Introduction to Biorisk Management

	Biorisk Assessment - Session 2 **Day 1 11:15 - 14:00** **Day 2 09:00 – 11:00**	**Time**
11:15 Objectives	The purpose of this session is for participants to: • Understand what is risk • Understand the components of a suitable risk assessment methodology, and the critical resources required • Understand the difference between a technical risk assessment and "acceptable risk," or a concern assessment.	Slide 1
	Opening slide: Risk management = **Risk assessment**, Risk mitigation, Performance. *Risk assessment is highlighted*.	
Group Exercise 3, Step 1	**In groups** (10-minute activity) Consider this scenario: a young child is left alone in a kitchen while there is boiling water on the stove. Use post-it notes and flip charts. 1. What could go wrong? List all the possibilities. 2. Choose the single most important risk for this scenario 3. Identify the hazard for that risk Allow 10 minutes of discussion. Start with first table and ask them to report some of their possibilities. Write them on a flip chart. Query additional tables to add to the list of possibilities (risks). Have the whole class vote through plenary session which is the single most important risk and discuss what the hazard for the risk is (this should be accomplished in an additional 10 minutes)	20 minutes Slide 2

	Ideally they will conclude that the most important risk is "Child being burned by the boiling water" and the hazard is the boiling water. However, if they come up with something else, that is OK the purpose of this discussion is to get the group thinking about what a hazard is and what is a risk.	
	Expected responses: • The water boils over and splashes the child • The child reaches the hot stove and burns fingers • The child climbs on a chair and pulls over the hot water and is scalded • If a gas stove the child could turn on the gas burner and cause an explosion	
11:35 Plenary Discussion	**ASK:** **What is a hazard?** • Hazard is a source that has a potential for causing harm • Hazard is not a risk without a specific environment or situation **ASK:** **What is risk?** • Risk is the likelihood of an undesirable event, involving a specific hazard, that has consequences	10 minutes Slides 3-6
11:45 Group Exercise 3, Steps 2 and 3	**In groups** (15-minute activity) **Consider again the two-year-old in the kitchen scenario.** Risk: child being burned by the boiling water Hazard: pot of boiling water on the stove • Identify the factors that influence the risk • Categorize the risk factors as influencing the likelihood or consequences (or both) • Group post-it notes accordingly • Evaluate the risk (low, moderate,	35 minutes Slide 7 - 8

	high) • Report your results to the class (additional 10 minutes) Have them put down one factor per post-it note. It would be nice if each group had their own wall or chart to be able to post their notes, select a speaker for the group and report back to the class their factors and whether they consider the risk low or high.	
	Expected Responses likelihood • The location of the pan on the stove • The ability of the child to reach the pan • Whether or not the child is restrained • The temperament of the child • The availability of something for the child to climb up on • How high/large the stove is **Expected responses consequences** • The amount of water in the pan • The temperature of the water in the pan • How much water spills • The type of clothing the child is wearing • Where the burn occurs/extent of the burn • How quickly first aid is administered **Expected responses that affect both** • How long the child is left alone • The age/size of the child	
12:20	Break	15 minutes
12:35 Debrief	Need to differentiate the risks Need to assess each risk separately Need to have clear questions about likelihood and consequences **Need to have access to information about the situation** Need for a structured process for	5 minutes

	assessing risk **Point out how these factors can be grouped, e.g. the pot, the child, and the environment.**	
12:40 Plenary Discussion	**ASK in general to the group:** **What would be different if the risk were the child being injured by an older brother, whose toy had just been broken by the two-year-old?** **Capture answers on a flip chart** • The child being unattended • The size, age of the older brother • Whether the older brother is carrying something that could be used as a weapon • The general demeanor of the older brother **ASK:** **What is the hazard (threat) now?** • The older brother **ASK:** **What is the difference between a hazard and a threat?** • 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 threat	10 minutes Slide 9-11
12:50 Key Learning Messages	**ASK:** **How do we define risk, likelihood, and consequences?** • Risk is the likelihood of an undesirable event, involving a specific hazard, that has consequences • Likelihood is the probability of an event occurring • Consequences is the severity of an event **Show:** **Demonstrate how to use the risk graph with the two-year-old in the kitchen scenario**	Slide 12-18 15 minutes

12:50 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	15 minutes Slide 18
13:05	**Yemeni presentation or Yemeni-led discussion of biorisk priorities in Yemen**	55 minutes
14:00	Note: Remind participants to review the WIV scenario (in handouts) overnight and be prepared to evaluate the risks with your groups tomorrow. **Adjourn**	
DAY 2 – 9:00	**Review of Day 1**	20 minutes
09:20 Group Exercise 4, Step 1	**In groups** **Consider the Hairy Infectious Virus (WIV) scenario** • Define the risks in this scenario After 10-15 minutes, allow a minute or two for each group to report one unique risk. Prompt each group to identify a unique risk, and capture all the unique possible risks. The more unique risks such as those listed below they identify the better step 2 will be.	20 minutes Slide 20
	Possible Responses: • Accidental auto-inoculation to the researcher • Accidental needlestick to the technician • Animal bite from the mouse • Splash or contact exposure to viral culture • Loss of research data • Improper data collection/poor results • Theft of research material by the technician or researcher • Infected mouse escaping from the facility • Theft of research material by an outsider	
9:40 Plenary Discussion	**ASK:** **What aspect of biorisk did you focus**	5 minutes Slide 21

	on? **Expected responses:** • Most will likely focus on safety, and not security Engage group in a discussion about risk assessors generally assessing the risks that they are most comfortable with. **Key Learning Message** • "We assess what we know," and this can bias our assessment and/or lead to a limited assessment	
9:45 Group Exercise 4, Step 2	**In groups** **Return to the WIV scenario.** 1. Choose one risk to assess 2. Define the hazard and/or threat 3. Can you evaluate the risk of this scenario? If so, what is it? (low/moderate/high) Ideally each group will have a separate risk to evaluate. However, with many groups, some groups will have duplicates. You may need to assign risks to assess to each group selected from the list of risks identified in step 1. Prepare a graph at the front of the room with likelihood and consequence axis. Have each group place a labeled post-it note (or star) on the graph where they believe the risk lies.	20 minutes Slide 22
10:05 Group Exercise 4, Step 3	**In groups** **Return to the WIV scenario.** • What different type of information do you need to do a risk assessment • Use post-it notes, one per category, and place your post-it notes on a flip chart.	30 minutes Slide 23
	By reminding the class of the categories from the earlier scenario (pot, child, environment), elicit specific categories, such as • Agent properties (Morbidity, mortality, treatment and prevention, routes of transmission, communicability, agent stability) • Laboratory Activities (Conc.,	5 minutes Slides 24 - 29

	clinical vs. culture, volume, use of sharps, procedures, genetic manipulations, use of animals) • Laboratory itself (infrastructure, such as floors, walls, cabinets, benches, and other existing elements that contribute to risk, such as animals) • People; Human factors; Level of training, experience • Mitigation measures (four categories) • Environment (including the community) **Key Learning message:** whenever you do a RA, you need to ask specific questions that cover all of these categories	
10:40 Plenary Discussion	**ASK:** **What are the benefits of a robust risk assessment?** • Facilitates risk assessment process; repeatable/reproducible, transparent • Facilitates risk mitigation decisions • Allows for comparison of risks; can see if risk changes over time • Helps to communicate risk • Helps in determining risk acceptability • Provides quality control documentation	10 minutes Slide 32-33
Plenary Discussion	**ASK: What might be missing from this technical risk assessment?** **Expected response:** • Perceived social, cultural, political concerns **ASK: What is "acceptable risk"?** **Expected response:** • Will depend on the "owner" of the risk: risk averse or risk tolerant	10 minutes Slides 35-41
Individual Reflection	**ASK:** • What was new today? • What insights have you had? What implications are there for	15 minutes Slide 42

	you? • What will you change when you return to your home institute? If you wish, share your thoughts with the class.	
Recap of Key Messages	**Key Learning Messages** • Hazard (threat) is a source that has a potential for causing harm • Risk is the combination of the likelihood and consequences of an undesirable event related to a specific hazard (or threat) • Risk can be expressed as an equation R = f (L,C) where ✓ Likelihood is the probability of an event occurring ✓ Consequences is the severity of an event • Benefits of a robust risk assessment ✓ Facilitates risk assessment process; repeatable/reproducible ✓ Facilitates risk mitigation decisions ✓ Provides quality control documentation • 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	5 minutes Slides 43
10:50	**BREAK**	

Introduction to Biorisk Management

	Biorisk Mitigation - Session 3 **11:05 -14:00**	**Time**
Objectives	The purpose of this session is for participants to: • Understand how biorisk mitigation fits into the AMP model • Understand the principal categories of control measures for biorisk management • Understand some key advantages and disadvantages of each principal category of control measures	
11:05	Introduce BioRAM	5 minutes Slide 1
11:10 Introduction to Risk Mitigation	Opening slide: Risk management = Risk assessment, **Risk mitigation**, Performance. *Risk mitigation is highlighted.* Review the AMP model. **ASK: What is mitigation?** Elicit from the class a definition for mitigation.	5 minutes Slide 2-3

11:15 Group Exercise 1, Step 1	**In the groups:**
	Using the WIV risk assessment scenario (15 minutes),
	• Identify at least 6 different potential risk mitigation measures
	  ○ four for safety,
	  ○ two for security
	• Use a post-it note for each mitigation measure
	Report to the class (15 minutes)
		30 minutes
		Slide 4

11:30 Instructor led	• 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 or threats* • Administrative Controls: *Policies, standards and guidelines used to*	10 minutes Slides 5-9

	control risks • Practices and Procedures: *Processes and activities that have been shown in practice to be effective in reducing risks* • Personal Protective Equipment: *Devices worn by the worker to protect against hazards in the laboratory*	
Note to Facilitator	Prepare four flip charts with a header for each of the controls	
11:40 **Group Exercise 1, Step 2**	**In your groups:** Place your post-it notes in the appropriate columns on the flip charts (10 minutes) • Engineering controls • Administrative controls • Practices and procedures • PPE Report your results to the class (10 minutes)	20 minutes Slide 10
12:00 **Group Exercise 1, Step 3**	**In the groups:** Assuming 8 groups, assign each group a control measure, and have them list all advantages and disadvantages for the control measure, 1 per post it note. Place post its on appropriate flip chart. (5 minutes) Note to facilitator:to engender friendly competition, have two groups working on the same control measure category. (give them different colors of post its) Discussion of results (5 minutes)	10 minutes Slide 11
12:10 **Instructor led**	Present the advantages and disadvantages for each control measure. Provide several examples using their supplied list of mitigation. Present the industrially accepted standard "hierarchy of controls" as what is generally considered the most effective to the least. Discuss the top of the list "Elimination or substitution". Tie it back to the WIV scenario and some of the mitigation controls they have already come up with to prioritize.	15 minutes Slide 12
12:25 **Debrief**	Use the analogy of the car versus the motorcycle to illustrate the decision-making challenge and that you have to work with what you've got. **Key Message:** • Industrially accepted standard "hierarchy of controls"	5 minutes Slides 13

12:30	**Break**	15 minutes
12:45	**Play the incident response video clip.** **ASK: Which category of mitigation controls appears in this video clip?** **Have them write down as many mitigation controls that they see. As a group try to identify as many as possible:** Hard hats (PPE) 2319 code, drill, training (admin/Practices and procedures) Red emergency button (engineering controls) Flashing lights (engineering controls) Cameras (engineering controls) Duck and cover drill (practices and procedures) Hazmat suits (PPE) Barriers, doors, pull down separation (engineering controls) Tongs (engineering controls/practices procedures) Decon chamber/incineration (Engineering) Decon Shower (engineering) Accident counter (admin, engineering) Separation of the coffee/food area from the work zone (admin) Management buy in (admin) Training and supervision (admin) **Play the video a second time, and point out mitigation measures that they identified.**	20 minutes Slide 14
13:05 **Plenary Discussion**	**Implementing mitigation measures** • 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 – 'acceptable risk'	10 minutes Slides 15
13:15 **Session 3 Summary**	**Key Message –** A robust methodological approach to risk mitigation gives you the ability • to justify decisions • to evaluate the impact of certain risk	5 minutes Slides 16

	mitigation decisions • to compare the cost effectiveness of various risk mitigation decisions **Show the updated AMP model and flow chart**	
13:20 Recap of Key Messages – Session 3	**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, and should give a "wow" effect	5 minutes Slides 17-18
13:40	**Adjourn**	

Introduction to Biorisk Management

	Performance - Session 4 **9:00 – 14:00**	**Time**
Objectives	The purpose of this session is for participants to: • Understand the role of Performance in biorisk management • Identify key elements of Performance • Apply Performance concepts to biorisk scenarios • Consider Performance issues that will improve biorisk management	
9:00	**Review of Days 1 and 2** **"Game show" format for review** Have each group come up with a list of five questions based on the material from days 1 and 2. Group 1 asks Group 2 a question, Group 2 asks Group 3 a question, etc. Award points.	30 minutes
9:30 Introduction	**Introduce the Access Control Performance video.** Tell participants they are going to see a video. Set the background for the story: At a secure and secret research lab a risk assessment was done and it was determined that there was a high likelihood that an intruder would try to break into the lab to steal secrets. Based on the risk assessment, the management for the facility has implemented a number of risk mitigation steps. **As Individuals.** Write down as many risk mitigation steps that you can see After the video. Have each group discuss the video and identify as many risk mitigation steps that they can. Query the group to identify (and write down on flip chart) the various mitigation efforts **Expected answers**: • Palm check • Belly button check • Nasal check • Foot check • Mom check	15 minutes Slide 1-2

	• Security guard and "pass" check Repeat video if necessary/desired. **ASK:** Did the mitigation work? **Obvious answer:** No **ASK:** Why not? **ASK:** Considering the AMP model, what is missing from this risk management scenario? **Expected answer:** Performance	
9:45 Introduction **Key Questions to Address**	**ASK:** Choose one of the following questions and discuss with your group: What is performance? **Expected answer**: • the way in which someone or something functions • the ultimate result of all the efforts of a company or organization In what way does performance improve biorisk management? **Expected answer**: • You know that your system works and is sustainable, and that the risk is acceptable Or...what specific steps are still missing from the system after assessment and mitigation? **Expected answer:** • Steps that allow us to check and/or verify the assessment and the mitigation measures are working properly. ○ Ex. Lab inspections, assessments, program reviews, audits, QA/QC, etc...	20 minutes Slides 3-4
Note to Trainer	• Hand out the "performance" scenario • Have each group identify the performance issues/problems in the scenario • Remind them to write each issue on a big, separate card using a felt tip marker	
10:05 Group Exercise 1, Step 1 **Identifying**	**In Groups**. You have 15 minutes. 1. Read the scenario (5 minutes) 2. Identify the performance issues/problems	30 minutes Slide 5

Performance: Control, Assurance, Improvement	in the scenario (10 minutes) 3. Write each issue on a post-it note, and place on a flip chart (5 minutes) Report your results to the class (10 minutes)	
	Answers could include: • Internal audits • Autoclave records • Medical surveillance • Lack of training (lab workers, transport company) • Contractual language • Incident reporting • Transfer of accountability	
10:35	**Break**	15 minutes
10:50	Show the slides that shows the definitions of: • Application • Assurance • Advancement	5 minutes Slide 6-9
Group Exercise 1, Step 2	**In your groups:** Organize the performance issues that you identified into either • Application • Assurance • Advancement Present your results to the class	30 minutes
	• Have the groups cluster the performance issues they identified into either Application, Assurance, or Advancement • You can choose to do this one group at a time, or one concept at a time During the debrief, probe the groups' responses, and drill for full understanding Note: any of the problems could fall into any of the three categories depending on the where in the process the issues fall. For example: autoclave records could fall under "Application" if the organization is not keeping any records. It could fall under "Assurance" if they are keeping records	

	but no one is checking the records to ensure accuracy and completeness and they could fall under "Advancement" if the organization is not working on ways to improve record keeping or if the information in the records are inadequate. **Expected Answers:** **Application** • Autoclave records • Records storage • Staff on leave/transfer of responsibilities • Incident reporting • Contractual language **Assurance** • Internal and external audits • Maintenance of equipment • Health surveillance **Advancement** • Training of staff • Training of transport company • Establishing goals • Soliciting internal and external feedback	
10:55 **Plenary Discussion**	**In plenary discussion:** Select examples developed by students during the exercise. Show/discuss how these examples can fit into the three categories (AAA) of performance. Emphasize the overlap between the three categories, and that almost any example can fit under any of the three categories. **ASK:** How does performance affect mitigated risks over time? Group discussion should be guided to the following conclusions: • Performance is the doing or implementing the mitigation (**Application**) • Performance includes checking to make sure the mitigation is working the way it is supposed to. (**Assurance**) • Without performance your risk may be much higher than what you think it is • Application and Assurance help you keep mitigated risks at the same level over time,	15 Minutes Slide 9

	but it is the third category **Advancement**, that helps lower risk over time.	
11:10 **Group Exercise 3, Step 1** **Cataract University Scenario** **Applying the AMP Model**	**Hand out Cataract University scenario. Divide into groups.** (40 minutes) • Have 1/3 of the groups identify ***problems*** in Assessment, 1/3 focus on Mitigation, and 1/3 focus on Performance • Use post-it notes, one for each problem • Place post-it notes on "university board" on section titled either Assessment, Mitigation, or Performance Report out results to full group, and discuss together (20 minutes)	45 minutes Slide 11
	Assessment • Inadequate risk assessment **Mitigation** • Procedures for cleaning biosafety cabinets • Inadequate material accountability system **Performance** • Clear procedures for reporting, investigating, and monitoring lab accidents • Training for reporting, investigating, and monitoring lab accidents • Clear responsibilities for reporting, investigating, and monitoring lab accidents • Timely inspections of lab accidents • Responsibilities for acting on inspection reports • President unaware of safety/security incidents	
11:40 **Plenary Discussion** **Introduction to the CWA 15793**	**Laboratory Biorisk Management Standard: CWA15793** Hand out the standard Explain that the CWA is based on plan, do, check, act, which is common for management systems. Short powerpoint presentation describing CWA. **ASK:** How does PDCA map to AMP? **Expected response:** A=P, D, C, A	30 minutes Slides 12-23

	M=P, D, C, A P=P, D, C, A	
12:10	**Break**	15 minutes
12:25 **Group Exercise 3, Step 2** **Return to Cataract**	**In the same groups** Use the table of contents of the CWA to develop recommendations for change at Cataract • Identify ***solutions*** for Assessment, Mitigation, and Performance • Agree on the benefits and challenges of making these changes at Cataract • Identify the specific paragraphs in CWA 15793 that apply to your selected solutions Record your conclusions on a flip chart Report out results to class	40 minutes Slide 24
13:05 **Individual reflection**	Individually reflect on the following questions. Write your responses on a piece of paper. You do not have to share these, so don't worry about confidentiality. 1. How does AMP apply to your own lab? 2. How could you improve biorisk management at your own lab, short-term and long-term? 3. What would be the challenges of implementing AMP? 4. What would be the benefits of implementing AMP?	10 minutes Slide 26
Debrief	Ask if anyone wants to share their reflections with the full group Reinforce appropriate insights and learnings	
13:25 **Session Summary**	Course content recap	5 minutes Slides 27-30
13:30	Course Evaluation	25 minutes
13:55	Closing remarks and Adjourn	

Course Introduction

Introduction to Biorisk Management

Sana'a Yemen

May 14 – 16, 2011

BIOSECURITY ENGAGEMENT PROGRAM

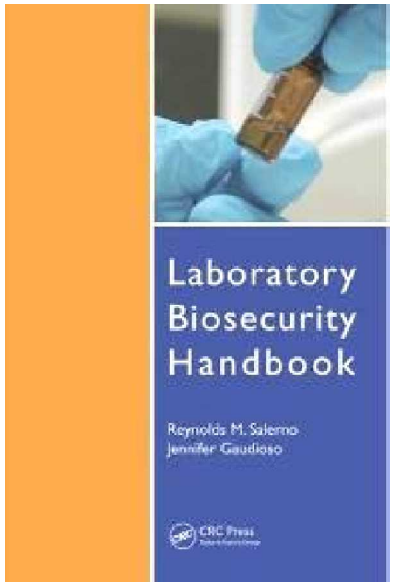
SAND No. 2008-0480P, 2008-0480P, 2008-1138
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
for the United States Department of Energy's National Nuclear Security Administration
under contract DE-AC04-94AL85000.

International BIOLOGICAL THREAT REDUCTION

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



BIOSECURITY ENGAGEMENT PROGRAM

International BIOLOGICAL THREAT REDUCTION

IBTR Program and Unique Technical Capabilities

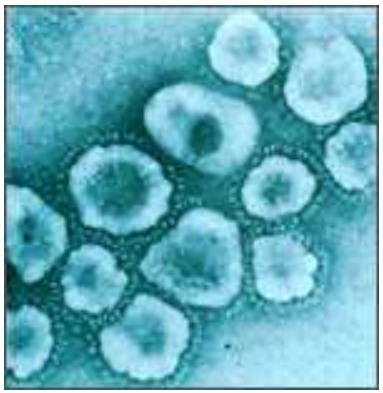
- **Lab biorisk assessments**
  - Biosafety
  - Biosecurity
- **Biosecurity implementation**
- **Biorisk systems implementation**
- **Biorisk management training for labs**
- **Integrated systems approach to biothreat identification, prevention, and response**
- **Structured decision analysis tools**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

BIOSECURITY ENGAGEMENT PROGRAM

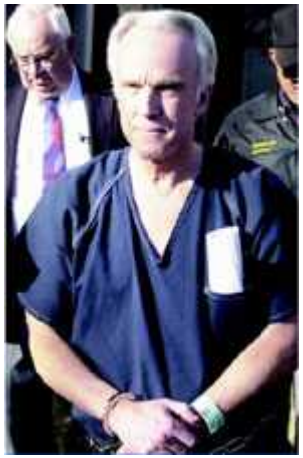
International BIOLOGICAL THREAT REDUCTION

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

BIOSECURITY ENGAGEMENT PROGRAM

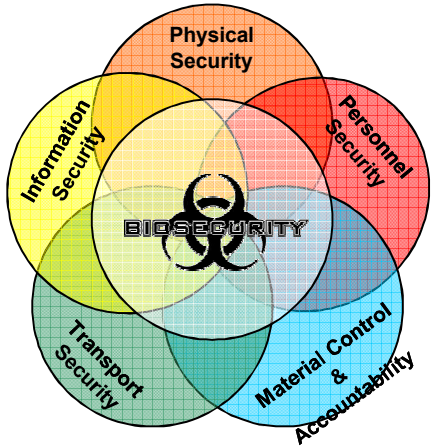
International BIOLOGICAL THREAT REDUCTION

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**



BIOSECURITY ENGAGEMENT PROGRAM

International BIOLOGICAL THREAT REDUCTION

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 and Materials

Course will include lecture, discussion, and activities

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

Acknowledgment

- **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**

WORLD HEALTH ORGANIZATION

BIOSECURITY ENGAGEMENT PROGRAM

International BIOLOGICAL THREAT REDUCTION

Performance Scenario

An employee of a waste transport and disposal company was diagnosed with Tuberculosis. After his diagnosis, he recalled an incident in which waste leaked from biohazard waste bags he carried from the local "TB Reference Laboratory," but did not report it at the time. During the same period, he visited relatives and went to public places in a country where TB was prevalent. One of his relatives in that country had just started TB treatments during his visit. The laboratory did not know about his infection until it was notified of this person's pending lawsuit, which claimed that the facility had not sufficiently treated the waste. Laboratory tests on samples from his lungs did not clearly point to a laboratory-based exposure. The waste transport and disposal company does not maintain an employee health monitoring program.

Upon review of lab and autoclave records, it was identified that on one day out of five the autoclave temperature, pressure, and time recordings were not available. Some staff seemed to think that this may have been because the autoclave printer ran out of paper on that day. The reference lab does not perform regular validation of its autoclaves.

Six months prior to this incident, in an internal occupational health and safety audit, it was recognized that autoclave printout records were kept in a drawer that was also used to store laboratory supplies. The internal audit was reviewed, and the laboratory manager determined that these records should be stored in a more appropriate and secure location. Another issue identified during the audit was that employees were not aware of autoclave maintenance procedures. The assistant laboratory manager was ordered to secure the records in a specific location and train lab personnel in autoclave procedures. However, he subsequently went on extended leave of absence, and no other effort was made to correct these problems.

The lawsuit resulted in a $5 million fine for the laboratory because the laboratory could not prove that the waste was treated appropriately as stipulated in its contract with the waste transport and disposal company.

Biorisk Management

Group exercise 1

Split into groups:

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

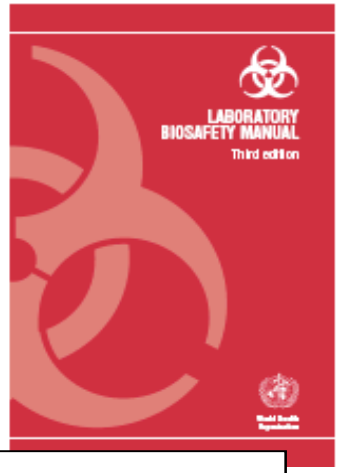
What are the risks of working in a laboratory with biological materials?

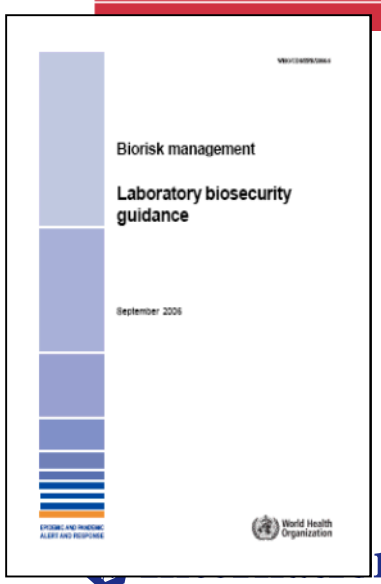
Write down your answers and be prepared to report to the class

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



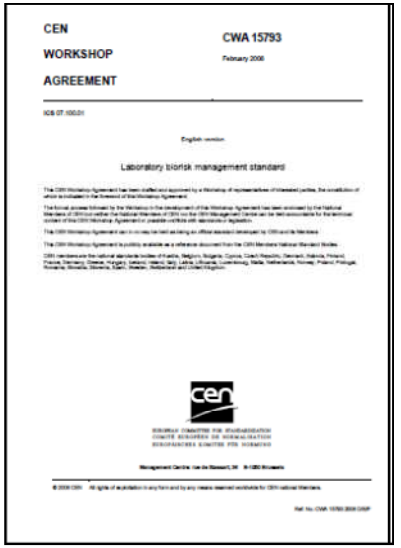


[1] *Laboratory biosafety manual, Third edition* (World Health Organization, 2004)

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

BIOSECURITY ENGAGEMENT PROGRAM

International
BIOLOGICAL THREAT REDUCTION

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

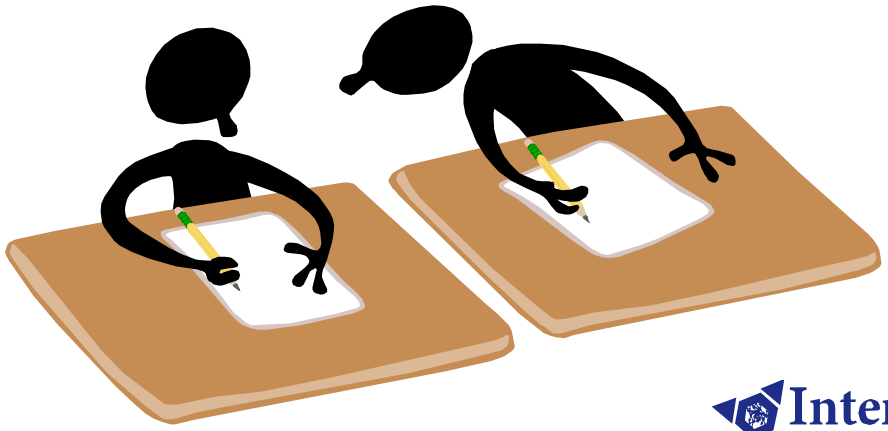
- Biorisk **Mitigation**

  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

Group Exercise 3, Step 1

Consider this scenario:

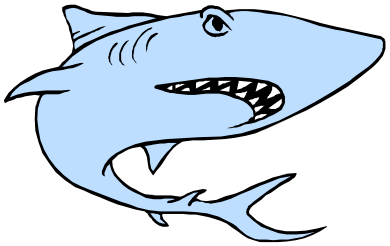
A young child is left alone in a kitchen while there is pot of water heating on the stove

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

What is a hazard?

Hazard

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

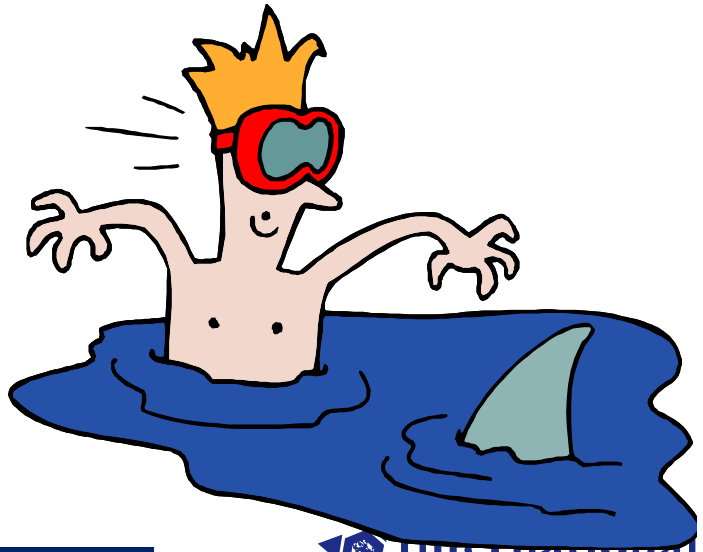


- **Hazard** is not a risk without a specific environment or situation

What is risk?

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 risk.
- Write one factor per post-it note

Slide 7

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

Small Group Exercise 3, Step 3

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

- Categorize the risk factors as influencing **likelihood** or **consequences** (or both)
- Group post-it notes accordingly
- Evaluate the risk (low, moderate, high)

Slide 8

bhb3 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?

What is the difference between a hazard and a threat?

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?

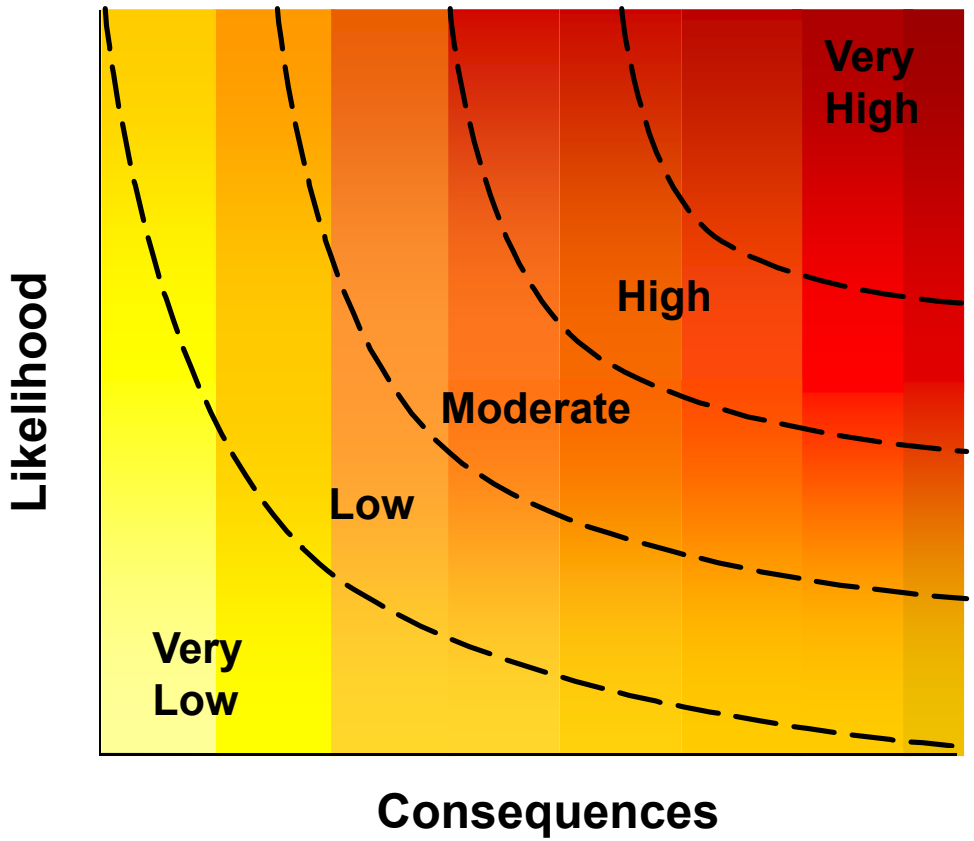
Risk, Likelihood, and Consequences

- **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

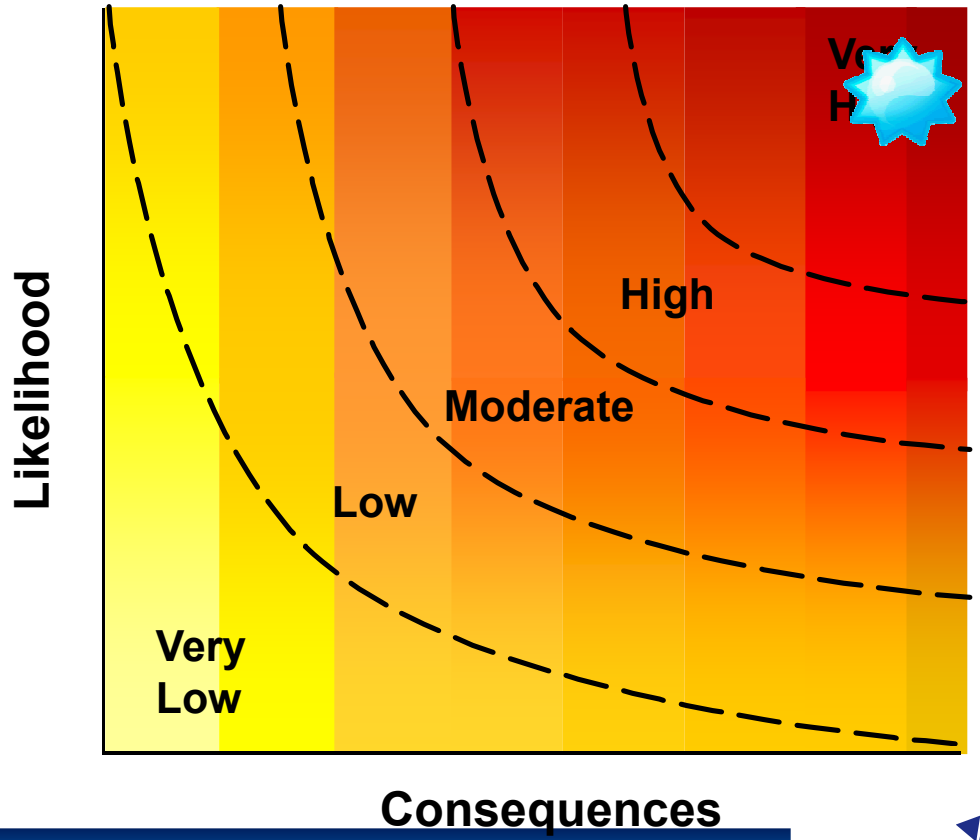
- **Consequences** is the severity of an event

Risk is a function of likelihood and consequences



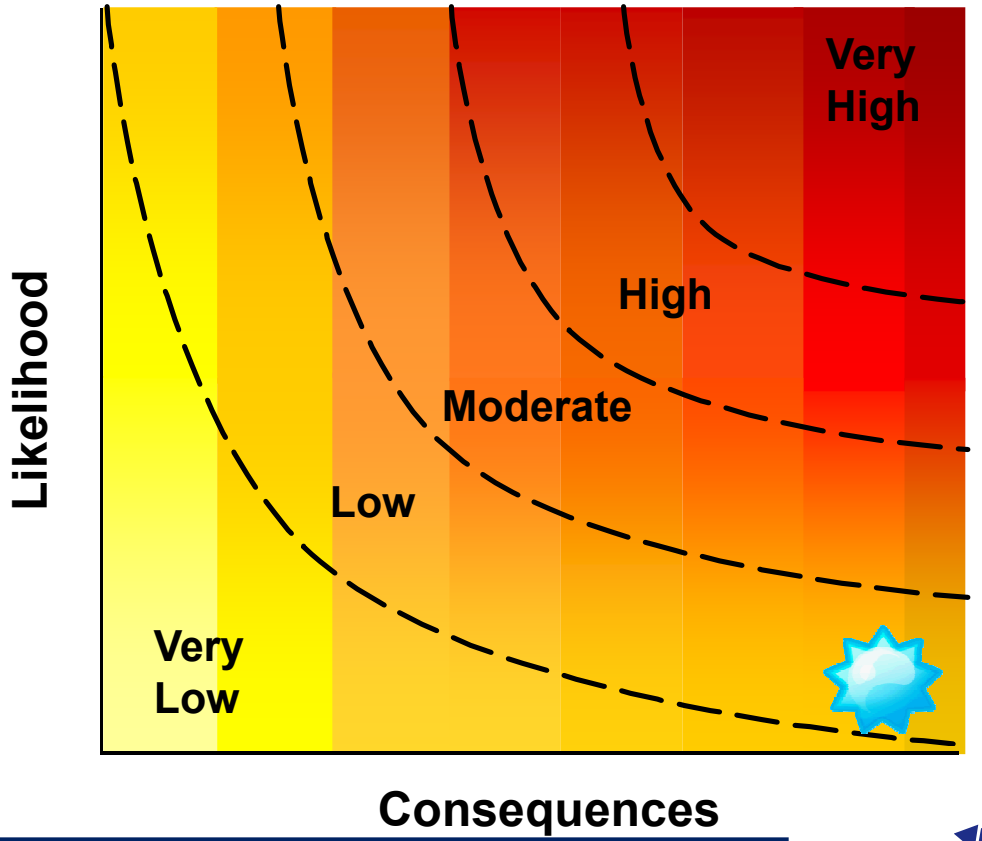
Risk Graph I

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



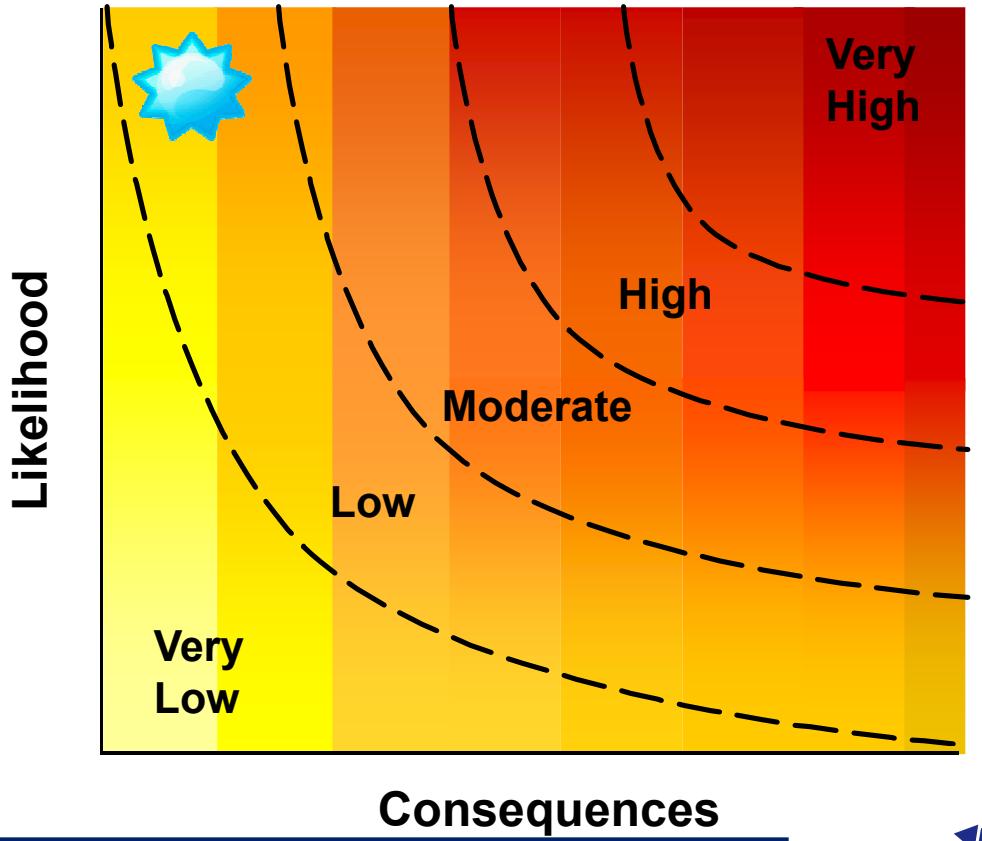
Risk Graph II

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



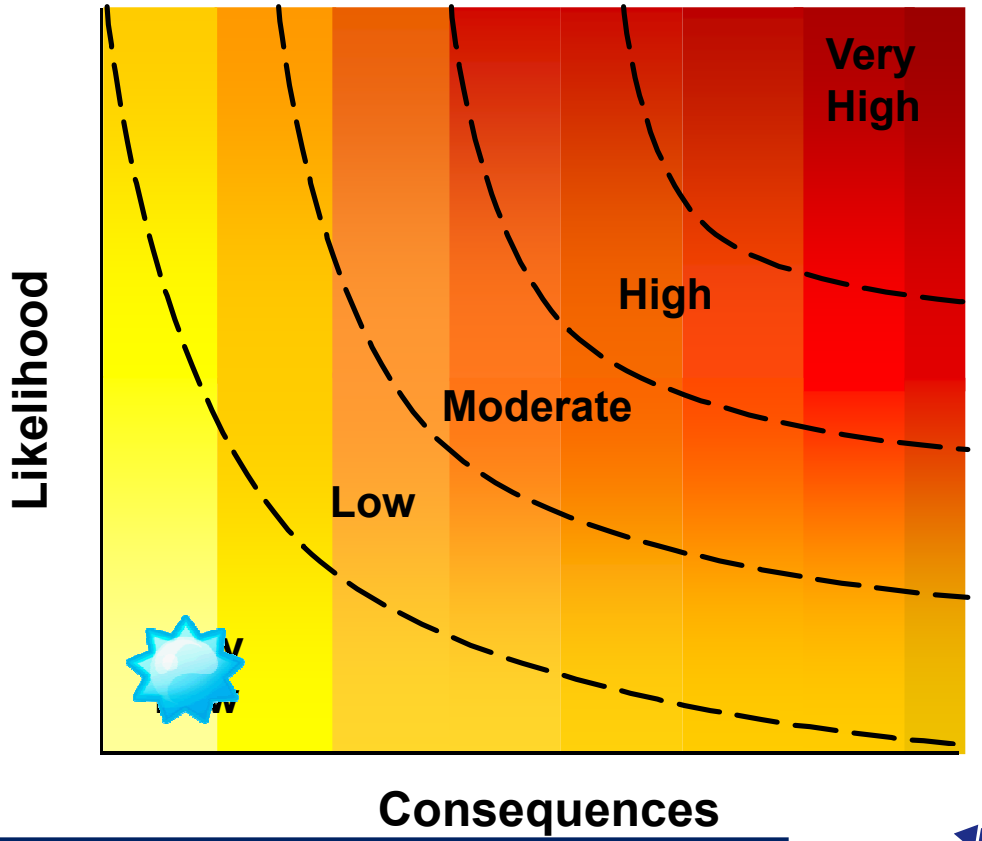
Risk Graph III

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



Risk Graph V

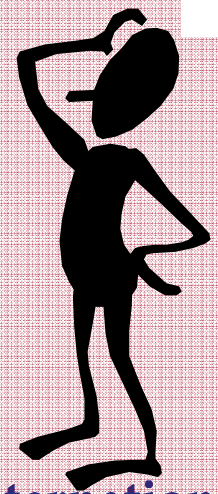
Small amount of cold water, no step stool, child strapped in a high chair



Individual reflection

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

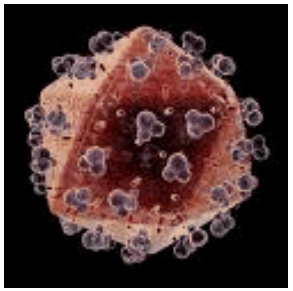
If you wish, share with the class



Group Exercise 4, Step 1

Consider the first biological scenario (WIV):

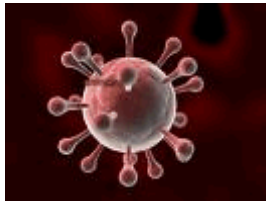
- Define the risks in this scenario
- Report out to the class



What aspect of biorisk did you focus on?

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 information do you need to do a risk assessment? List these factors.
- Use post-it notes, one idea per note, and place your post-it notes on a flip chart.
- Try to group these factors into general categories.

Agent Properties

- Pathogenicity / virulence
- Infectious dose
- Potential outcome of exposure
- Potential routes of infection
- Stability of the agent in the environment
- Morbitity/mortality
- Availability of effective therapeutic interventions

Laboratory Activities

- Concentration of the agent
- Clinical samples vs. cultures
- Volume of material to be manipulated
- Use of sharps
- Procedures that generate aerosols
- Procedures that could result in splash/splatter
- Genetic manipulations
- Use of infectious agents in animals

Laboratory Infrastructure

- Heating, ventilation and air conditioning (HVAC) system
- Open windows
- Public access
- Work surfaces
- Work flow
- Pest control

Human Factors

- Level of training and experience
- Workload, fatigue
- Technique (Good Laboratory Practices)
- Handwashing practices
- Health and immune status of the workforce

Mitigation Measures

- Housekeeping
- Waste disposal practices
- Use of a Biological Safety Cabinet
- Disinfectant use
- Vaccination
- Engineering controls
- Work practice controls
- Administrative controls
- Use of personnel protective equipment (PPE)

Environment/Community Factors

- Presence of the agent in the environment around the lab
- Immune status of the community
- Population density around the lab: urban vs. rural
- Presence of a suitable hosts or vectors

'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

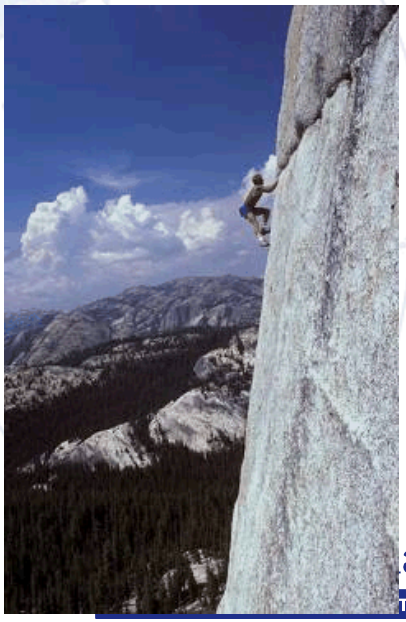
Summary

- **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

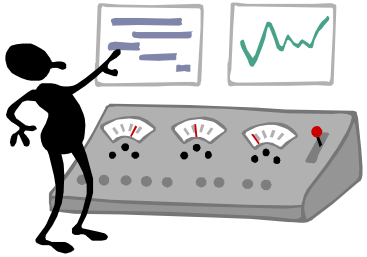
What might be missing from this technical risk assessment?

What is 'acceptable risk'?

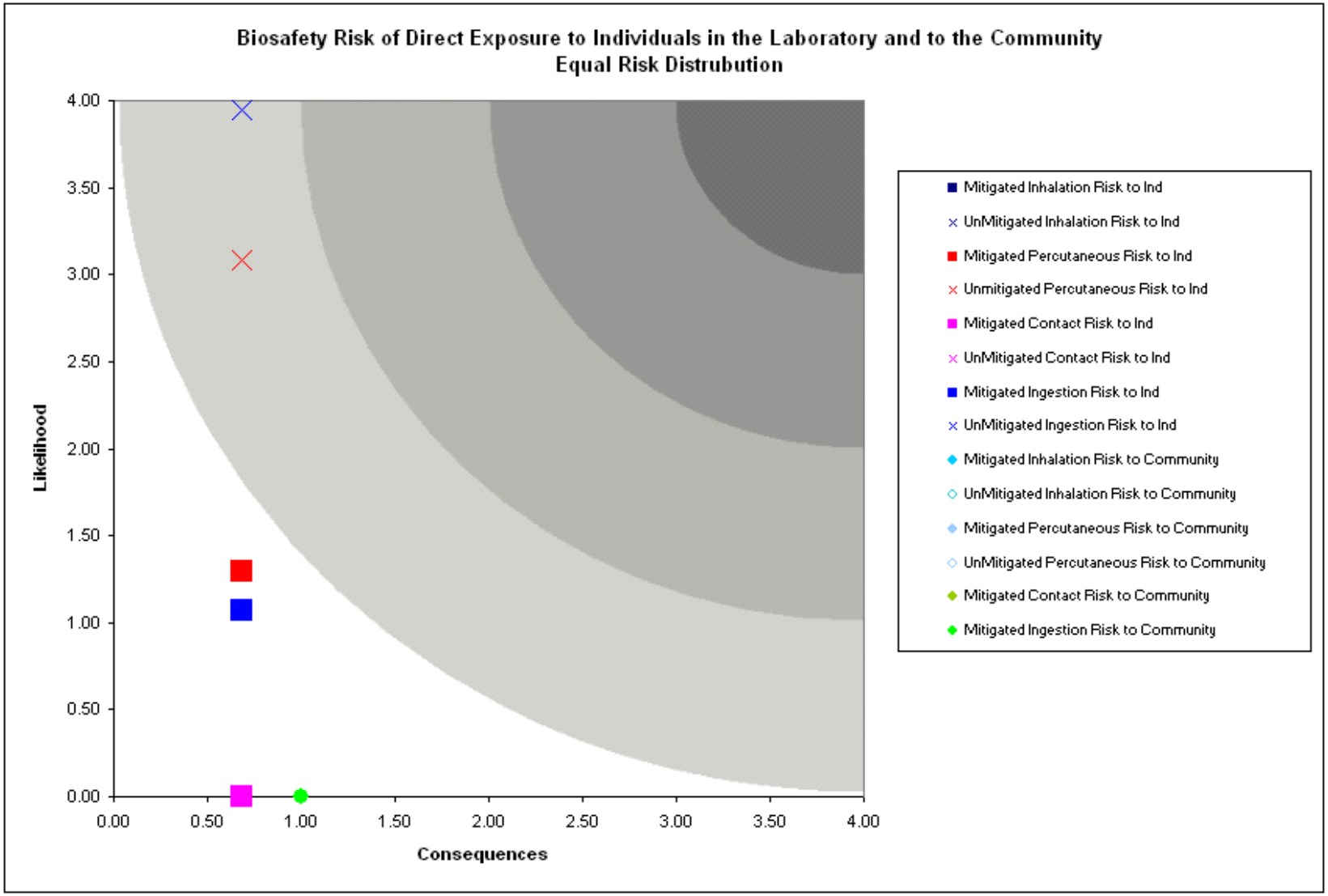


Technical Risk Assessment

- 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


Biosafety Risk of Direct Exposure to Individuals in the Laboratory and to the Community
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Consequences
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UnMitigated Inhalation Risk to Ind
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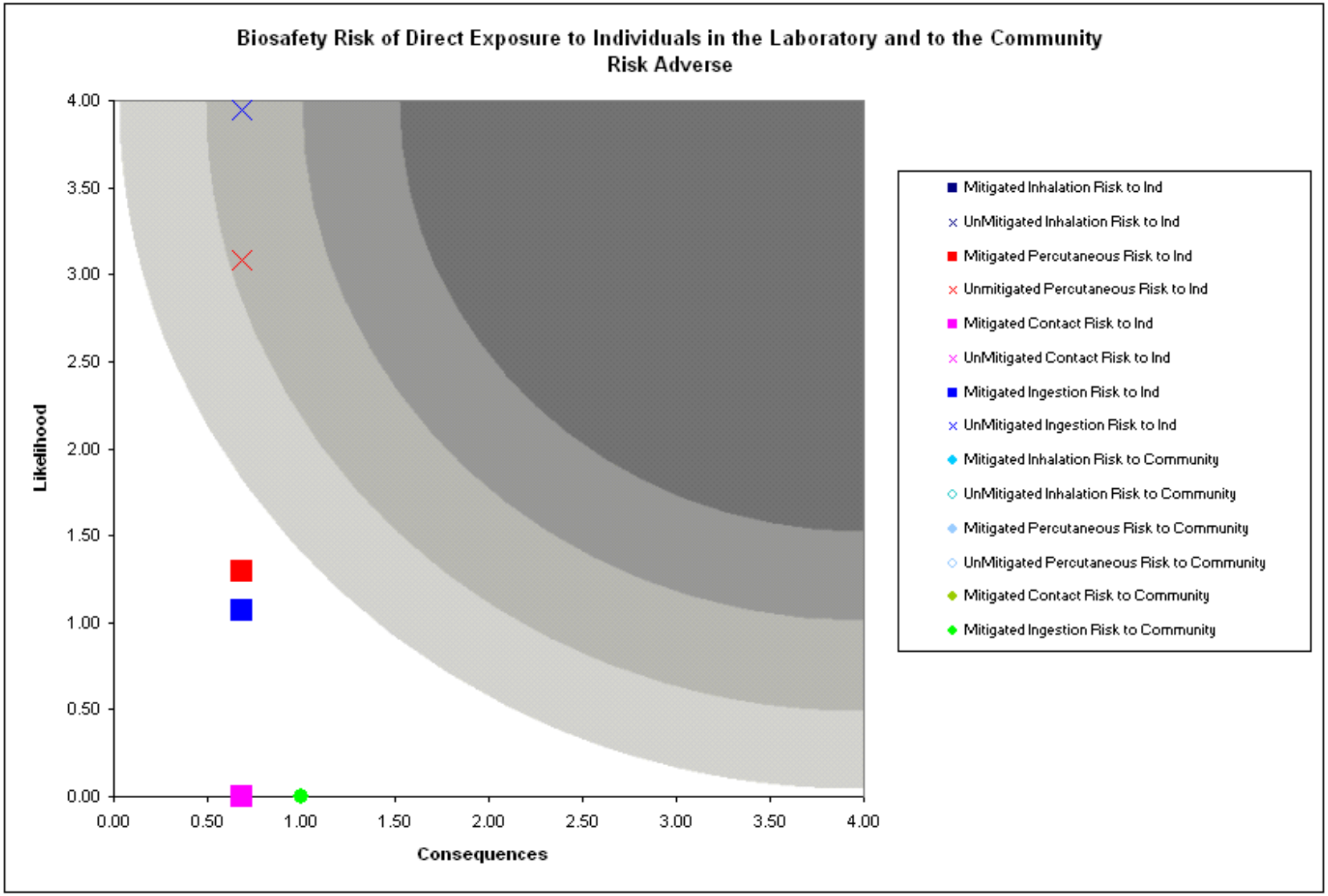
Biosafety Risk of Direct Exposure to Individuals in the Laboratory and to the Community
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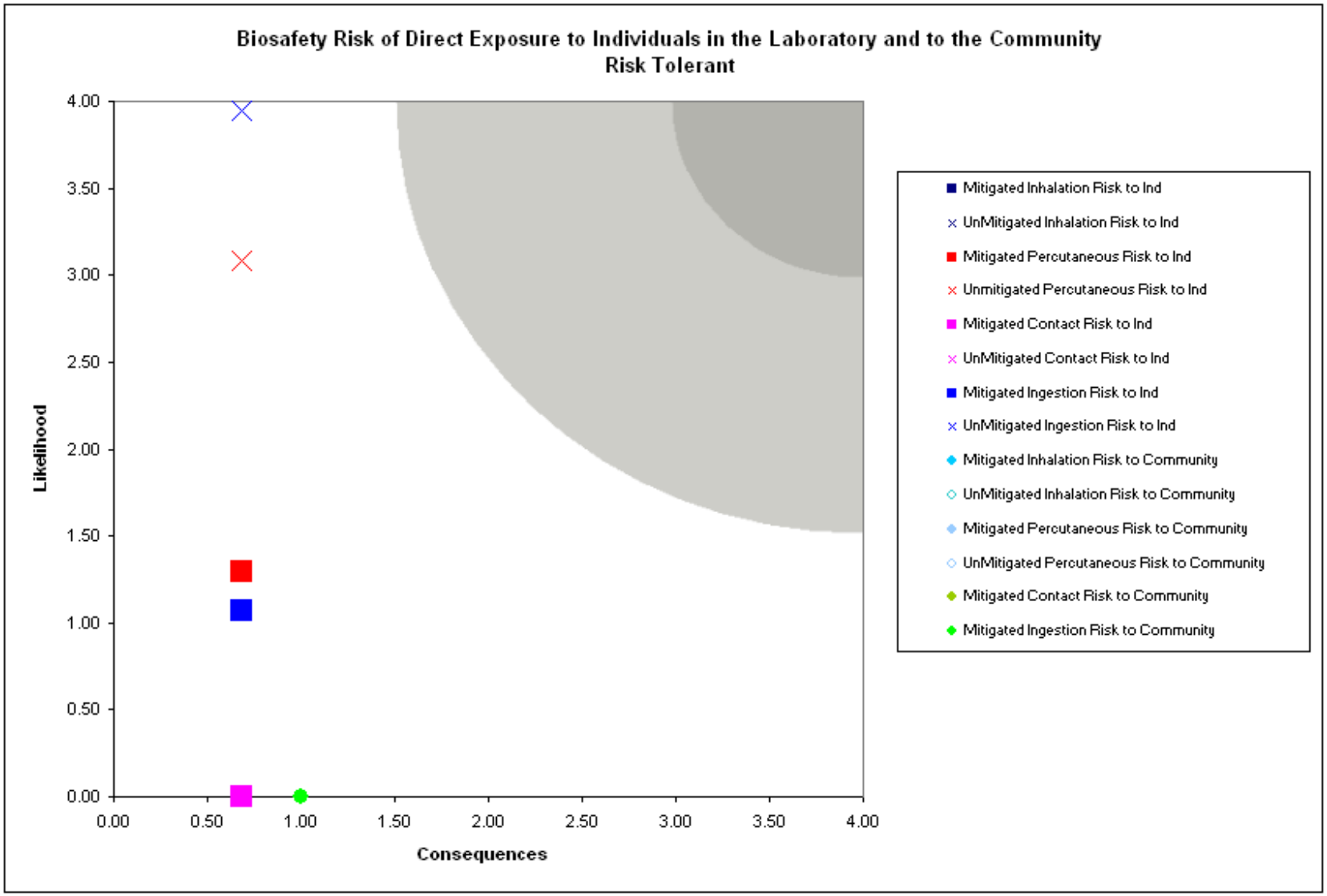
Biosafety Risk of Direct Exposure to Individuals in the Laboratory and to the Community
Risk Tolerant
Likelihood
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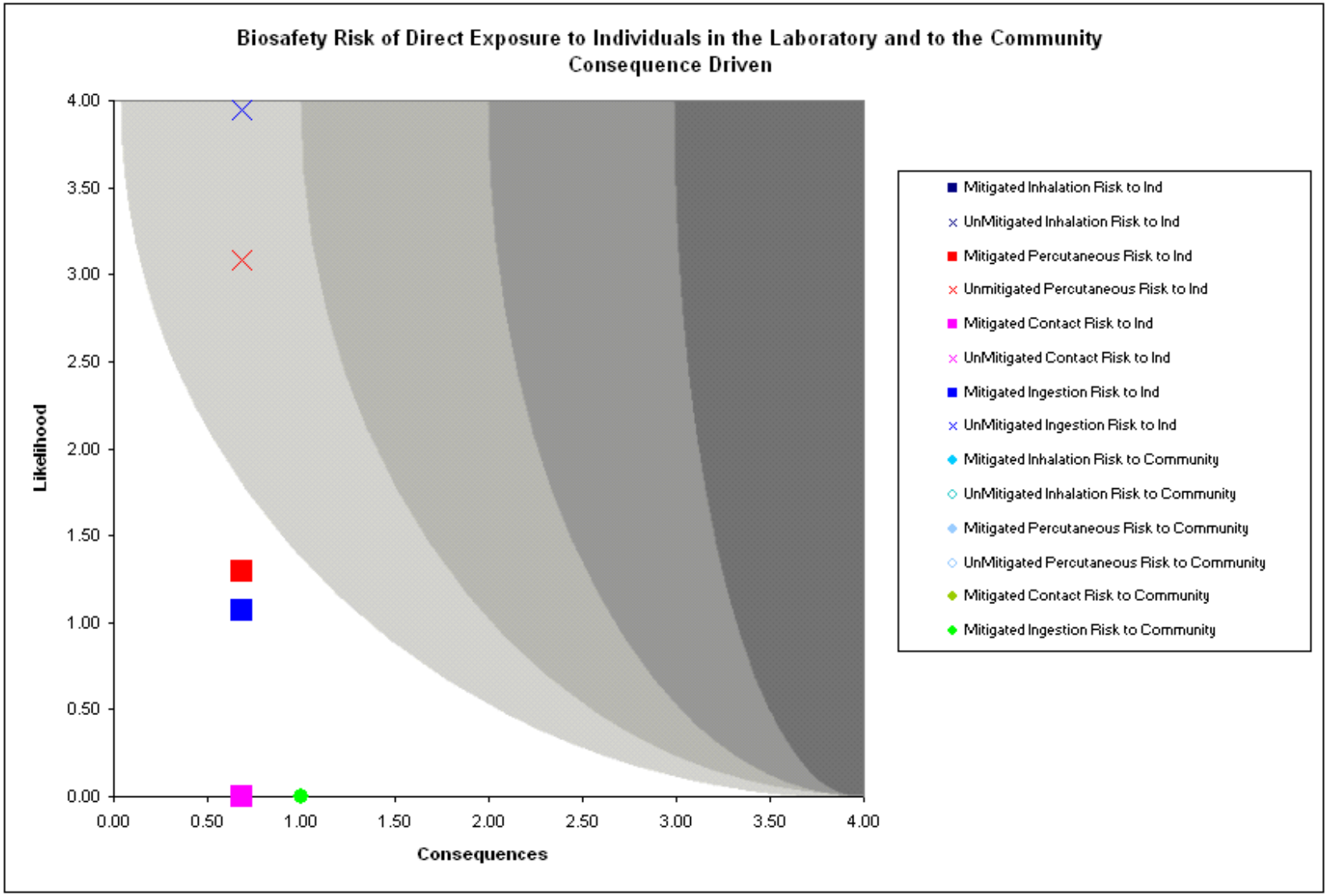
Biosafety Risk of Direct Exposure to Individuals in the Laboratory and to the Community
Consequence Driven
Likelihood
Consequences
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Mitigated Inhalation Risk to Community
UnMitigated Inhalation Risk to Community
Mitigated Percutaneous Risk to Community
UnMitigated Percutaneous Risk to Community
Mitigated Contact Risk to Community
Mitigated Ingestion Risk to Community

Individual reflection

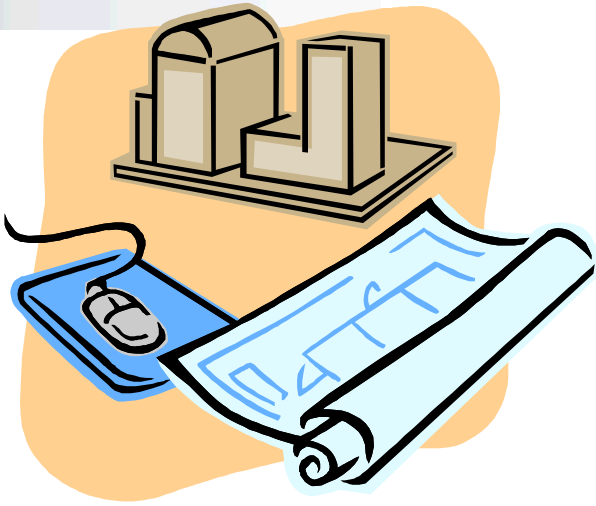
- What was new today?
- What insights have you had? What implications are there for you?
- What will you change when you return to your home institute?

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

BioRAM



- **Bio**safety **R**isk **A**ssessment **M**odel
- **Bio**security **R**isk **A**ssessment **M**odel
- Both have relied extensively on external experts from the international community
- Available through the following URL:

http://www.biosecurity.sandia.gov/BioRAM/

Biorisk Mitigation

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

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International
BIOLOGICAL THREAT REDUCTION

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

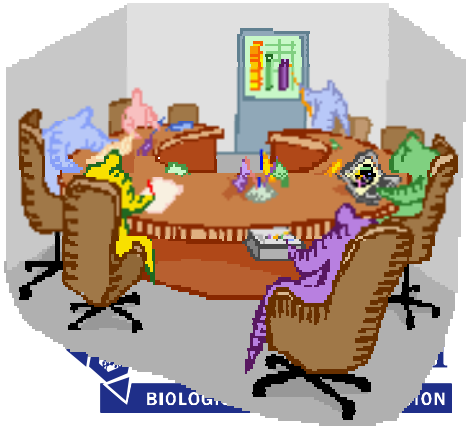
Group Exercise 5, Step 1

Using the WIV risk assessment scenario, identify six different potential 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



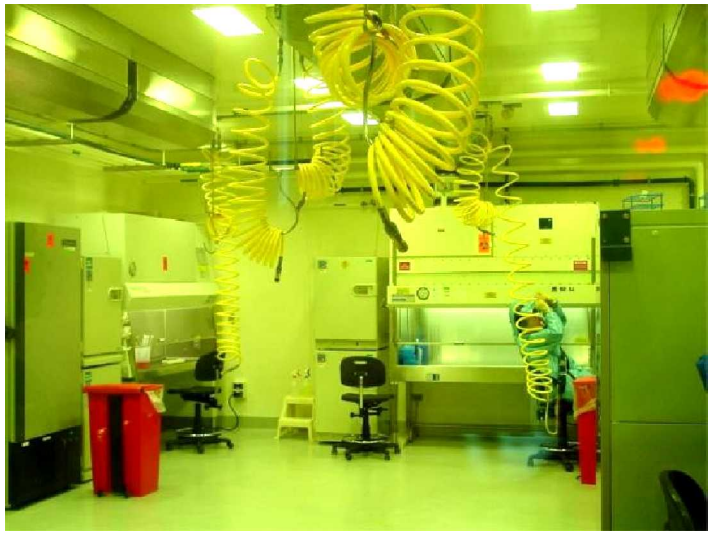
Mitigation Control Measures

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

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Group Exercise 5, Step 3

Considering these mitigation control measures:

Elimination or Substitution

Engineering

Administrative

Practices & Procedures

PPE

- Identify their advantages and disadvantages

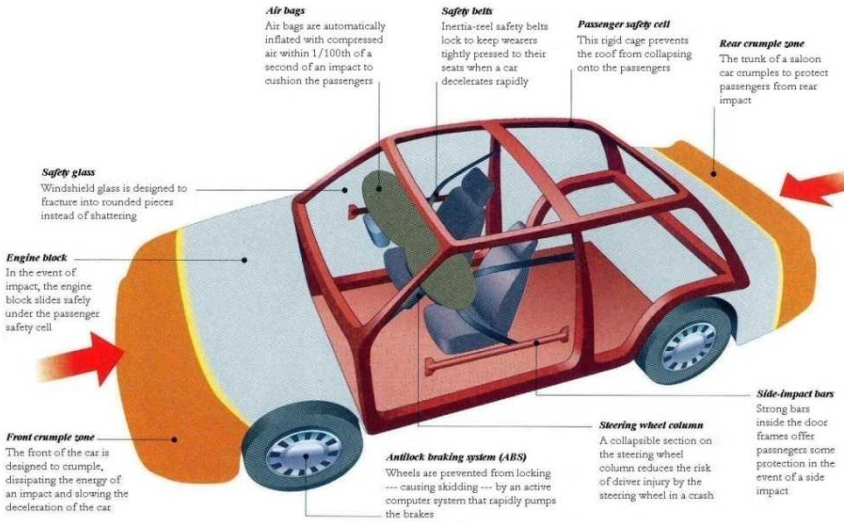
Report your findings to the class

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

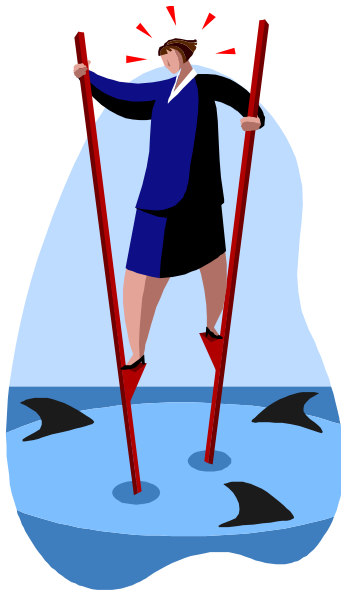
Which category of mitigation controls appears in this video clip?

Implementing Mitigation Measures

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

Ideally, you should first consider elimination or substitution

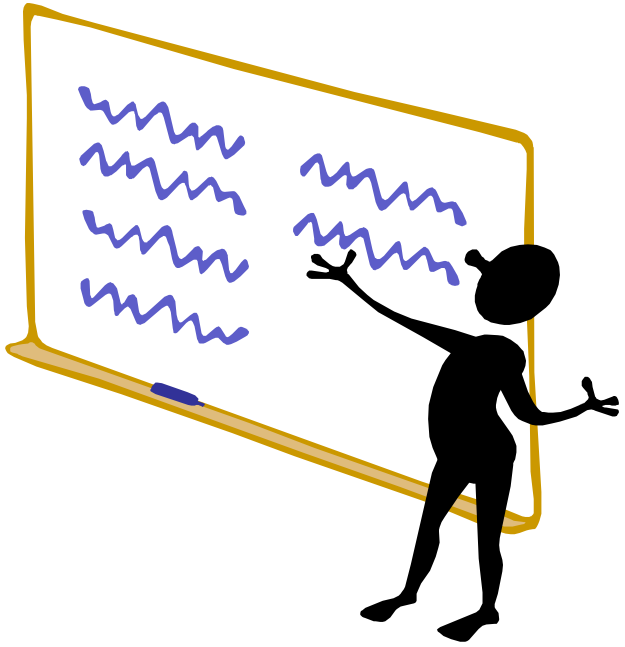
A combination of control measures should be used based on their effectiveness and your ability to implement them



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

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

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

Choose one of the following questions and discuss with your group:

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

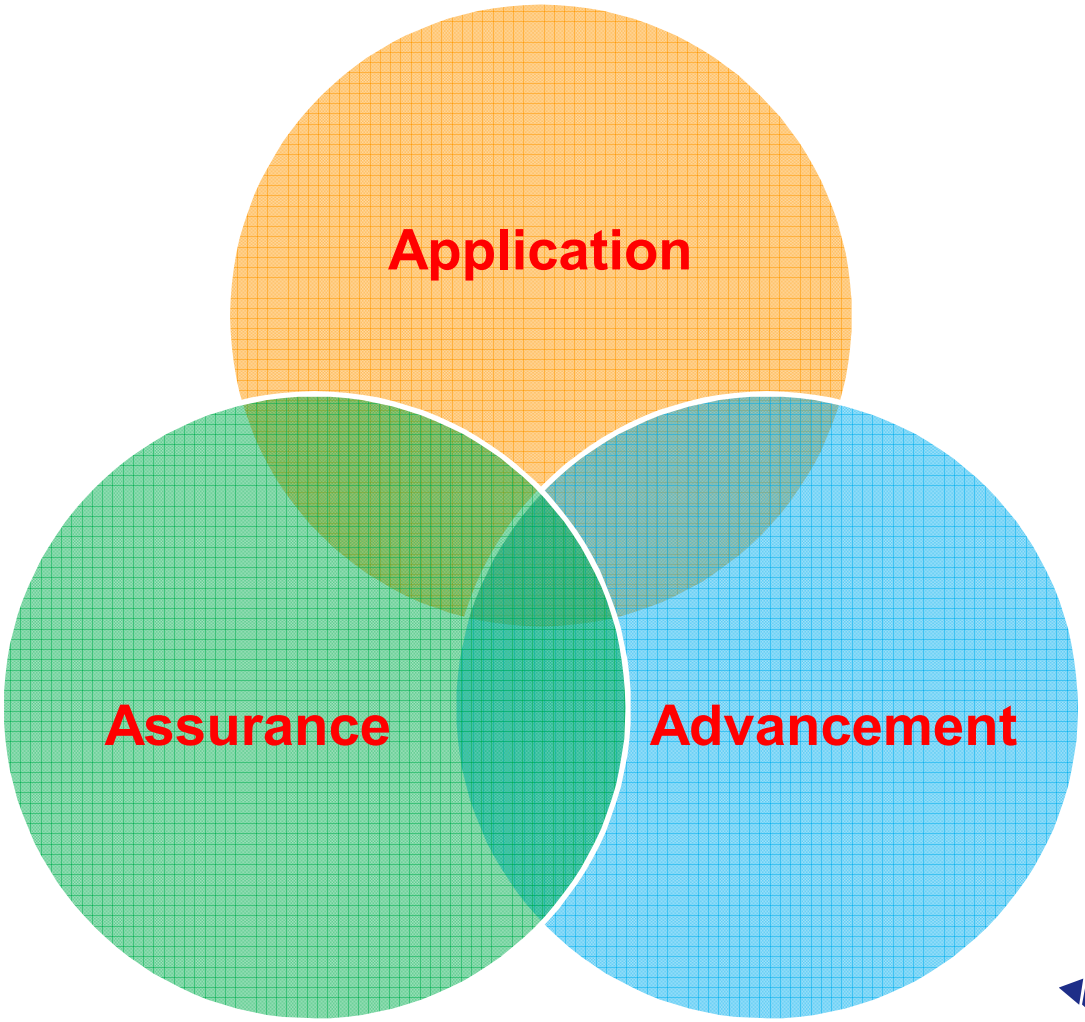
Review the performance scenario

- 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

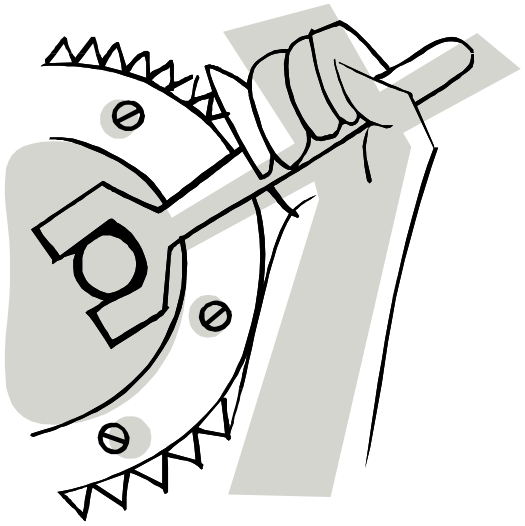
Performance



Performance

Application:

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



Performance

Assurance:

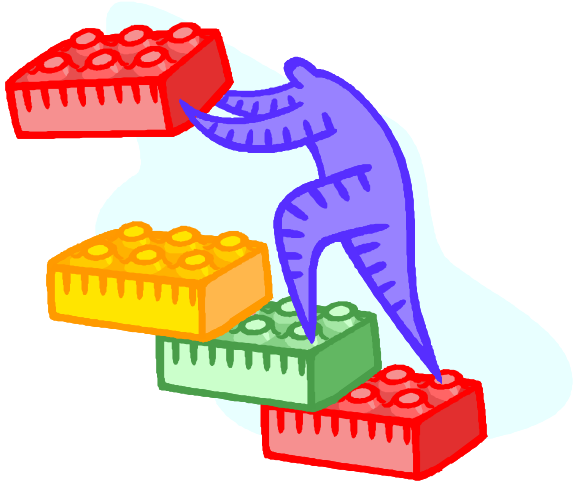
Systematic process of checking the system through audits and inspections

.

Performance

Advancement:

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




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

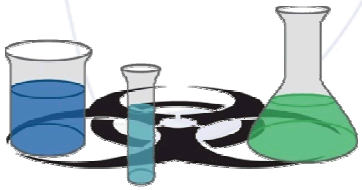
BIOSECURITY ENGAGEMENT PROGRAM

International BIOLOGICAL THREAT REDUCTION

Awareness and Implementation of CWA 15793:2008

www.biosecurity.sandia.gov

Special thanks to Stefan Wagener



SAND No. 52918762011-1041C
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
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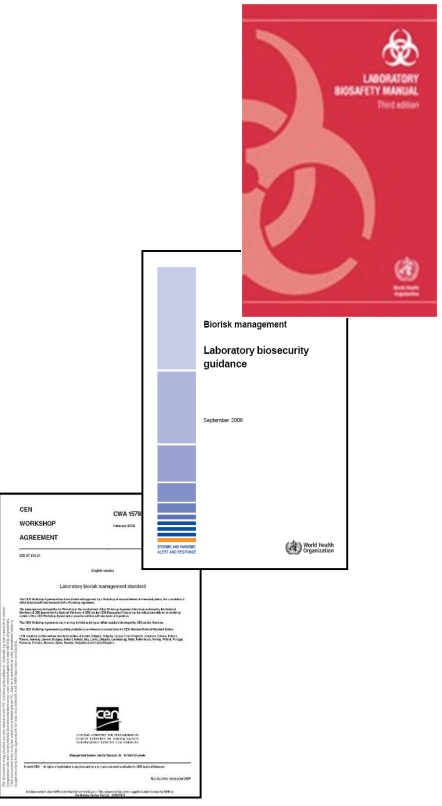
International Laboratory Biorisk Management Documents



- **Technical: World Health Organization**
  - Laboratory Biosafety Manual (2004)
  - Biorisk Management: Laboratory Biosecurity Guidance (2006)

- **Management: CEN Workshop Agreements**
  - CWA 15793 Laboratory Biorisk Management Standard
  - CEN WS 55 – CWA 15793 Guidance Document (under development)
  - CEN WS 53 – Biosafety Professional Competence

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International BIOLOGICAL THREAT REDUCTION

What is CEN?

- **CEN = Comité Européen de Normalisation**
- **CEN has 30 national members**
- **Produces technical specifications, technical reports, and European Standards (EN)**

- **CEN Workshop Agreements (CWA) produced by**
  - Any interested parties
  - Consensus documents

CWA 15793: Laboratory Biorisk Management

- **Developed by 76 participants from 24 countries**
- **Is a management system standard consistent with other international standards such as**
  - ISO 9001 / 14001 and OSHAS18001
- **The Standard is performance oriented**
  - Describes what needs to be achieved
  - How to do it is up to the organization
- **Does not replace national regulations**
  - Compliance with regulations is mandatory under CWA 15793
- **Designed to be comprehensive blueprint for biosafety & biosecurity (biorisk) program**
  - Risk-based; applicable to broad range of organizations, not just high containment labs

Purpose of the CWA 15793:2008

- **The Standard is used for:**
  - Improving overall laboratory biorisk performance
  - Increasing awareness and the adoption of performance approaches for biosafety and biosecurity
  - Improving international laboratory collaboration and safety harmonization
  - Support laboratory certification/accreditation, audits/inspections

CWA 15793:2008

- **International Approach**

  - Extensive definition section
  - Not country specific
  - Based on international, acceptable best practices
  - Local solutions possible
  - The Standard is based around the current WHO Biosafety and Biosecurity Guidelines

Example: Waste Management

4.4.4.5.3 Waste Management

The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.

- **The standard is not a technical document**
- **Describes what needs to be achieved, but allows organizations to determine how best to achieve those objectives**
- **Provides Biorisk management framework for the day-to-day functions of the institute / organization**
  - **During normal operations and times of emergency**

Reasons for Implementing CWA 15793

- **Enables organizations to:**
  - Establish and maintain a biorisk management system to control or minimize risk to acceptable levels to employees, the community and others
  - Provide assurance that the requirements are in place and implemented effectively
  - Provide a framework that can be used as basis for training and awareness raising
  - Seek and achieve certification or verification by an independent third party

- **Document available on CEN website**

  ftp://ftp.cenorm.be/PUBLIC/CWAs/workshop31/CWA15793.pdf

- **Electronic copy provided in your supplementary materials**

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

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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
Laboratory biorisk management standard

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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

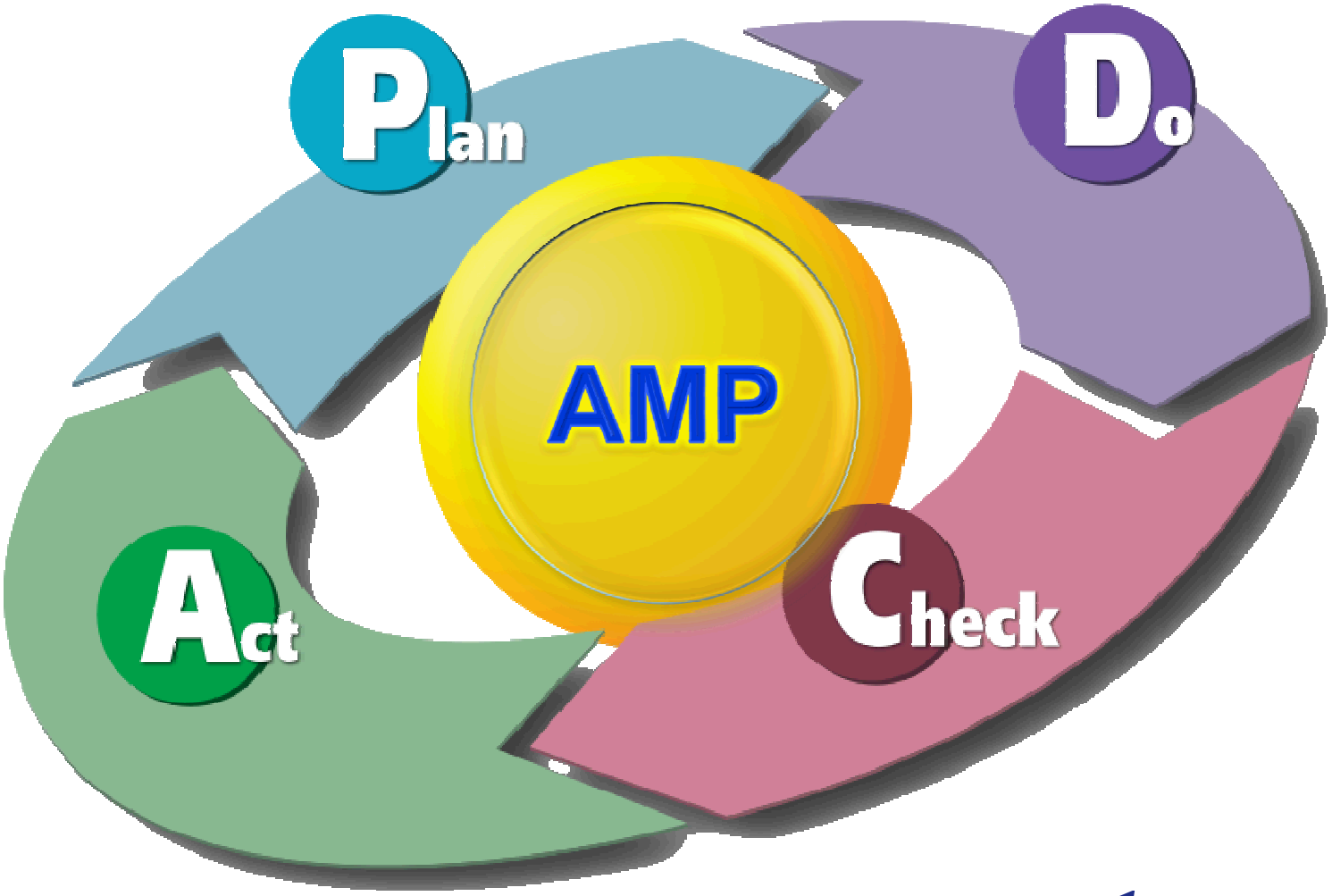
Summary II

The AMP model

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

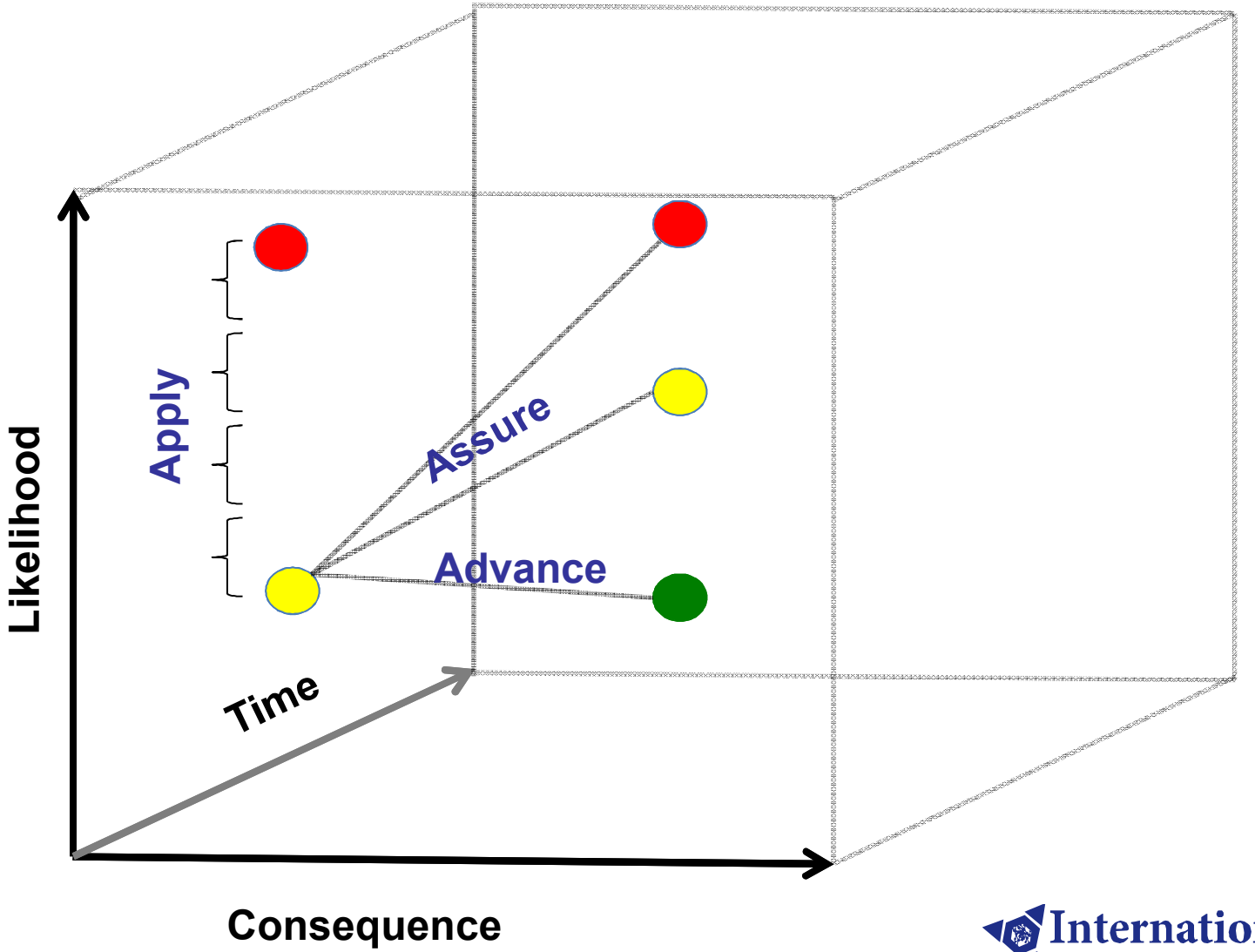
Mitigation is improved and sustained when performance measures are included

CWA 15793:2008


Plan
Do
AMP
Act
Check

OPTIONAL SLIDES TIME AND INTEREST PERMITTING

How does performance affect risk over time?


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

Scenario
Wooly Infectious Virus (WIV)

Summary of Experiment

A veteran researcher is working to create a new animal model for WIV studies. Using nude mice, he plans on injecting the mice with high titer cultures of WIV using 1ml needles. A recently hired technician will hold the animals for the researcher during inoculation. They plan on using a biosafety cabinet, nitrile gloves, goggles, and lab coats. The researcher recently has been distracted with personal issues and appears stressed. All details of this research are kept in the researcher's log book, which he keeps to himself.

Agent Criteria

Infectious Dose: Unknown, but thought to be around 500 – 10,000 viral particles for percutaneous route and much higher for contact with non-intact skin or mucosal membranes.

Stability:

> ***SUSCEPTIBILITY TO DISINFECTANTS:*** Susceptible to many disinfectants - 1% sodium hypochlorite, 2% glutaraldehyde, formaldehyde, ethanol
>
> ***PHYSICAL INACTIVATION:*** Effectiveness of 56·C - 60·C heat in destroying WIV in serum not certain, however, heating small volumes of serum for 30 min at 56·C before serologic testing reduces residual infectivity to below detectable levels
>
> ***SURVIVAL OUTSIDE HOST:*** Drying in environment causes rapid (within several hours) 90-99% reduction in WIV concentration

Incubation Period: Epidemiologic evidence suggests that duration from exposure to onset of symptoms has a minimum range from 6 months to more than 7 years.

Mortality Rate: 100% of untreated patients will die from various complications related to compromise of the immune system within 10 years. Patients can be treated and survive with WIV as a chronic infection. However, the treatment can be expensive and there is evidence that some strains of WIV will mutate and develop resistance to the treatments.

Morbidity:

> *Duration of Illness:* Initial infection produces flu-like symptoms. An WIV positive patient can be asymptomatic for many years before developing the disease. Untreated patients may survive 6-10 years post-infection, with illness worsening towards the end of this period.

Severity of Illness: High.

Duration of Infection: Lifetime

Long term effects after infection: Active disease can be triggered at any time after the establishment of a latent infection, though the probability of developing active disease is higher 1-2 years after infection, in immune compromised patients, small children, young adults, and the very old.

Allergen (yes/no): No

Carcinogenic/mutagenic (yes/no): Potentially

Abortogenic (yes/no): No

Toxin Production (yes/no): No

Immune Suppression (yes/no): Yes

Ability to Mutate in Host or Environment (yes/no): Yes

Infection Mitigation Measures:

For human pathogens

Immunization: No. (Various experimental vaccines have been developed)

Prophylaxis: Anti-WIV drugs

Post Infection Treatment: Anti-WIV drugs

Existence of Diagnostic tests: Yes.

Routes of Infection:

Inhalation: No

Ingestion: No

Percutaneous: Yes

Contact: Possible (fluid contact with damaged skin or mucosal membranes)

Vector-Borne: No

Sexual Transmission: Yes

Vertical Transmission: Yes

Communicability: WIV is a virus that only infects humans. Studies indicate that it replicates only in a certain subset of human T-lymphocytes. Infections occur primarily through contact with infected body fluids, sexual transmission, during child birth, blood transfusions, and sharing intravenous needles. Efforts are underway to engineer animal models that will be able to be infected with the virus.

Human to Human: Yes

Human to Animal: No Evidence

Animal to Animal: No Evidence

Animal to Human: No Evidence (although some theories on the emergence of WIV involve animal to human transmission through fluid contact)

Multiple Species: No

Where is it present: Worldwide.

Perception of malicious use: LOW

Culture: Virus isolation and culture is possible in a relatively simple diagnostic laboratory using fresh peripheral blood cells from healthy donors or suitable culture lines such as T-lymphomas. This procedure is typically not used in diagnosis as it is tedious and lengthy in comparison with other diagnostic techniques. It is mainly used in characterizing viruses.

International
BIOLOGICAL THREAT REDUCTION

Table of Contents: Introduction to Biorisk Management

Course Schedule

Day 1 – Saturday, 14 May 2011

Introduction to Laboratory Biorisk Management – Day 1	
9:00	**Welcome Message** **Course Introduction**
10:00	**Session 1 - Introduction to Biorisk Management**
10:50	**Break**
11:05	**Session 2 - Principles of Biorisk Assessment**
12:50	**Break**
13:05	**Discussion on Infectious Diseases and Needs for Biorisk Management in Yemen** *(Discussion of specific infectious disease agents present in Yemen – this could be delivered by a Yemeni SME, and group discussion of risk assessment in Yemen)*
14:00	**Adjourn**

Day 2 – Sunday, 15 May 2011

Introduction to Laboratory Biorisk Management – Day 2	
9:00	**Recap of Day 1 and Discussion of Lessons Learned**
9:20	**Session 2, Continued – Principles of Biorisk Assessment**
10:35	**Break**

10:50	**Session 3 - Principles of Biorisk Mitigation**
12:45	**Break**
13:00	**Session 3, Continued - Principles of Biorisk Mitigation**
13:40	**Adjourn**

Day 3 – Monday, 16 May 2011

Introduction to Laboratory Biorisk Management – Day 3	
9:00	**Recap of Days 1 & 2 and Discussion of Lessons Learned**
9:30	**Session 4 – Principles of Biorisk Performance**
10:25	**Break**
10:40	**Session 4 - Principles of Biorisk Performance, Continued**
11:40	**CEN Workshop 15793:2008**
12:10	**Break**
12:25	**CWA group exercise**
13:00	**Course summary and wrap-up**
13:30	**Course evaluation**
13:55	**Closing Remarks, Certificates, and Adjourn**

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Learning Objectives: Introduction to Biorisk Management

This course will expose students to the basic principles of laboratory biorisk management. By the end of the course, participants should be able to:

- Understand the need for laboratory biorisk management
- Understand and define the concepts of hazard, threat, and risk
- Be familiar with the AMP (Assessment, Mitigation, Performance) model for laboratory biorisk management
- Understand basic aspects of the risk assessment process
- Understand basic biorisk mitigation measures, including the major categories of risk mitigation measures
- Understand the concept of biorisk management performance, and how performance influences risk
- Be familiar with CWA 15793:2008
- Understand the relationship between the PDCA and AMP models

These objectives form the foundation of the course materials and are reinforced through guided discussion sessions and interactive exercises.

Acronyms:

ABSL - Animal Biosafety Level
BSC - Biosafety Cabinet
BSL - Biosafety Level
HEPA - High Efficiency Particulate Air
HPAI - Highly Pathogenic Avian Influenza
IACUC - Institutional Animal Care and Use Committee
IBC - Institutional Biosafety Committee
IBTR - International Biological Threat Reduction
MDR - Multi-drug resistant
PCR - Polymerase Chain Reaction
PPE - Personal Protective Equipment
RT-PCR - Reverse transcriptase polymerase chain reaction
SNL - Sandia National Laboratories
UN - United Nations
WHO - World Health Organization

Glossary:

Aerosol - A substance consisting of very fine particles of a liquid or solid suspended in a gas.
Animal Biosafety Level - Combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and are based on the potential hazards imposed by the agents used and for the laboratory function and activity in an area where animals are present.
Autoclave - An apparatus in which steam under pressure effects sterilization.

Biohazard - A biological agent, such as an infectious microorganism, that constitutes a threat to humans or to the environment.
Biosafety Cabinet - A device enclosed (except for necessary exhaust purposes) on three sides and top and bottom, designed to draw air inward by means of mechanical ventilation, operated with insertion of only the hands and arms of the user, and in which virulent pathogens are used. Biosafety Cabinets are classified as: Class I, Class II and Class III, each providing different levels of protection.
Biosafety Level - A combination of work practices, primary containment devices and construction technology to reduce the risk of exposure resulting in laboratory acquired infection or release of a microbe to the environment.
Biosafety Level 1 – Represents a basic level of containment that relies on standard microbiological practices with no special primary or secondary barriers recommended, other than a sink for handwashing.
Agents that can be worked with at BSL1: Microorganisms not known to cause disease in healthy adult humans
Biosafety Level 2 – Similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that (1) laboratory personnel have specific training in handling pathogenic

agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; (3) extreme precautions are taken with contaminated sharp items; and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.
Agents that can be worked with at BSL2: Indigenous, moderate-risk agents associated with human disease of varying severity
Biosafety Level 3 – All procedures in this laboratory involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.
Agents that can be worked with at BSL3: Indigenous or exotic agents where the potential for infection by aerosol exists and disease may have serious-to-lethal consequences
Biosafety Level 4 – The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building. A specific facility operations manual is prepared or adopted.
Within work areas of the facility, all activities are confined to Class III biological safety cabinets, or Class II biological safety cabinets used with one-piece positive pressure personnel suits ventilated by a life support system. The Biosafety Level 4 laboratory has special engineering and design features to prevent microorganisms from being disseminated into the environment.
Agents that can be worked with at BSL4: Dangerous and exotic agents that pose a high risk of life threatening disease
Blood-borne Pathogen - Micro-organisms that are present in human/ primate blood, tissues or fluids that can cause disease in humans. These pathogens include (but are not limited to) hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Carrier - A person, animal, or plant that serves as a host for a pathogen and can transmit it to others, but is immune to it.
Centrifuge - Equipment that separates substances of different densities in a sample by rotation at very high speed, forcing the substance to be displaced outward, sometimes through a series of filters or gratings. Substances with greater density are displaced from the center more than ones that are less dense.
Containment - The control of biohazards through practices & procedures, primary barriers, and secondary barriers.

Decontamination – Removing disease-causing organisms from contaminated articles or surfaces.
Disinfection - Selective elimination of certain undesirable microorganisms in order to prevent their transmission.
Doffing - To remove or take off.
Donning - To put on or dress in.

Endemic - Relating to a disease consistently present in a population in a particular locality.
Enzootic - Relating to a disease consistently present in a population of animals in a particular locality.

Epidemic – Disease occurring in larger numbers than usual or in excess of normal expectancy.
Epizootic - A disease affecting many animals at the same time, and spreading from animal to animal in a particular locality.

Fomite - An inanimate object or substance that is capable of transmitting infectious organisms from one individual to another.

Germicide - Any antimicrobial chemical agent used to kill disease-causing organisms.

Homogenize - To form by blending unlike elements; to make uniform or similar, as in composition or function.
Host - The animal or plant on which or in which another organism lives.

Incident - abnormal or unplanned event or conditions that adversely affect or potentially affect safety or security.
Infection - Invasion by and multiplication of pathogenic microorganisms in body tissues, which may produce subsequent tissue injury and progress to overt disease through a variety of cellular or toxic mechanisms.

Laboratory biosafety - A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological hazard
Laboratory biosecurity - A set of preventive measures designed to reduce the risk of intentional removal (theft) of a valuable biological material
Latent infection - An infectious agent or disease that remains in an inactive or hidden phase; dormant.
Lyophilizer - Equipment used for freeze-drying.

Mucous membrane - Any of the membranes lining the passages of the body, such as the respiratory and digestive tracts, that open to the outside. Cells in the mucous membranes secrete mucus, which lubricates the membranes and protects against infection.

Pathogen - An agent that causes infection or disease, such as a bacterium or protozoan, or a virus.
Polymerase Chain Reaction - A technique for amplifying DNA sequences in vitro by separating the DNA into two strands and incubating it with oligonucleotide primers and DNA polymerase.

Reservoir - An organism or a population that directly or indirectly transmits a pathogen while being virtually immune to its effects.
Risk - The function of the likelihood and consequences of an adverse event; biorisks involve biological agents or their products.
Risk assessment - A systematic, structured process for analysis and determination of risks
Risk Group - Infectious agents are categorized in risk groups based on their relative risk. Risk group classifications are primarily used in the research environment as part of a comprehensive biosafety risk assessment.

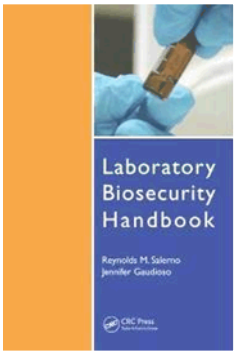
Risk Group 1 - No or low individual and community risk, A microorganism unlikely to cause human or animal disease.
Risk Group 2 - Moderate individual risk, low community risk. Pathogen causes human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. May cause serious infection but effective treatments and preventive measures are available. Risk of spread is limited.
Risk Group 3 - High individual risk, low community risk. Pathogen usually causes serious human or animal disease but does not ordinarily spread to others. Effective treatment and preventive measures are available.
Risk Group 4 - High individual and community risk. A pathogen causes serious human or animal disease; readily transmitted from one individual to another. Effective treatment and preventive measures are usually not available.
Rotor - The device used to hold tubes during centrifugation.
Reverse transcriptase polymerase chain reaction - PCR process by which copies of DNA are generated from RNA.

Valuable Biological Material – A biological agent that has use either in research or for malicious purposes, commonly both
Vector -
a. An insect or other organism that transmits a pathogenic fungus, virus, bacterium, etc.
b. Any agent that acts as a carrier or transporter, as a virus or plasmid that conveys a genetically engineered DNA segment into a host cell.
Vortexer - A device used to mix, by means of a rapid whirling or circular motion.

Zoonotic Diseases - A disease of animals, such as rabies or psittacosis, which can be transmitted to humans.

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

BIOSECURITY ENGAGEMENT PROGRAM

International BIOLOGICAL THREAT REDUCTION

Notes:

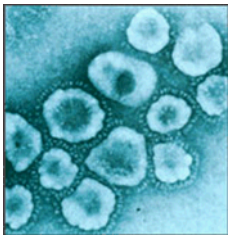
IBTR Program and Unique Technical Capabilities

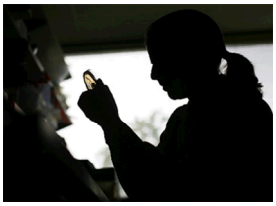
- **Lab biorisk assessments**
  - Biosafety
  - Biosecurity
- **Biosecurity implementation**
- **Biorisk systems implementation**
- **Biorisk management training for labs**
- **Integrated systems approach to biothreat identification, prevention, and response**
- **Structured decision analysis tools**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

Notes:

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

International BIOLOGICAL THREAT REDUCTION

Notes:

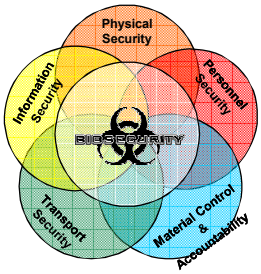
How Do You Avoid Similar Problems at Your Institution?

- **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?

Notes:

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**



Notes:


Strengthening Biological Risk Management
Vision for Integrated BioRisk Management:
Biosafety
Biorisk
Biosecurity
Working Safely
Integrated Biorisk Management
Keeping the Work Secure
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"
2
WORLD HEALTH ORGANIZATION

Notes:

Acknowledgment

- **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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WORLD HEALTH ORGANIZATION

International BIOLOGICAL THREAT REDUCTION

Notes:

Biorisk Management – Session 1

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

1._____

2._____

3._____

4._____

5._____

6._____

7._____

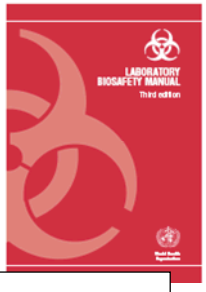
8._____

9._____

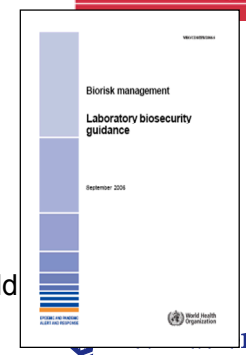
10._____

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)

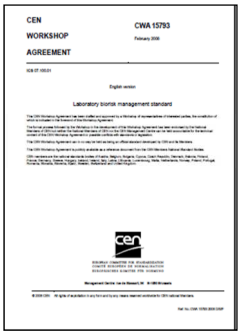
BIOLOGICAL THREAT REDUCTION

Notes:

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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AGREEMENT
CWA 15793
February 2008
English version
Laboratory biorisk management standard

BIOSECURITY ENGAGEMENT PROGRAM

International
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Notes:

Biorisk

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

- Biorisk encompasses biosafety and biosecurity

Notes:

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

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?

Biorisk Management: the AMP Model

Biorisk Management =
Assessment, Mitigation, Performance

BIOSECURITY ENGAGEMENT PROGRAM

International BIOLOGICAL THREAT REDUCTION

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

Notes:

Key Components of Biorisk Management

☣Biorisk **Mitigation**

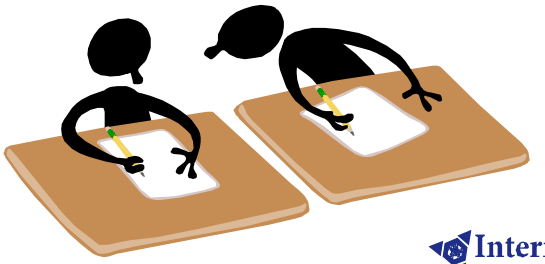
Actions and control measures that are put into place to reduce or eliminate the risks associated with biological agents and toxins

Notes:

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.



Notes:

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

Notes:

Biorisk Assessment – Session 2

Biorisk Management = Assessment, Mitigation, Performance

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 could go wrong? List all the possibilities:

What is the single most important risk for this scenario?

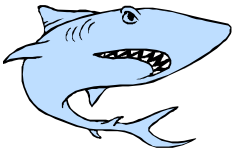
What is the "hazard" for that risk?

What is a hazard?

Notes:

Hazard

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



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

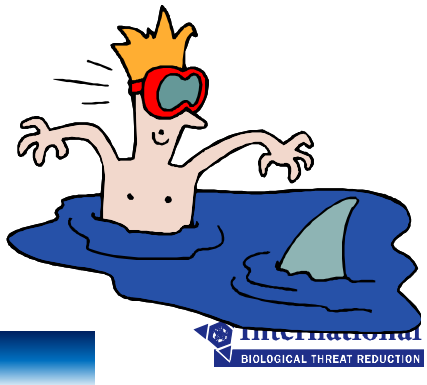
Notes:

What is risk?

Notes:

Risk

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



Notes:

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

Factors that influence likelihood and consequences:

Evaluate the risk: (Low, moderate or high)?

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?

Notes:

What is the difference between a hazard and a threat?

Notes:

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

Notes:

Risk, Likelihood, and Consequences

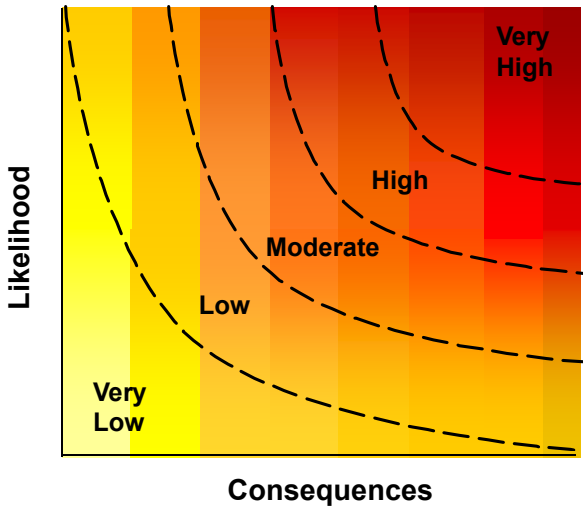
- **Risk** is the likelihood of an undesirable event, involving a specific hazard (or hazard and threat), that has consequences

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

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

Notes:

Risk is a function of likelihood and consequences



Notes:

Individual reflection

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

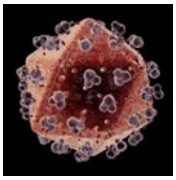
If you wish, share with the class

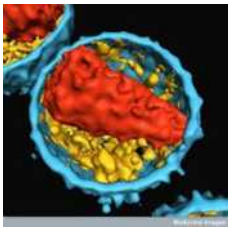
How do you assess risk in your own lab?:

Group Exercise 4, Step 1

Consider the first biological scenario (WIV):

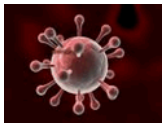
- Define the risks in this scenario
- Report out to the class





What are the risks in this scenario?:

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

Which risk are you assessing?:

_____

_____

_____

What is the hazard and/or threat?

_____

_____

_____

_____

Is the risk low, moderate or high?

_____

_____

_____

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.

List the different types of information needed to do a risk assessment:

Agent Properties

- Pathogenicity / virulence
- Infectious dose
- Potential outcome of exposure
- Potential routes of infection
- Stability of the agent in the environment
- Morbitity/mortality
- Availability of effective therapeutic interventions

Laboratory Activities

- Concentration of the agent
- Clinical samples vs. cultures
- Volume of material to be manipulated
- Use of sharps
- Procedures that generate aerosols
- Procedures that could result in splash/splatter
- Genetic manipulations
- Use of infectious agents in animals

Laboratory Infrastructure

- Heating, ventilation and air conditioning (HVAC) system
- Open windows
- Public access
- Work surfaces
- Work flow
- Pest control

Human Factors

- Level of training and experience
- Workload, fatigue
- Technique (Good Laboratory Practices)
- Handwashing practices
- Health and immune status of the workforce

Mitigation Measures

- Housekeeping
- Waste disposal practices
- Use of a Biological Safety Cabinet
- Disinfectant use
- Vaccination
- Engineering controls
- Work practice controls
- Administrative controls
- Use of personnel protective equipment (PPE)

Environment/Community Factors

- Presence of the agent in the environment around the lab
- Immune status of the community
- Population density around the lab: urban vs. rural
- Presence of a suitable hosts or vectors

Notes:

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

Notes:

What are the benefits of a robust risk assessment?

Notes:

Benefits of a Robust Risk Assessment

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

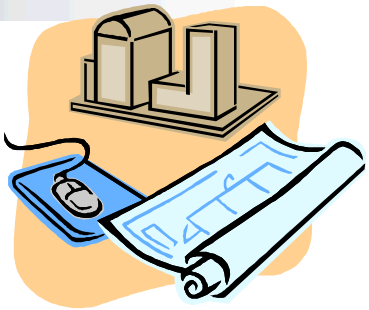
Notes:

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

Notes:

BioRAM



- **Bio**safety **R**isk **A**ssessment **M**odel
- **Bio**security **R**isk **A**ssessment **M**odel
- Both have relied extensively on external experts from the international community
- Available through the following URL:

http://www.biosecurity.sandia.gov/BioRAM/

LDRD
LABORATORY DIRECTED RESEARCH & DEVELOPMENT

International
BIOLOGICAL THREAT REDUCTION

Notes:

Biorisk Mitigation

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

BIOSECURITY ENGAGEMENT PROGRAM

International
BIOLOGICAL THREAT REDUCTION

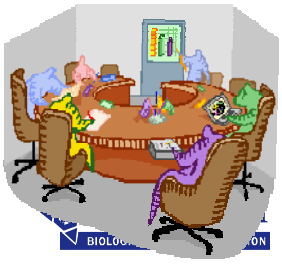
Group Exercise 5, Step 1

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



List at least four mitigation measures for safety:

List at least two mitigation measures for security:

Mitigation Control Measures

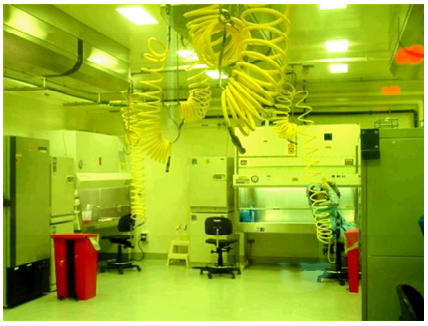
Five categories of mitigation control measures:

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

Notes:

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



Notes:

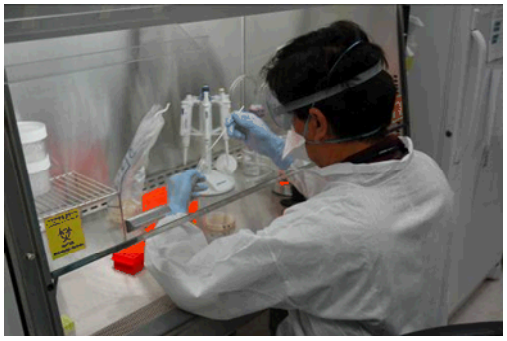
Mitigation Control Measures

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

Notes:

Mitigation Control Measures

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



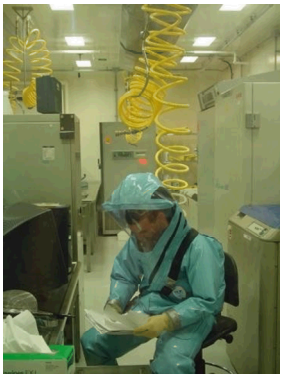
Notes:

Mitigation Control Measures

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







Notes:

Group Exercise 5, Step 3

Considering these mitigation control measures:

Elimination or Substitution

Engineering

Administrative

Practices & Procedures

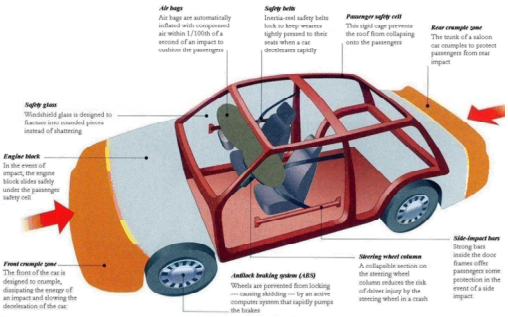
PPE

- Identify their advantages and disadvantages

Report your findings to the class

	Advantages	Disadvantages
Elimination or Substitution		
Engineering Controls		
Administrative Controls		
Practices and Procedures		
PPE		

Car vs. Motorcycle Safety



- Car safety is all about engineering systems

- Motorcycle safety is all about PPE

Notes:

Implementing Mitigation Measures

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

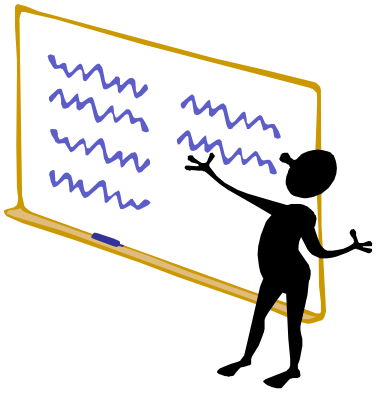
Ideally, you should first consider elimination or substitution

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

Notes:

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

Notes:

Biorisk Management

Notes:

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

Notes:

Biorisk Performance – Session 4

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

BIOSECURITY ENGAGEMENT PROGRAM

International BIOLOGICAL THREAT REDUCTION

Choose one of the following questions and discuss with your group:

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?

International BIOLOGICAL THREAT REDUCTION

Notes:

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

Notes:

Group Exercise 6, Step 1

Split into groups

Review the performance scenario

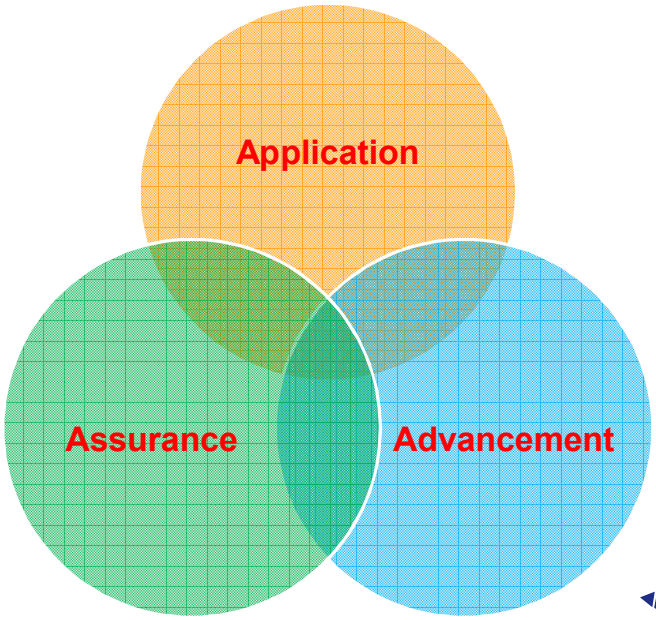
- Identify the performance issues/problems in the scenario
- Write each issue on a separate *post-it* using a felt-tip marker

Place *post-its* on your flip chart

Present to the class

List the issues/problems related to "Performance":

Performance



Notes:

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.

Notes:


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

Notes:

Group Exercise 7, Step 1

Individually, carefully read the *Cataract University* exercise

Split into groups

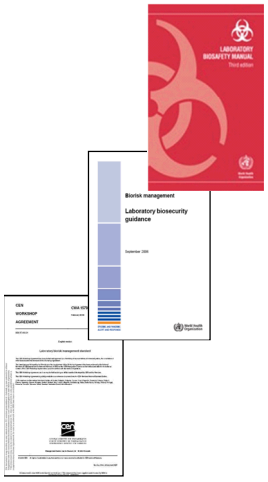
- Identify ***problems*** in Assessment, Mitigation, and Peformance
- Use post-it notes, one for each problem
- Place post-it notes on “university board” in appropriate section

How have these problems affected the university?

Report out results to full group

Problems associated with Assessment/Mitigation/Performance:

International Laboratory Biorisk Management Documents



- **Technical: World Health Organization**
  - Laboratory Biosafety Manual (2004)
  - Biorisk Management: Laboratory Biosecurity Guidance (2006)
- **Management: CEN Workshop Agreements**
  - CWA 15793 Laboratory Biorisk Management Standard
  - CEN WS 55 – CWA 15793 Guidance Document (under development)
  - CEN WS 53 – Biosafety Professional Competence

BIOSECURITY ENGAGEMENT PROGRAM

International BIOLOGICAL THREAT REDUCTION

Notes:

What is CEN?

- **CEN = Comité Européen de Normalisation**
- **CEN has 30 national members**
- **Produces technical specifications, technical reports, and European Standards (EN)**

- **CEN Workshop Agreements (CWA) produced by**
  - Any interested parties
  - Consensus documents

Notes:

CWA 15793: Laboratory Biorisk Management

- **Developed by 76 participants from 24 countries**
- **Is a management system standard consistent with other international standards such as**
  - ISO 9001 / 14001 and OSHAS18001
- **The Standard is performance oriented**
  - Describes what needs to be achieved
  - How to do it is up to the organization
- **Does not replace national regulations**
  - Compliance with regulations is mandatory under CWA 15793
- **Designed to be comprehensive blueprint for biosafety & biosecurity (biorisk) program**
  - Risk-based; applicable to broad range of organizations, not just high containment labs

Notes:

Purpose of the CWA 15793:2008

- **The Standard is used for:**
  - Improving overall laboratory biorisk performance
  - Increasing awareness and the adoption of performance approaches for biosafety and biosecurity
  - Improving international laboratory collaboration and safety harmonization
  - Support laboratory certification/accreditation, audits/inspections

Notes:

CWA 15793:2008

- **International Approach**

  - Extensive definition section
  - Not country specific
  - Based on international, acceptable best practices
  - Local solutions possible
  - The Standard is based around the current WHO Biosafety and Biosecurity Guidelines

Notes:

Example: Waste Management

4.4.4.5.3 Waste Management

The organization shall establish and maintain an appropriate waste management policy for biological agents and toxins.

- **The standard is not a technical document**
- **Describes what needs to be achieved, but allows organizations to determine how best to achieve those objectives**
- **Provides Biorisk management framework for the day-to-day functions of the institute / organization**
  - **During normal operations and times of emergency**

Notes:

Reasons for Implementing CWA 15793

- **Enables organizations to:**
  - Establish and maintain a biorisk management system to control or minimize risk to acceptable levels to employees, the community and others
  - Provide assurance that the requirements are in place and implemented effectively
  - Provide a framework that can be used as basis for training and awareness raising
  - Seek and achieve certification or verification by an independent third party

Notes:

- **Document available on CEN website**
  ftp://ftp.cenorm.be/PUBLIC/CWAs/workshop31/CWA15793.pdf
- **Electronic copy provided in your supplementary materials**

Notes:

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

Notes:

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

Laboratory biorisk management standard

International
BIOLOGICAL THREAT REDUCTION

Notes:

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

Notes:

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

Notes:

Summary II

The AMP model

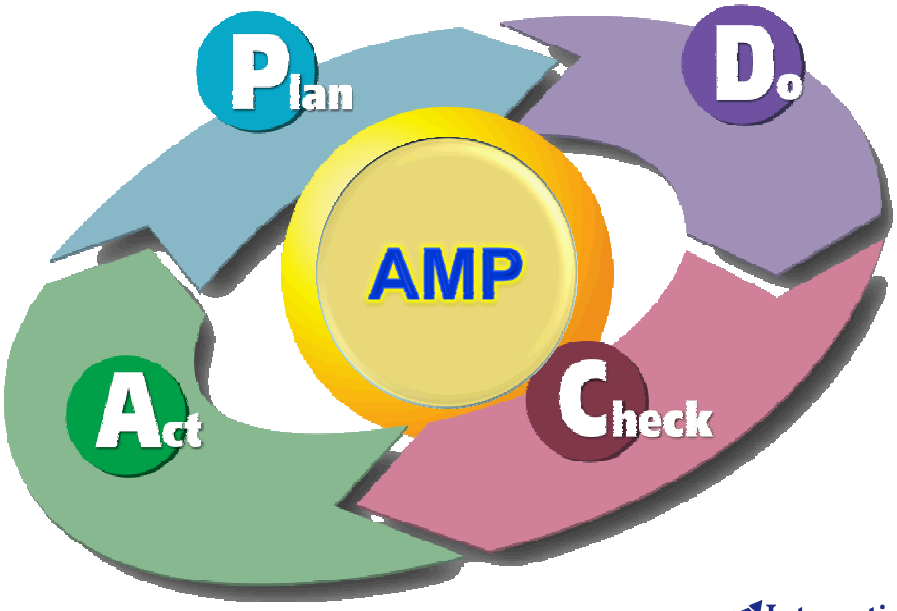
- Assessment = Plan, Do, Check, Act
- Mitigation = Plan, Do, Check, Act
- Performance = Plan, Do, Check, Act

Mitigation is improved and sustained when performance measures are included

Notes:

CWA 15793:2008

Notes:



Notes:

Cataract University Scenario

Alan works in a Biosafety Level 2 (BSL-2) research lab at Cataract University studying anthrax vaccines. He recently visited the emergency room with a serious skin infection on his neck. Doctors determined this infection was caused by *Bacillus anthracis* and started treating him with antibiotics. He is expected to make a full recovery.

Alan was surprised to learn of this diagnosis because he only works in the lab with the Sterne strain of *Bacillus anthracis,* a non-lethal strain used to vaccinate animals. Although the high containment lab in the adjacent building works with the fully virulent strain, Alan never enters there. However, Bill sometimes borrows reagents from the high containment lab.

Upon learning of the infection through the local newspaper, the lab director asked for a study to be done to determine what went wrong and whether or not Alan contracted the agent in the lab. Alan reported that he had been working with Bill two weeks before his diagnosis, to grow up cultures of the non-lethal, live vaccine strain. Bill was working in the Biological Safety Cabinet (BSC) to prevent contamination. After transferring a small amount of broth culture to a micro-centrifuge tube, Bill sealed the tube and wiped it down with alcohol before transferring the tube to Alan, who placed the tubes in a empty pipette box and walked them down the hallway to put them in refrigerator used by several research groups. Alan was not wearing gloves during the process as he explained, "I was not directly handling the agent and Bill was wiping them down with alcohol so I did not think there was anything to worry about." Neither researcher was aware of the fact that alcohol would have little effect on Bacillus spores.

The lab director suggested that the cultures in the lab be tested to determine whether or not the strains were indeed the vaccine version or the fully virulent strain. However, the samples turned up missing after a search of the common refrigerator where they had been stored. No one is sure what happened to them. Researchers from other laboratories in the building also use the refrigerator, and often samples get rearranged to make room for new samples. In fact, Carla cleaned out the refrigerator the week before and may have inadvertently tossed them in the trash but does not remember. Fortunately, Bill saved some of the stock solution and upon testing was surprised to find that it was the fully virulent strain of *B. anthracis* and matched the strain that was cultured from Alan's lesion.

Bill had ordered the vaccine strain from Acme Labs several months ago. When he asked Acme Labs about the possibility of sending the wrong strain to Cataract University, a manager at Acme Labs reported that it is very unlikely because they only shipped the virulent strains to labs that are registered with Acme, and only the high containment lab at Cataract was registered. However, the manager did admit that Acme's shipping supervisor was on vacation when the shipment was sent to the BSL-2 lab at Cataract, and there may have been some confusion. Unfortunately detailed records were not kept during the supervisor's absence.

Introduction to Biorisk Management

	Biorisk Management - Session 1 **10:00 - 10:50**	**Time**
Objectives	The purpose of the session is to: • Discuss biorisk management as a concept • Identify the key components of biorisk management	
Group Exercises	Divide the room into groups of about five people each. (use numbered cards?) Try to get at least one good English speaker in each group.	
Group Exercise 1 Question for the groups	In groups, address the following question (10 minutes): • **What are the risks of working in a laboratory with biological materials?** Go table to table and solicit one unique risk (10 minutes) Each unique idea is captured on the flip chart.	20 minutes Slide 2
Expected Responses	• Accidental infection • Accidental release • Intentional theft and/or misuse • Others (e.g. rad/chem/phys safety)	
10:20 Instructor led slides	**How do we define laboratory biosafety and laboratory biosecurity? (WHO LBM 2004)** • 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	5 minutes Slide 3
	How do we define laboratory biorisk management? (CWA 15793:2008) • 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	Slides 4-5
10:25	Break	15 minutes

10:40 **Group Exercise 2** **Questions for the groups** **Step 1**	In groups, address the following questions (10 minutes): • **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?** Each group uses post-it notes to identify at least three different items for each question, one idea per post-it note. Facilitator should be checking in with each table periodically to ensure that they are addressing all three questions and are putting them down one idea per post it.	20 Minutes Slide 6
Expected Responses	• Risk assessment • Hazard identification • PPE, BSC, SOPs • Audits, less accidents	
11:00 **Group Exercise 2** **Step 2**	***Present the key components of Biorisk Management and briefly define AMP.*** ***How can we organize these ideas/items?*** • Draw three columns: Assessment, Mitigation, and Performance Have students each pick a post-it note, and place it in one of the three columns: ***Assessment, Mitigation, Performance***	10 minutes Slide 7 - 11
11:10 **Key messages**	**The risk associated with biological materials in the laboratory has a safety and a security component** **Biorisk encompasses both biosafety and biosecurity** **The AMP model** • Understand that the components of biorisk management are: ○ **Biorisk management = Assessment, Mitigation, Performance** **Make sure that students do not assume a straight additive or multiplicative relationship here. The relationship is not a clear mathematical relationship.**	5 minutes Slides 11
Debrief	Use summary slides to reinforce this discussion and ensure that both biosafety and biosecurity are addressed	Slide 12