SAND2012-10656P

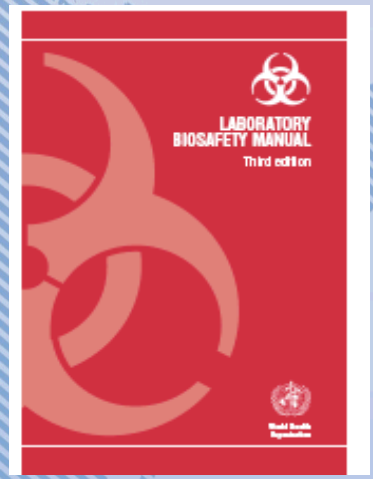
# Biorisk Management Overview

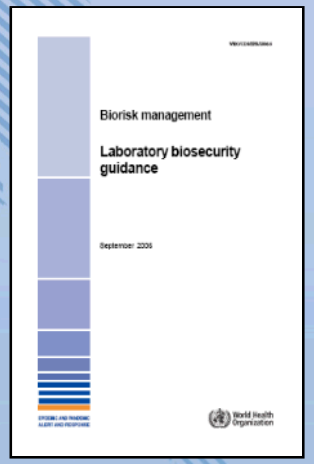
# Group Activity

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

# Definitions

- **Laboratory biosafety**: containment principles, technologies, and practices implemented to prevent unintentional exposure to pathogens and toxins, or their unintentional release[1]
- **Laboratory biosecurity**: protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release. [2]




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

[2] Biorisk management - Laboratory biosecurity guidance (World Health Organization, 2006)

# Biorisk

- The risk associated with biological materials in the laboratory

- Biorisk encompasses biosafety and biosecurity
  - **Consider the risks we have just discussed!**

# Risk

**Question:** What is "**risk**"?

**In your groups**, please spend **5 minutes** to develop a **definition** for "**risk**". Choose someone from your group to share the definition with the class.

What did your group come up with?

# Risk

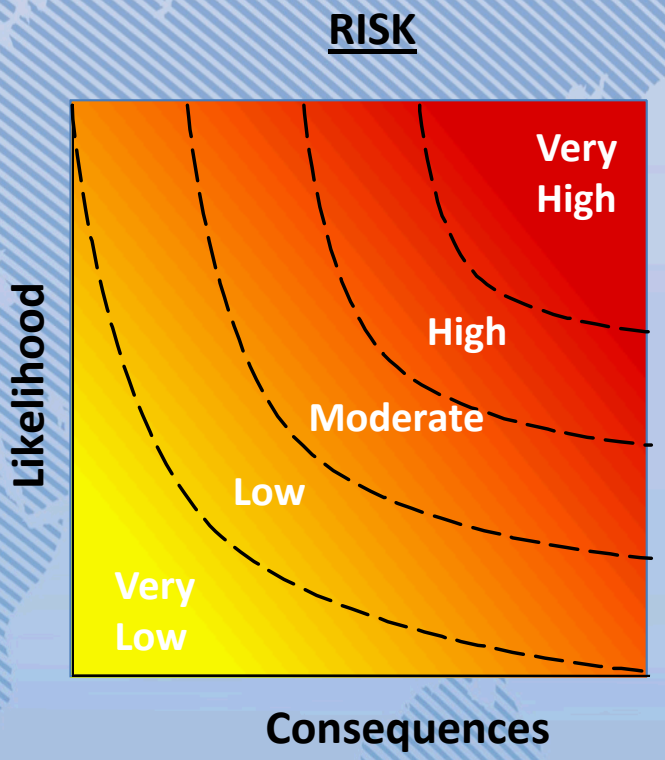
**Question:** What is Risk?

***Risk is the likelihood of an undesirable event happening, that involves a specific hazard or threat and has consequences***

**Risk = f (likelihood, consequences)**

or, more simply,

**Risk** is a function of both the **Likelihood** of something happening and **Consequences** of that occurrence



# Hazards and Threats

Part of this process is the identification of the appropriate **hazard** or **threat**.

The **hazard** or **threat** is the **source** or **causative agent** of a particular **risk**.

The term **hazard** is used in the **biosafety** context, and **threat** is used in the **biosecurity** context.

# Risk Assessment

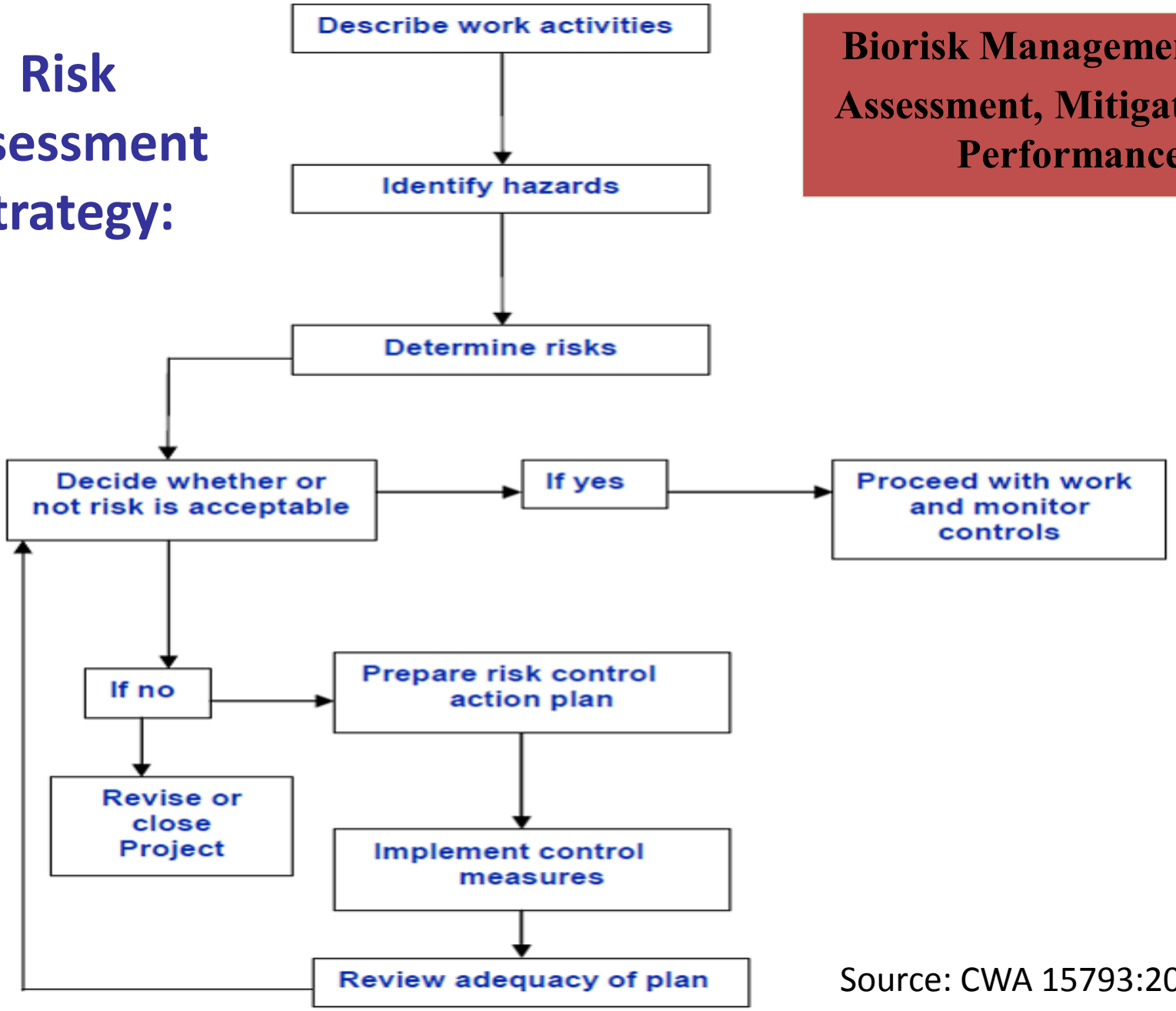
**Question: How do you perform a risk assessment?**

In your group: Develop a step-by-step strategy for performing **either**:

- An assessment of a **biosafety** risk
- An assessment of a **biosecurity** risk

# Risk Assessment Strategy:

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




Source: CWA 15793:2011

# Risk Assessment

**Remember: Risk characterization requires consideration of several categories of information**

For example (for biosafety risk assessment):

- Agent properties
- Procedures
- Lab Operation
- Infrastructure
- Environmental and Community
- Personnel

# Risk Characterization

**Some factors to consider when conducting a risk characterization:**

## Agent Properties

- Pathogenicity / Virulence
- Infectious Dose
- Potential Outcome of Exposure
- Potential Routes of Infection
- Stability of the Agent in the Environment
- Morbidity / Mortality
- Availability of Therapeutic Interventions

# Risk Characterization

**Some factors to consider when conducting a risk characterization:**

## Laboratory Activities

- Concentration of the Agent
- Clinical Samples vs. Cultures
- Volume of Material Manipulated
- Use of Sharps
- Procedures that Generate Aerosols
- Procedures that Could Result in Splashes or Splatters
- Genetic Manipulations
- Use of Infectious Agents in Animals

# Risk Characterization

**Some factors to consider when conducting a risk characterization:**

## Laboratory Infrastructure

- Heating, Ventilation, and Air Conditioning (HVAC) System
- Open Windows
- Public Access
- Work Surfaces
- Work Flow
- Pest Control
- Equipment

# Risk Characterization

**Some factors to consider when conducting a risk characterization:**

## Human Factors

- Level of Training
- Level of Experience
- Proper Technique
- Workload and Fatigue
- Health and Immune Status of the Workforce

# Risk Characterization

**Some factors to consider when conducting a risk characterization:**

## Operational Factors

- Good Laboratory Practices
- Housekeeping and Cleanliness
- Use of Biological Safety Cabinets
- Use of Personal Protective Equipment
- Proper Decontamination
- Waste Management
- Occupational Health
- Other Administrative Controls

# Risk Characterization

**Some factors to consider when conducting a risk characterization:**

## Environment and Community Factors

- Presence of the Agent in the Environment Around the Laboratory
- Immune Status of the Community
- Population Density of the Community
- Presence of Suitable Hosts or Vectors

# 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

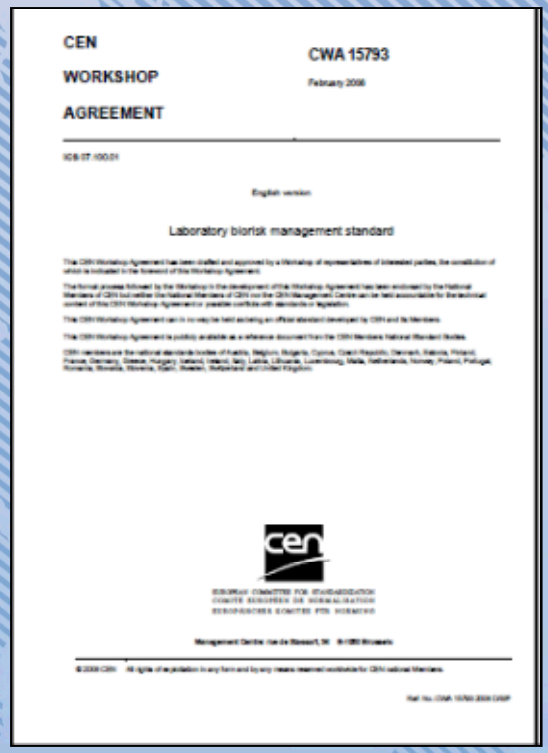
- **Performance**
  - The implementation of the entire biorisk management system, including evaluating and ensuring that the system is working the way it was designed. Another aspect of performance is the process of continually improving the system.

# Biorisk Management: The AMP Model

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

# 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



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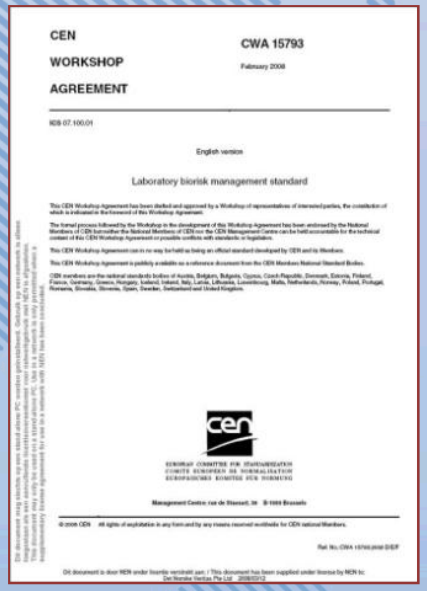
CWA 15793

February 2006

Laboratory biorisk management standard

# CWA 15793:2011 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



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CWA 15793

February 2008

English version

Laboratory biorisk management standard

# Review of Biorisk Management

- Biorisk Management = Biosafety + Biosecurity
- Biorisk Management System is a means to reduce Biorisk
- AMP = Assessment, Mitigation, Performance
- CWA 15793 outlines a comprehensive, international biorisk management system framework