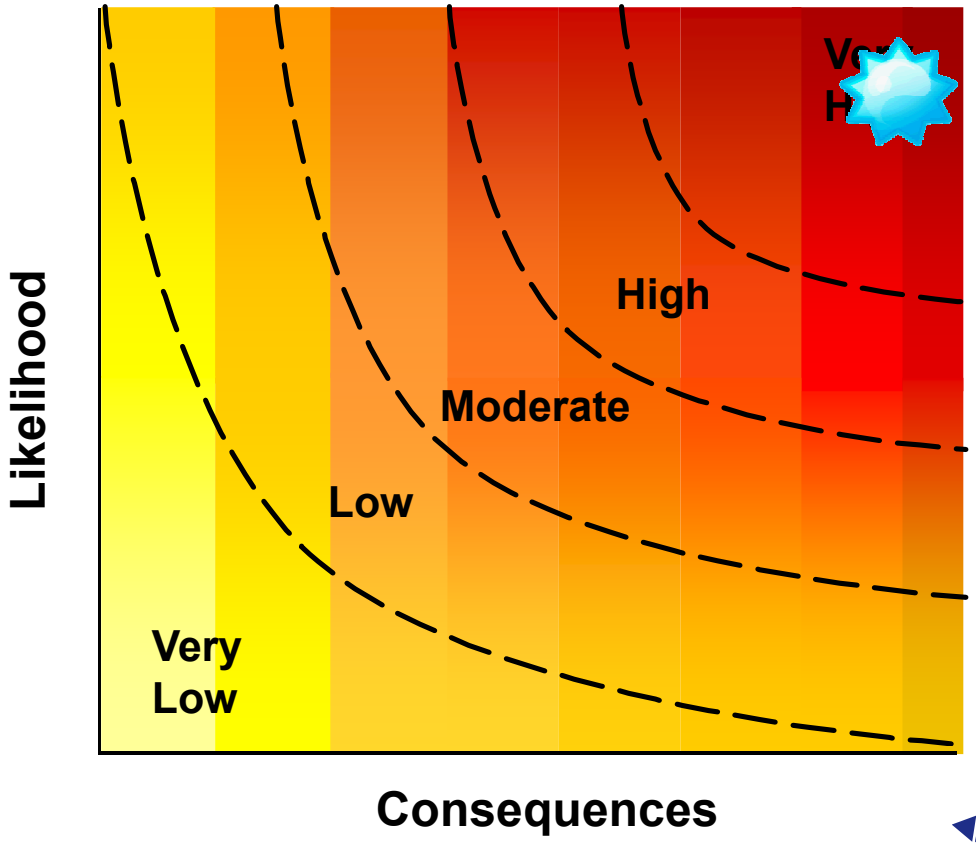
- **Consequences** is the severity of an event

Risk is a function of likelihood and consequences



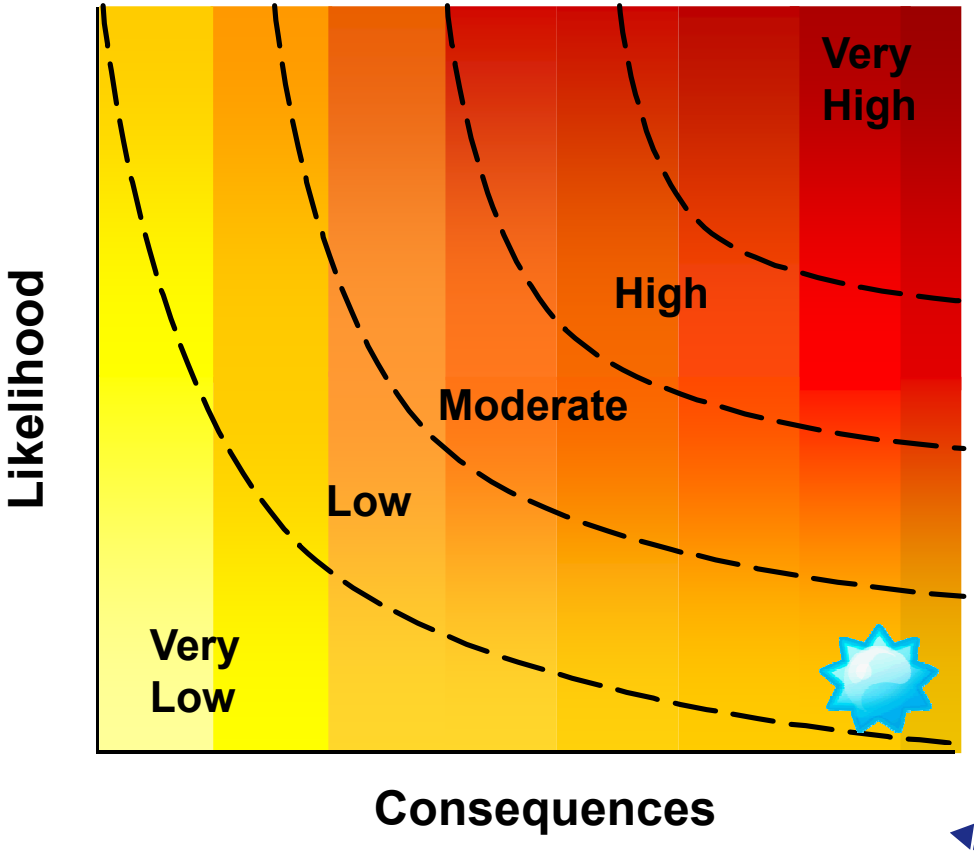
Risk Graph I

Large amount of boiling water on front of stove, step stool next to stove, child not restrained



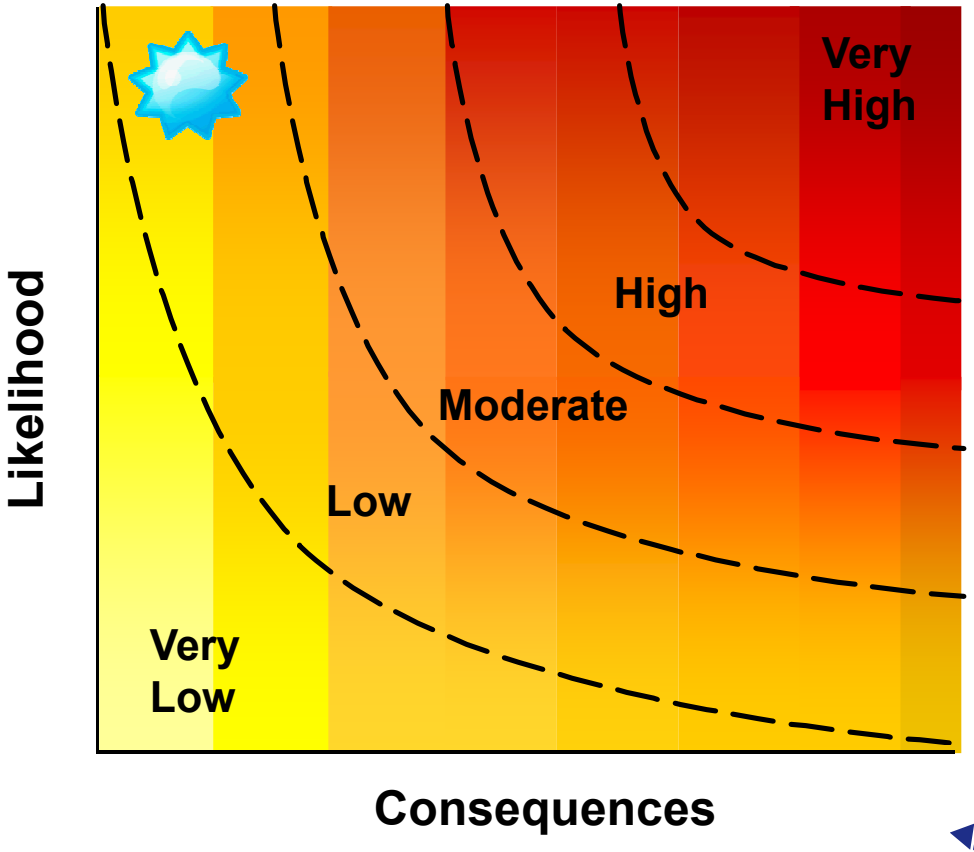
Risk Graph II

Large amount of boiling water, no step stool, child strapped in a high chair



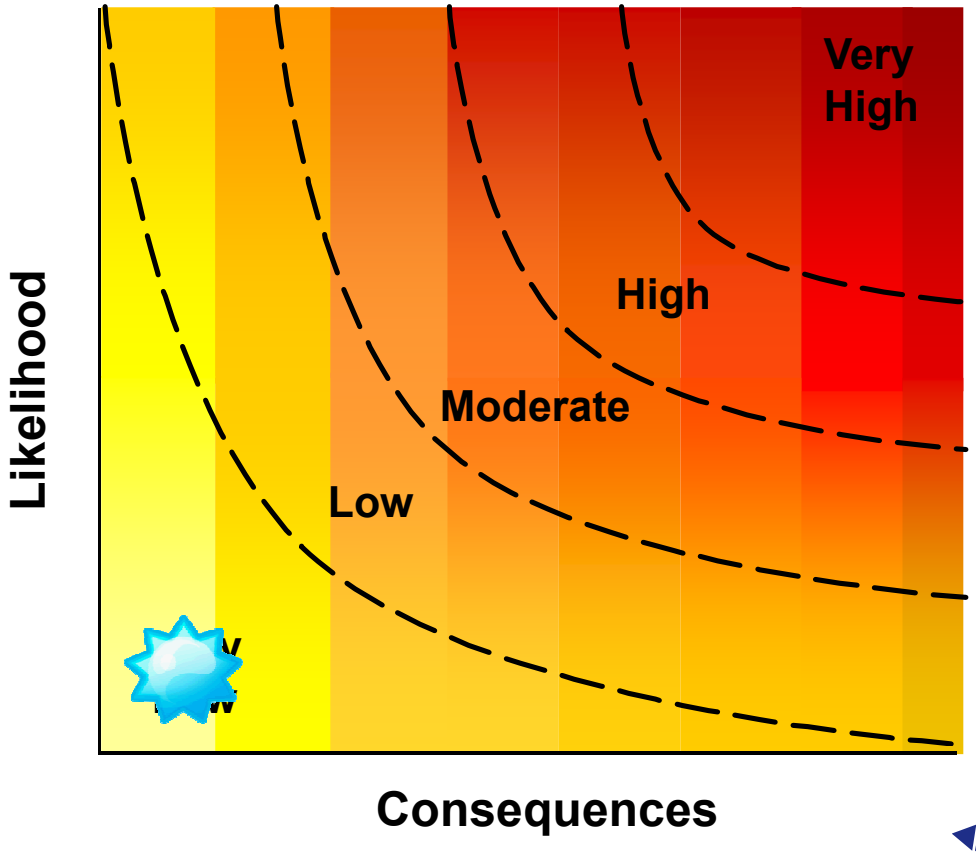
Risk Graph III

Small amount of cold water in the pan, step stool next to stove, child not restrained



Risk Graph V

Small amount of cold water, no step stool, child strapped in a high chair



Individual reflection

- How do you assess risk in your own labs?
- Write down your own answers, and then share with others at your table

If you wish, share with the class

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Group Exercise 4, Step 1

Consider the first biological scenario (WIV):

- Define the risks in this scenario
- Report out to the class

What aspect of biorisk did you focus on?

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Group Exercise 4, Step 2

Using the WIV scenario:

- Choose one risk to assess
- Define the hazard and/or threat
- Can you evaluate the risk of this scenario? If so, what is it (low/moderate/high)?
- Capture answers on a flip chart, and report to the class

Group Exercise 4, Step 3

Using the WIV scenario:

- What different types of information do you need to do a risk assessment?
- Use post-it notes, one idea per note, and place your post-it notes on a flip chart.

'Some bloke wants to know if we've carried out a thorough risk assessment?'

What are the benefits of a robust risk assessment?

Benefits of a Robust Risk Assessment

- Facilitate a risk assessment process that is reproducible, transparent, repeatable
- Facilitate risk mitigation decisions
- Provide quality control documentation

Summary

- **Hazard** (threat) is a source that can cause harm
- **Risk** is the combination of the likelihood and consequences of an undesirable event related to a specific hazard (or hazard and threat)
- **Likelihood** is the probability of an event occurring
- **Consequences** is the severity of an event

OPTIONAL SLIDES TIME AND INTEREST PERMITTING

What might be missing from this technical risk assessment?

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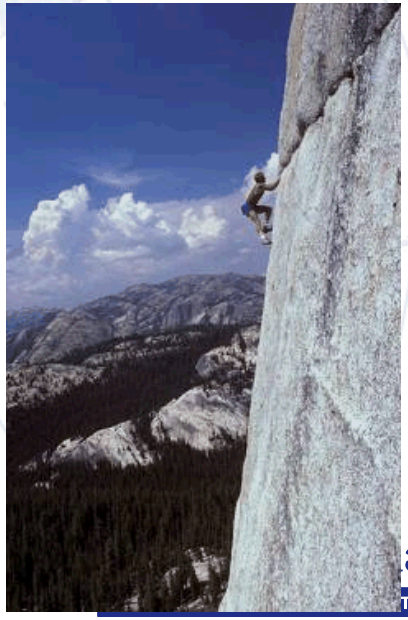
What is 'acceptable risk'?



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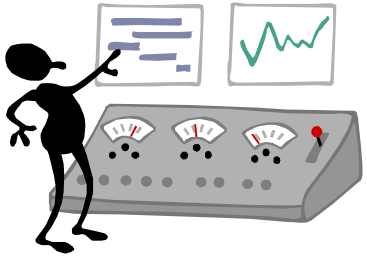
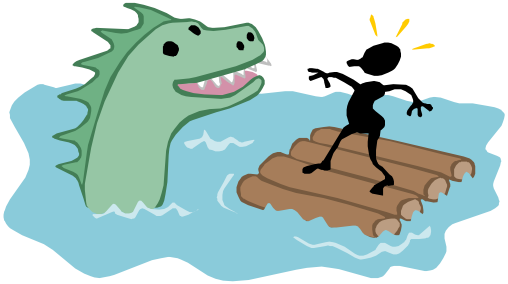
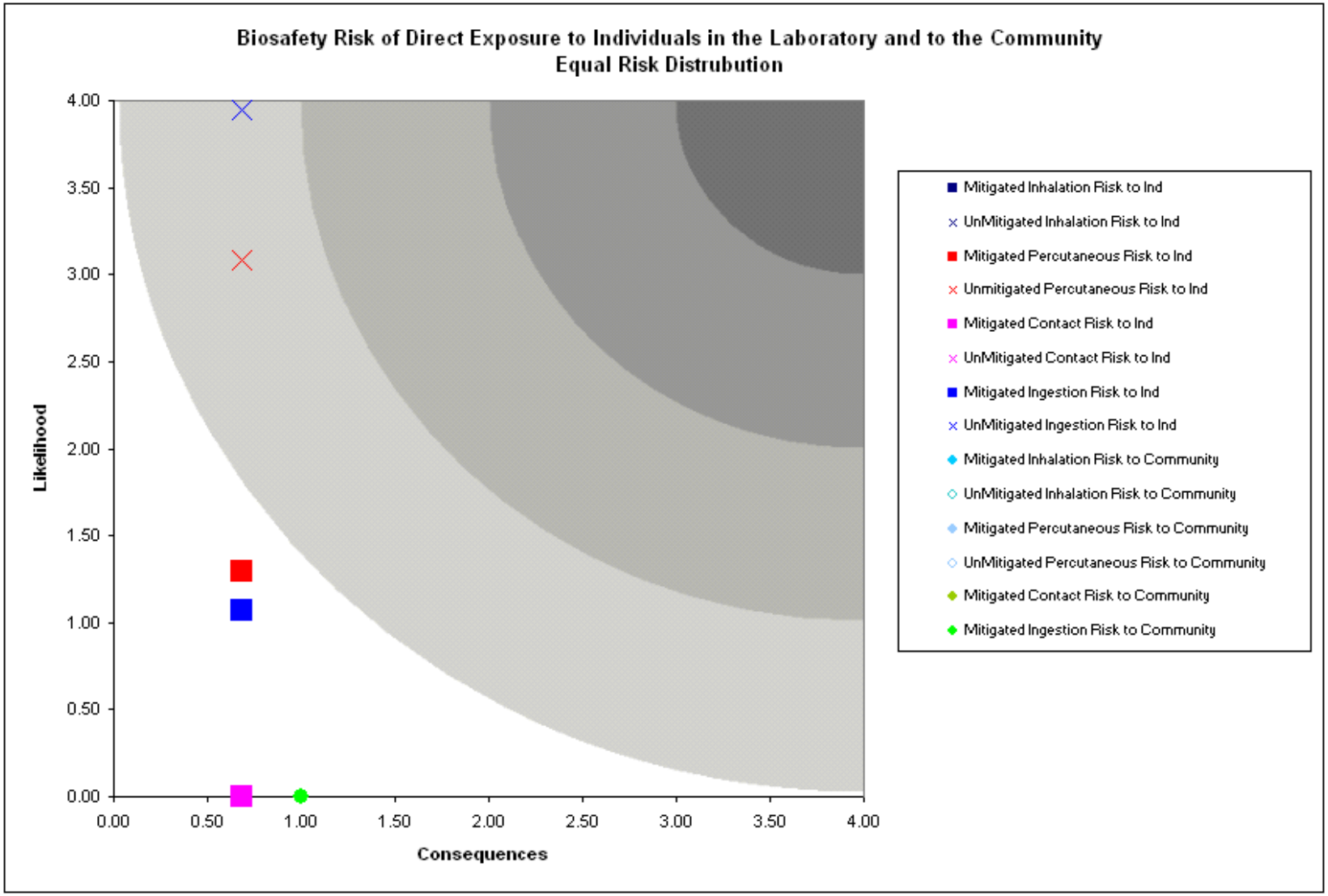
Technical Risk Assessment

- Technical risk assessments are generally based on scientific data and/or observations, and/or expert opinion



- Concern assessments are generally based on risks 'perceived' by management and/or the general public

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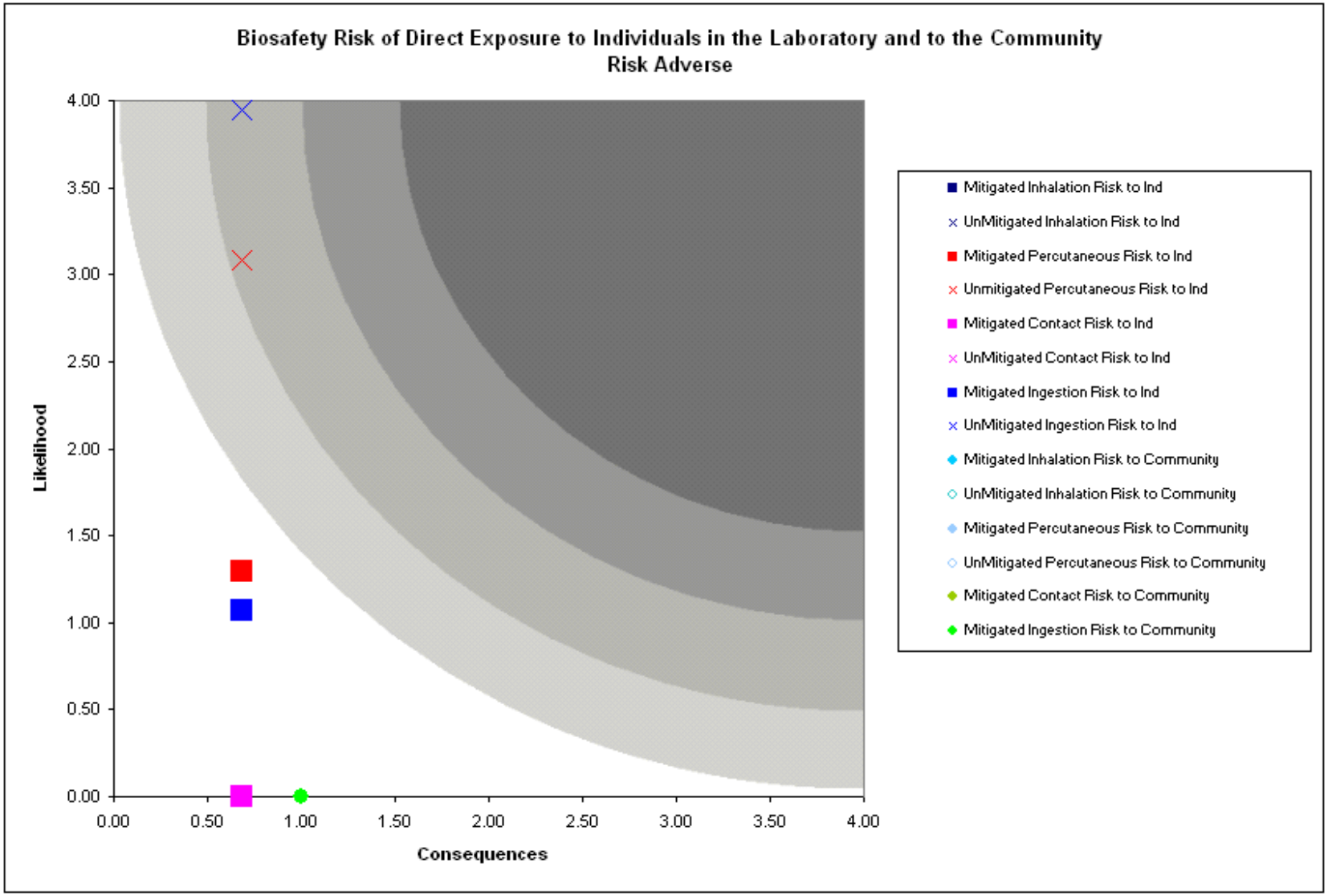
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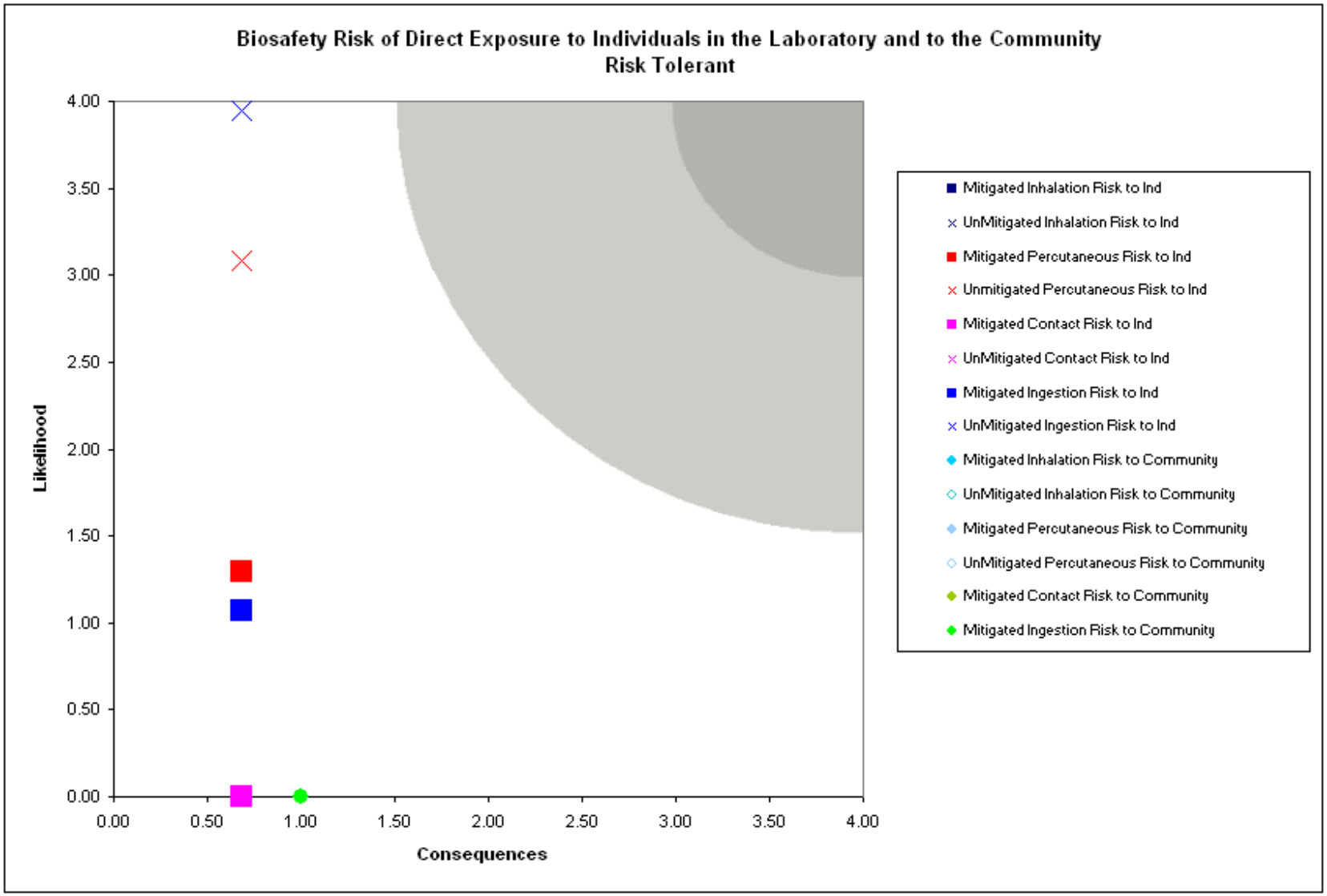
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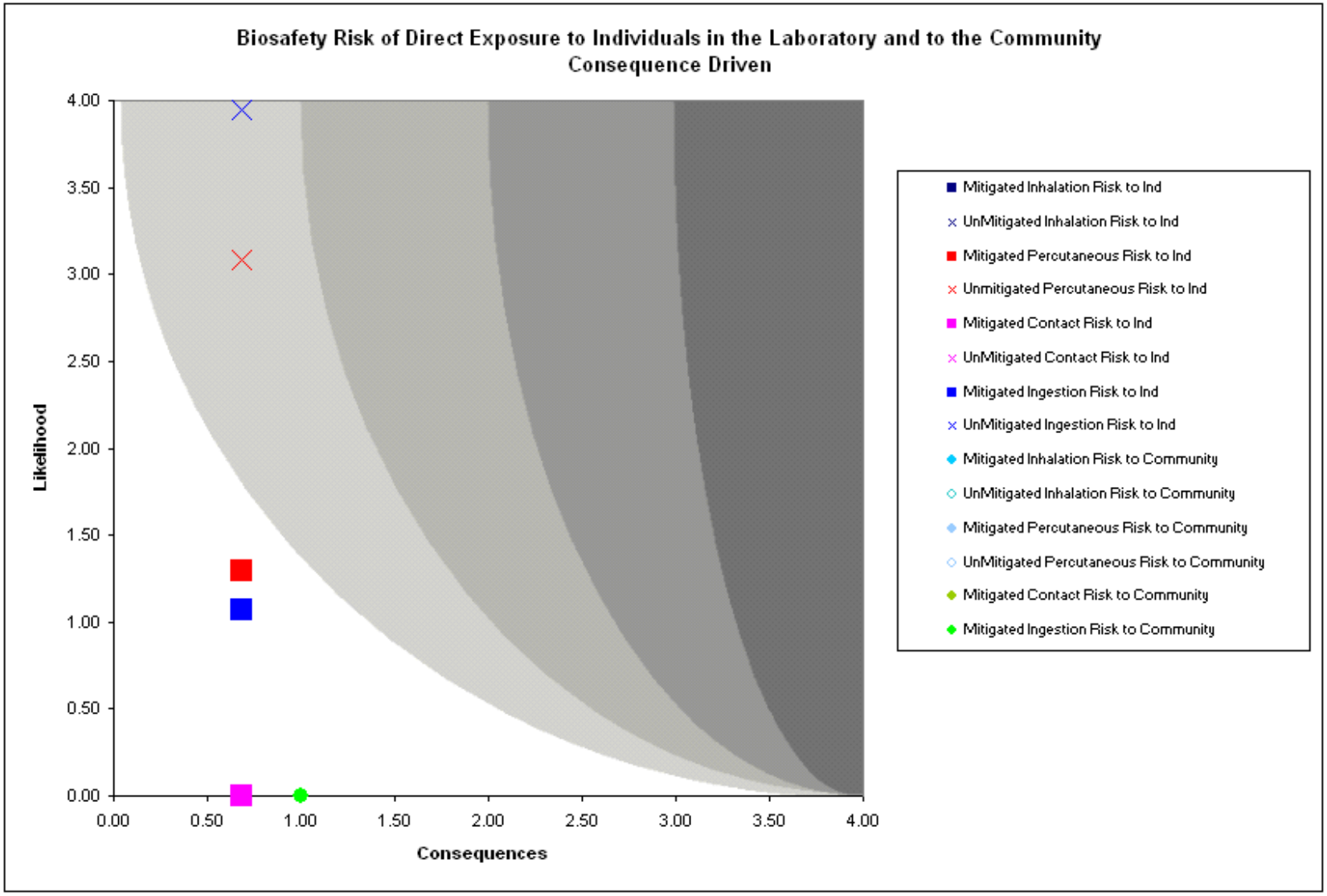
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Individual reflection

- What was new today?
- What insights have you had? What implications are there for you?
- What will you change when you return to your home institute?

If you wish, share your thoughts with the class

Summary III

- Technical risk assessments generally do not include perceived social, cultural, political concerns
- Risk acceptance will depend on the ‘owner’ of the risk: risk averse or risk tolerant

Biorisk Mitigation

Biorisk Management =
Assessment, **Mitigation,** Performance

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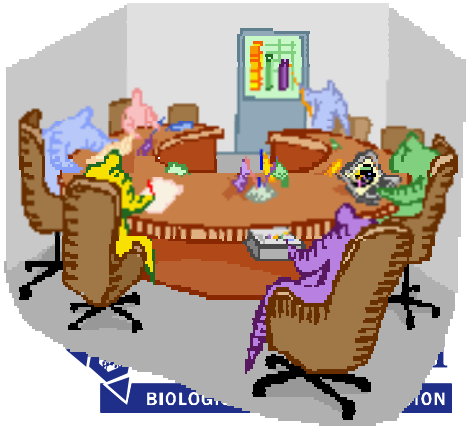
Group Exercise 5, Step 1

Using the WIV risk assessment scenario, identify six different risk mitigation measures

- At least Four for safety and
- Two for security

Use a *post-it note* for each mitigation measure you identify

Report on your answers to the class



Mitigation Control Measures

Five categories of mitigation control measures:

- Elimination or Substitution
- Engineering Controls
- Administrative Controls
- Practices and Procedures
- Personal Protective Equipment

Mitigation Control Measures

- Engineering Controls: Physical changes to work stations, equipment, materials, production facilities, or any other relevant aspect of the work environment that reduce or prevent exposure to hazards

Mitigation Control Measures

- Administrative Controls: Policies, standards and guidelines used to control risks

Mitigation Control Measures

- Practices and Procedures: Processes and activities that have been shown in practice to be effective in reducing risks

Mitigation Control Measures

- Personal Protective Equipment: Devices worn by the worker to protect against hazards in the laboratory





Group Exercise 5, Step 2

Place your *post-it notes* in the appropriate columns on the flip chart:

Engineering Controls	Administrative Controls	Practices and Procedures	Personal Protective Equipment (PPE)

Report your results to the class

Group Exercise 5, Step 3

Considering these mitigation control measures:

Elimination or Substitution

Engineering

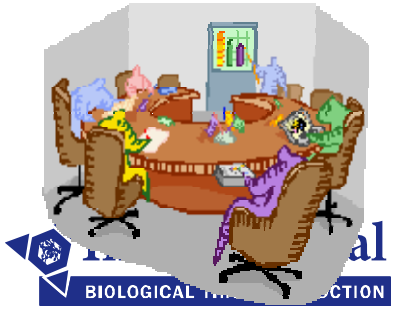
Administrative

Practices & Procedures

PPE

- Identify their advantages and disadvantages

Report your findings to the class

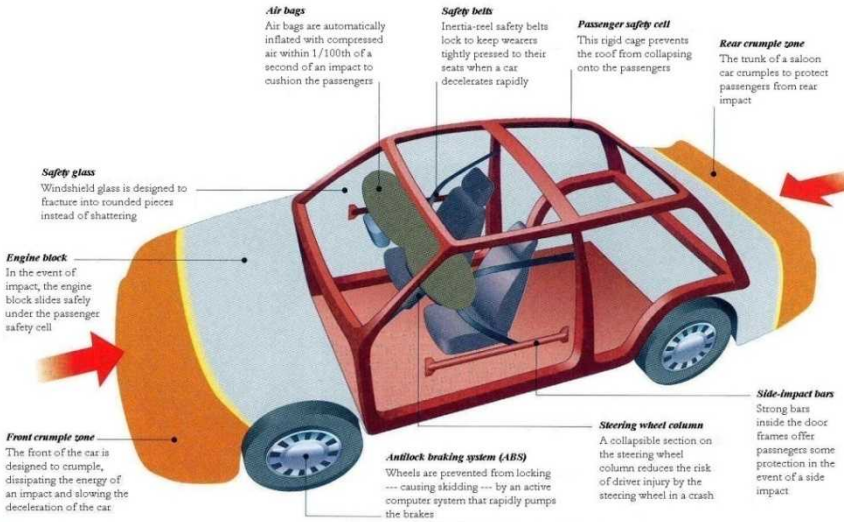


Advantages/Disadvantages

Control Measure	Advantages	Disadvantages
Elimination or Substitution	Most effective at removing risk	May not be feasible, or may impede laboratory work
Engineering	Efficient, eliminates hazard	Cost, complexity
Administrative	Authority approach	Indirect approach, primarily addresses the human factor
Practices & Procedures	SOP based (standardized approach)	Training and supervision requirements
PPE	Ease of use, relative cost	Does not eliminate hazard, PPE fails exposure happens, uncomfortable, limits ability

Control methods at the top of the list are in general more effective and protective than those at the bottom.

Car vs. Motorcycle Safety



- Car safety is all about engineering systems

- Motorcycle safety is all about PPE

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Video Clip

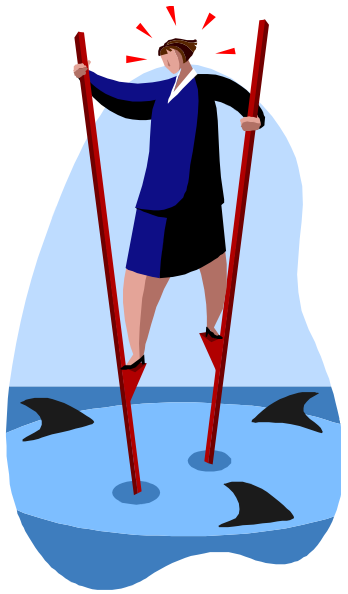
Which category of mitigation controls appears in this video clip?

Implementing Mitigation Measures

Mitigation measures should be implemented based on a thorough risk assessment.

Ideally, you should first consider elimination or substitution

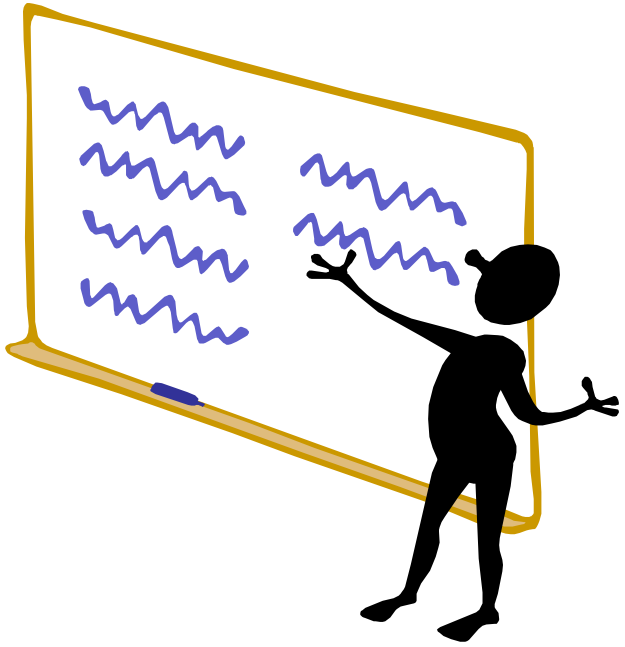
A combination of control measures should be used based on their effectiveness and your ability to implement them



Robust risk mitigation

A robust methodological approach to risk mitigation gives you the ability to:

- Justify decisions
- Evaluate the impact of certain risk mitigation decisions
- Compare the cost effectiveness of various risk mitigation decisions



Biorisk Management

Summary

- Four categories of mitigation control measures
  - Engineering Controls
  - Administrative Controls
  - Practices and Procedures
  - Personal Protective Equipment

- Implementing mitigation controls
  - Should first consider elimination or substitution
  - A combination of control measures should be used based on their effectiveness and your ability to implement them
  - Should be based on the results of the risk assessment, “acceptable” risk

Access Control Performance Video

- Secure research facility
- Risk assessment determined high likelihood for outside intruder
- As you watch, write down all the risk mitigation steps that you see

Biorisk Performance – Session 4

Biorisk Management =
Assessment, Mitigation, **Performance**

What is performance?

In what way does performance improve biorisk management?

Or…what specific steps are still missing from the system after assessment and mitigation?

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Performance

Performance is the way in which someone or something functions

Performance is the result of all the efforts of a company or organization

Performance improves biorisk management: you know that your system works and is sustainable, and that the risk is acceptable

Group Exercise 6, Step 1

Split into groups

Review the performance scenario

- Identify the performance issues/problems in the scenario
- Write each issue on a separate *post-it* using a felt-tip marker

Place *post-its* on your flip chart

Present to the class

How could you categorize these performance issues?

Performance

Application:
Processes, procedures, structures, and responsibilities to manage biorisk. Applying, working, doing the mitigation

Assurance:
Systematic process of checking the system through audits and inspections

Advancement:
Setting and achieving biorisk management goals; improving existing mitigation or adding new mitigation based on based on internal and external feedback.

How does performance affect risk over time?


Biorisk Management =
Assessment, Mitigation, Performance
Risk identification
Hazard/threat identification
Likelihood evaluation
Consequences evaluation
Elimination or Substitution
Engineering Controls
Administrative Control
Practices and Procedures
Personal Protective Equipment
Application
Assurance
Advancement

Group Exercise 7, Step 1

Individually, carefully read the *Cataract University* exercise

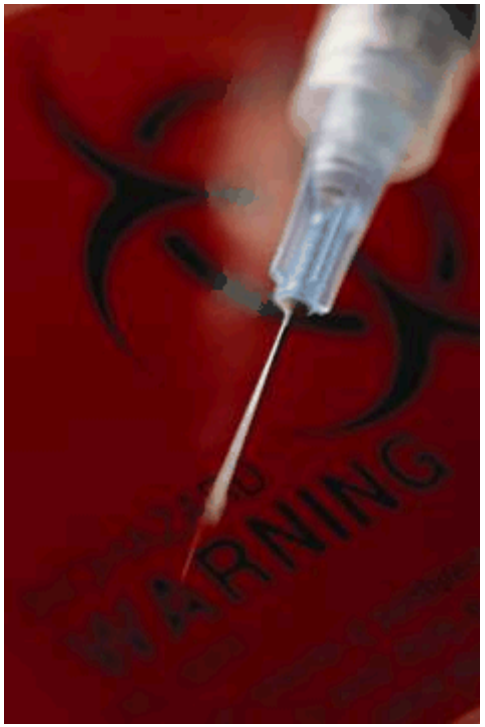
Split into groups

- Identify ***problems*** in Assessment, Mitigation, and Peformance
- Use post-it notes, one for each problem
- Place post-it notes on “university board” in appropriate section

How have these problems affected the university?

Report out results to full group

- International -
Laboratory Biorisk Management Standard
CWA 15793:2008



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Laboratory Biorisk Management Standard CWA 15793:2008

CWA 15793:2008

is a

Management System Standard

Consistent with other international standards such as ISO 9001 / 14001 and OSHAS18001

Contains definitions, requirements and notes for guidance

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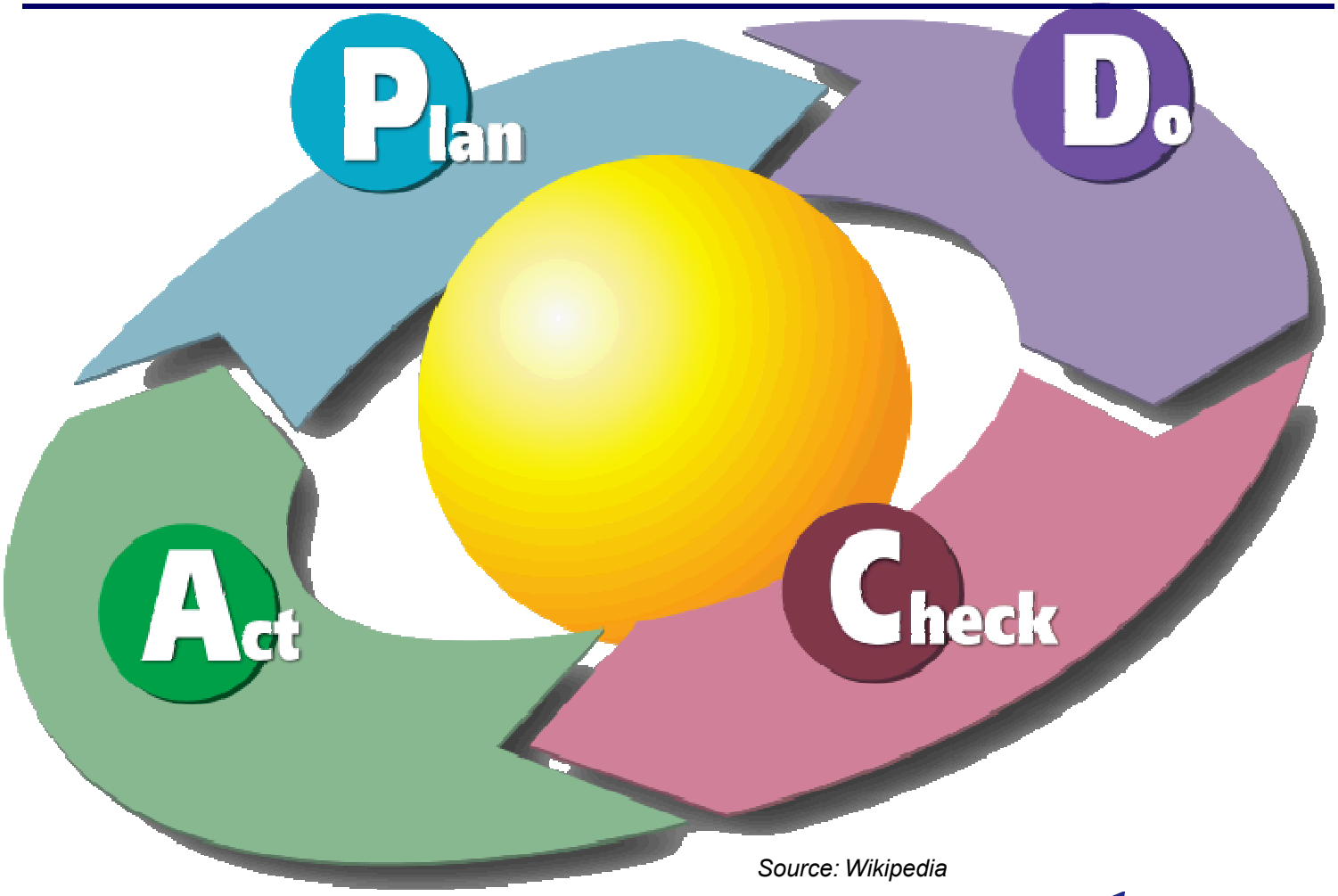
What is a Management System?

- A framework that integrates best practices and procedures
- Ensures that an organization can effectively achieve all of its objectives
- Frequently built around the **Plan, Do, Check, Act** cycle

Systematic Approach



Source: Wikipedia

Purpose of the CWA 15793:2008

The Standard can be used for:

- Improving overall laboratory biorisk performance
- Increasing awareness of biosafety and biosecurity risk
- Effective management of complex laboratory safety and security processes
- Improving international laboratory collaboration and safety harmonization
- Basis for new or revised legislation or regulations
- Support laboratory certification/accreditation, audits/inspections

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Scope

- **The Standard is <u>not</u> a technical document**
- **The Standard is Performance oriented**
  - Describes what needs to be achieved
  - How to do it is up to the organization

Scope

- **The Standard is <u>not</u> intended to replace any national or sub-national regulatory requirements that may apply to the laboratory/facility**
  - Compliance with regulatory requirements is mandatory

Integration

- **The standard is designed to complement other management standards**
  - ISO9001 (Quality)
  - ISO14001 (Environmental)
  - OHSAS18001 (Occupational Health and Safety)

Content

CWA 15793:2008

- Extensive Definition Section
- **Policy, Planning, Implementation & Operation, Checking and Corrective Action, Review**

Conclusions…

- ***Adoption and implementation of the CWA 15793:2008 will be an integral part of the future biorisk management agenda for laboratories worldwide and a necessity to protect people and the environment as well as building community confidence***

Group Exercise 7, Step 2

In the same groups, use the table of contents of the CWA15793 to develop recommendations for change at Cataract University

- Identify ***solutions*** for Assessment, Mitigation, and Performance
- Identify the specific paragraphs in CWA 15793 that apply to your selected solutions

Record your conclusions on a flip chart

Report the results to class

CWA 15793:2008

Examples of topics covered:

- Biorisk Management Policy
- Hazard identification, risk assessment and risk control
- Roles, responsibilities and authorities
- Training, awareness and competence
- Operational control
- Emergency response and contingency plans
- Inventory monitoring and control
- Accident and incident investigation
- Inspection and audit
- Biorisk management review


CEN
WORKSHOP
AGREEMENT
CWA 15793
February 2008
English version
Laboratory biorisk management standard

BIOSECURITY ENGAGEMENT PROGRAM

International
BIOLOGICAL THREAT REDUCTION

Individual Reflection

How does AMP apply to your own lab?

How could you improve biorisk management at your own lab, short-term and long-term?

What would be the challenges of implementing AMP?

What would be the benefits of implementing AMP?

Write your answers on a piece of paper; you only have to share your answers if you wish

Summary I

How does performance improve biorisk management?

- You know that your system works and is sustainable, and that the risk is acceptable

Three components of performance

- Apply, assure, and advance

CWA 15793:2008: Laboratory Biorisk Management standard

- Plan, do, check, act

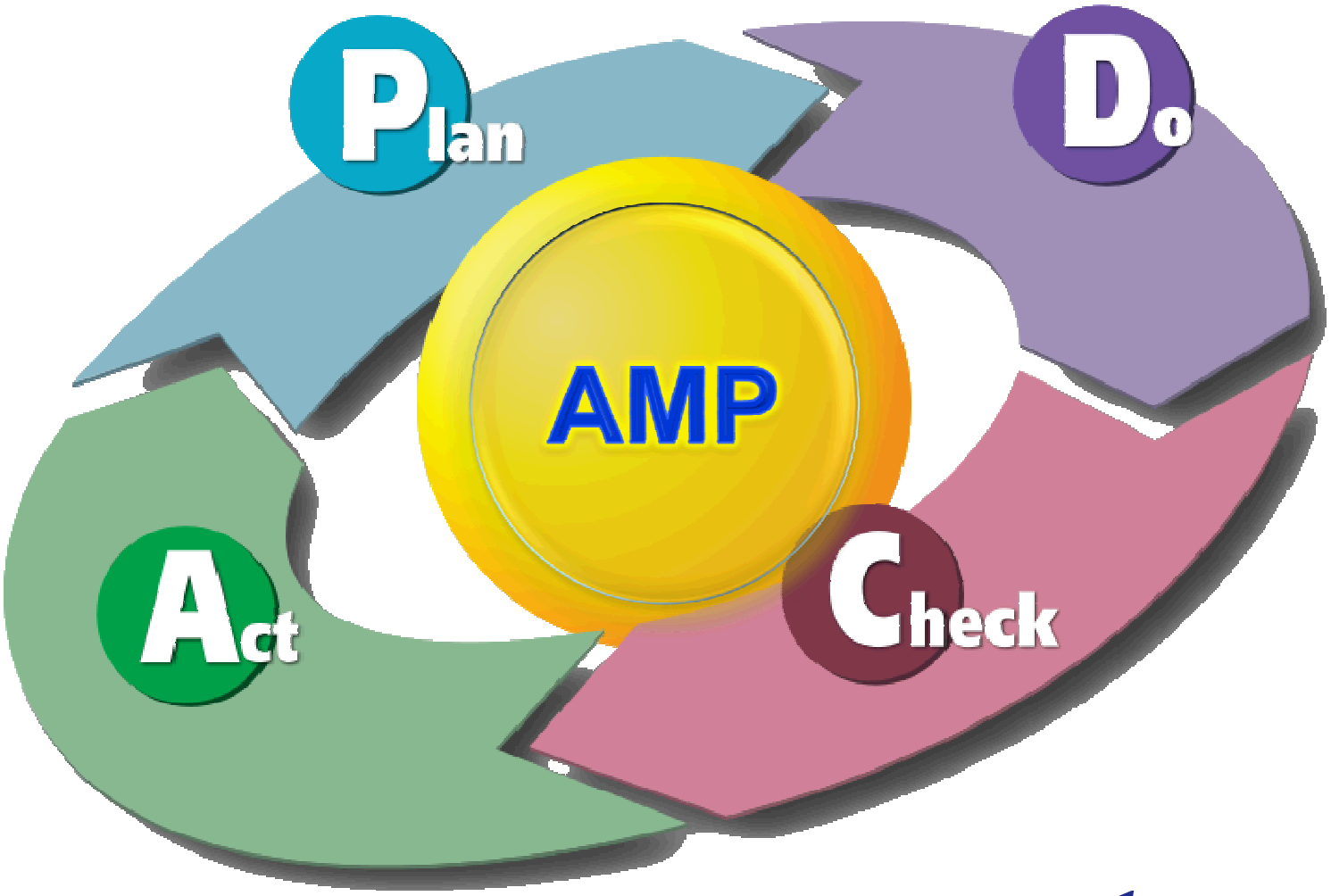
Summary II

The AMP model

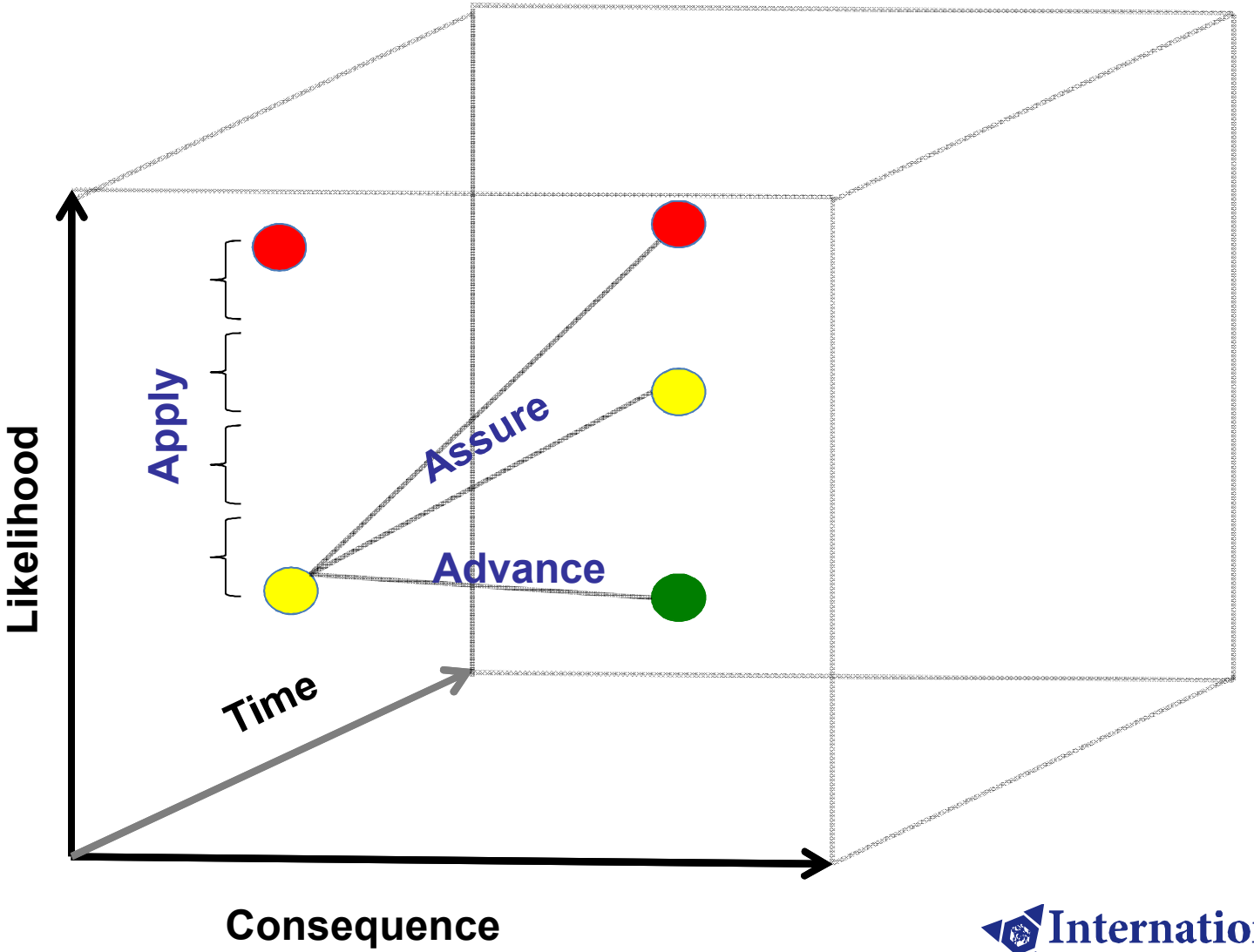
- Assessment = Plan, Do, Check, Act
- Mitigation = Plan, Do, Check, Act
- Performance = Plan, Do, Check, Act

Mitigation is improved and sustained when performance measures are included

CWA 15793:2008


Plan
Do
AMP
Act
Check

OPTIONAL SLIDES TIME AND INTEREST PERMITTING


Likelihood
Apply
Assure
Advance
Time
Consequence

Group Exercise 1, Step 2

Organize the performance issues that you identified into either

- Application
- Assurance
- Advancement

Present your results to the class