SAND2011-1388C

Biorisk Assessment

African Biosafety Association Pre-Conference Course

March 2011

Eric Cook
International Biological Threat Reduction
encook@sandia.gov

www.biosecurity.sandia.gov

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*What do I want to **know** after leaving this class?*

*How do I want to **feel** at the end of this course?*

*What do I want to be able to **do** at the end of the day?*

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Split into groups:

In your group, take 5 minutes to discuss and answer the following question:

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

Write down your answers, one risk per sticky note.

In your group, take 5 minutes use the risks that you've identified to develop a definition for **Biorisk**:

What is Biorisk?

Write your definition on the flip chart.

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Biorisk is the combination of the probability of occurrence of harm and the severity of that harm where the source of harm is a biological toxin or agent

The source may be an unintentional exposure, accidental release or loss, theft, misuse, diversion, unauthorized access, or intentional unauthorized release.

Biorisk is the integration of biosafety and biosecurity


CEN

WORKSHOP

AGREEMENT

CWA 15793

Laboratory biorisk management standard

Source: CWA 15790 Laboratory Biorisk Management Standard, Feb 2008

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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

The Biorisk AMP Model

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Key Components of Biorisk Management

- Biorisk **Assessment**

  Process of evaluating the biorisk(s) arising from a biohazard(s), taking into account the adequacy of any existing controls, and deciding whether or not the biorisk(s) is acceptable

Key Components of Biorisk Management

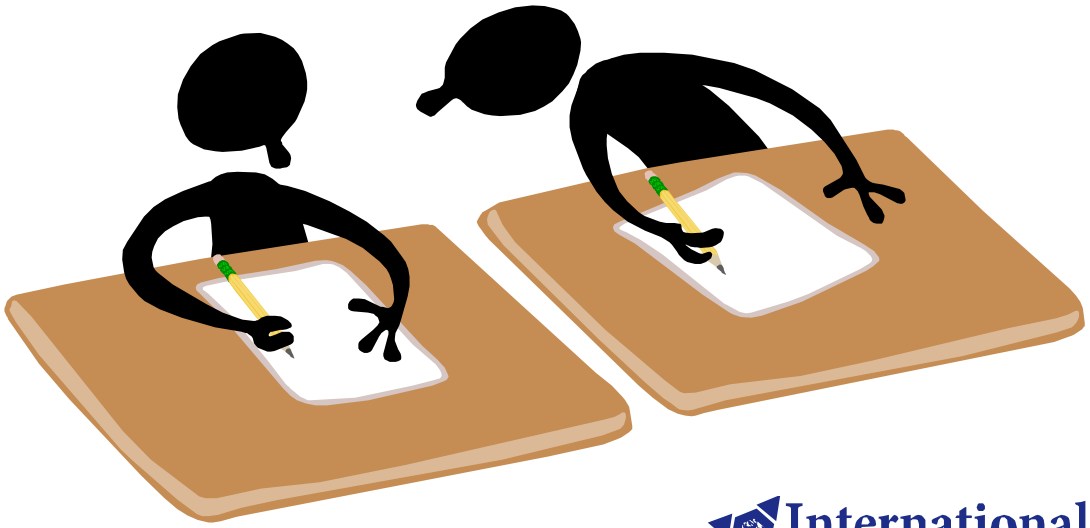
- Biorisk **Mitigation**

  Actions and control measures that are put into place to reduce or eliminate the risks of working with biohazards

Key Components of Biorisk Management

Performance

The way in which a biorisk management system functions, including system evaluation and improvement



Let's get organized:

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

Assessment	Mitigation	Performance

Risk Assessment

Why is risk assessment so important?

Think about this question:

Is conducting a risk assessment simple? Why or why not?

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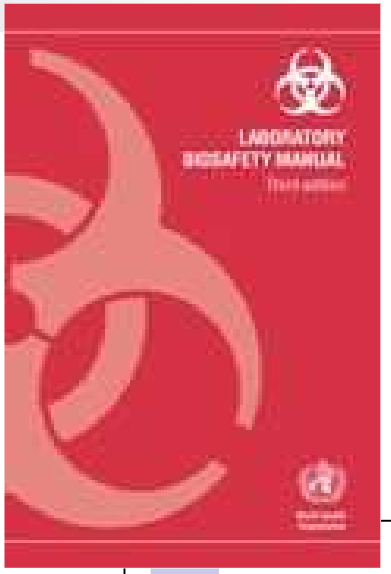
Why Risk Assessment?

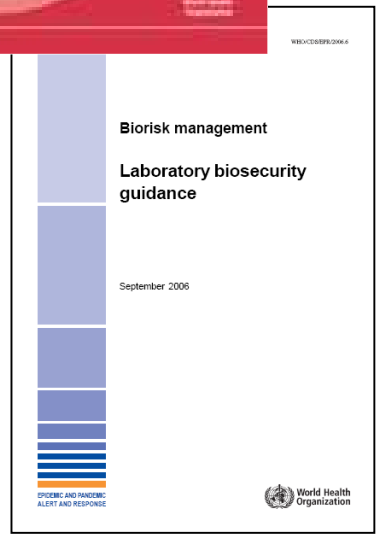
Laboratory Biosafety

A set of preventive measures designed to reduce the risk of accidental exposure to or release of a biological agent



Laboratory Biosecurity

A set of preventive measures designed to reduce the risk of intentional removal (theft) and misuse of a biological agent – intent to cause harm



Identification of preventive measures is determined by the RISK ASSESSMENT

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What is the risk of being attacked by a tiger?

Work in your group to identify factors that would help you determine this risk.

Write these factors on the sticky notes. (Put one factor per sticky note)

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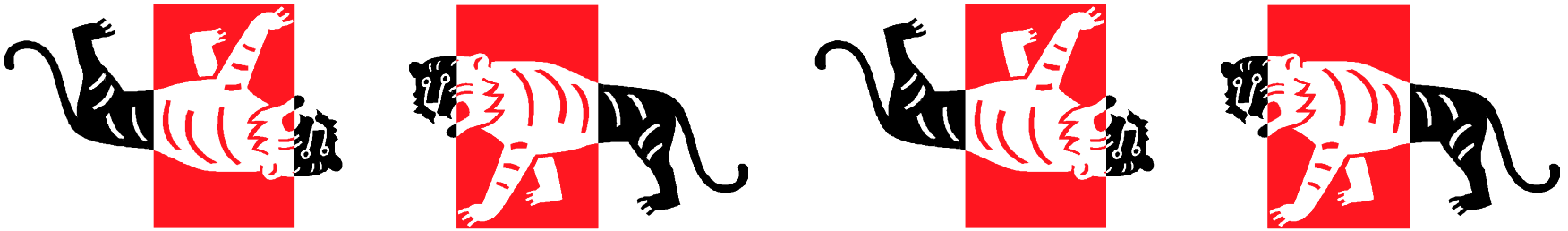
Characterize the factors

By looking at all the factors your group defined, are there any natural groupings?

What are the natural groupings you see?

Place all your factors into natural groupings



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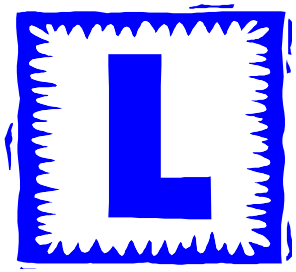
Characterize the factors (part II)

Likelihood

Factors that influence the **potential** for a tiger attack

- Place an “L” on factors that you defined which influence the potential for a tiger attack



Consequences

Factors that influence the **impact** of a tiger attack

- Place a “C” on factors you defined which influence the impact of a tiger attack

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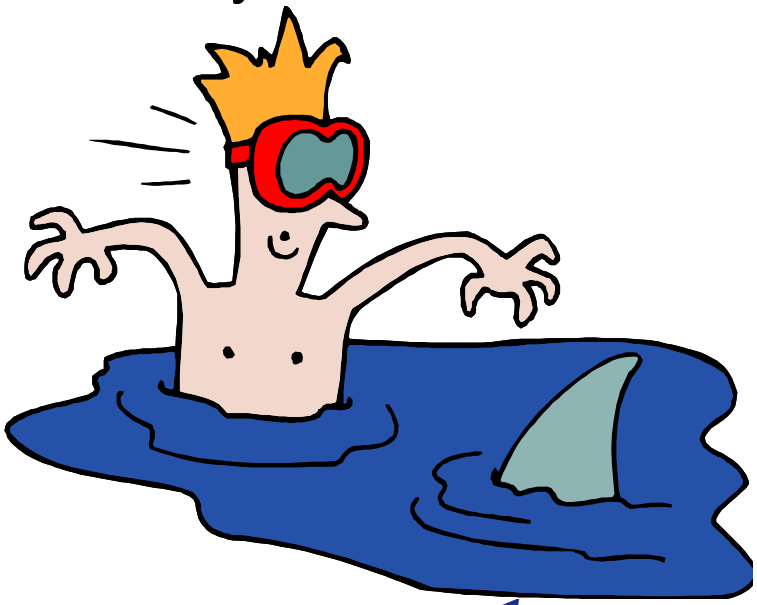
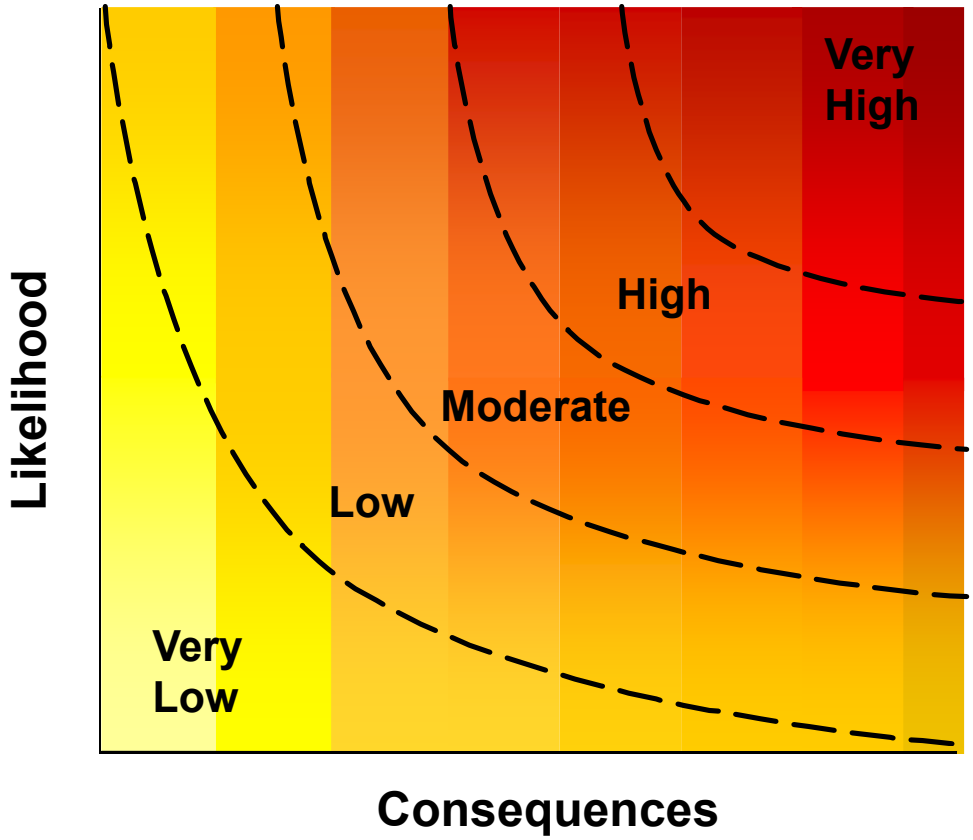
Risk

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

- **Risk** is a combination of the probability of occurrence of harm and the severity of that harm
  (ISO/IEC Guide 51:1999)

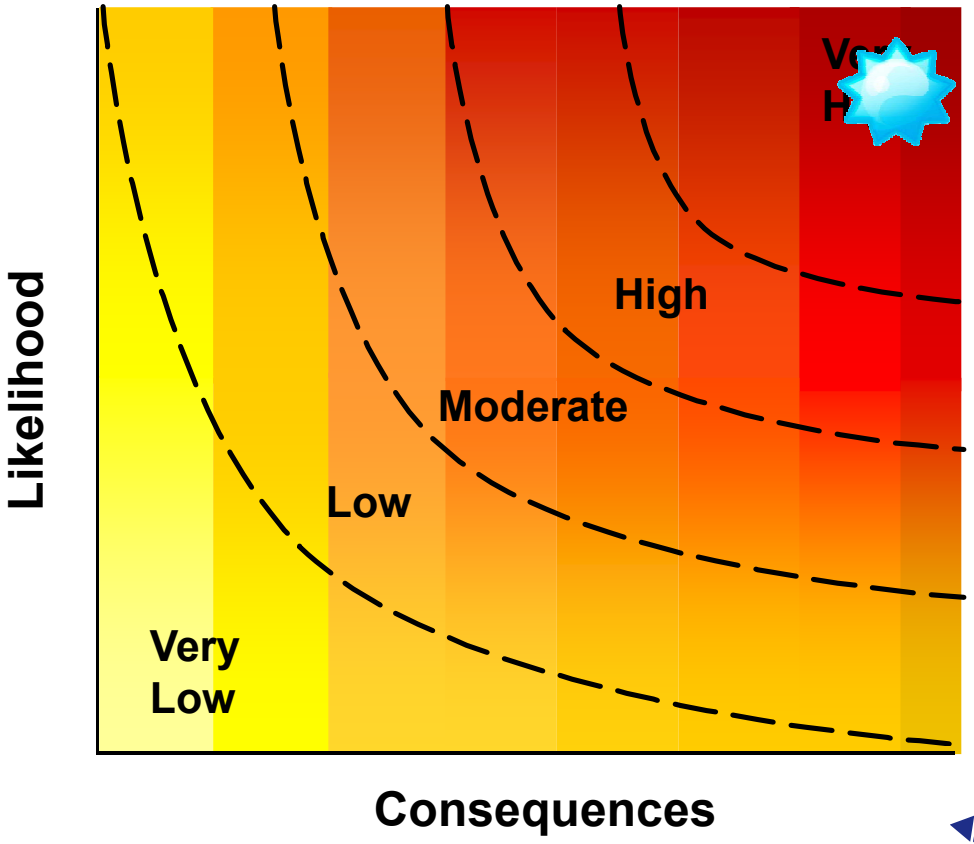


Risk is a function of likelihood and consequences R = f(L,C)



Risk = f(L,C)

You are in an open field next to a very hungry, aggressive, adult tiger that is unrestrained and sees you as a food source.



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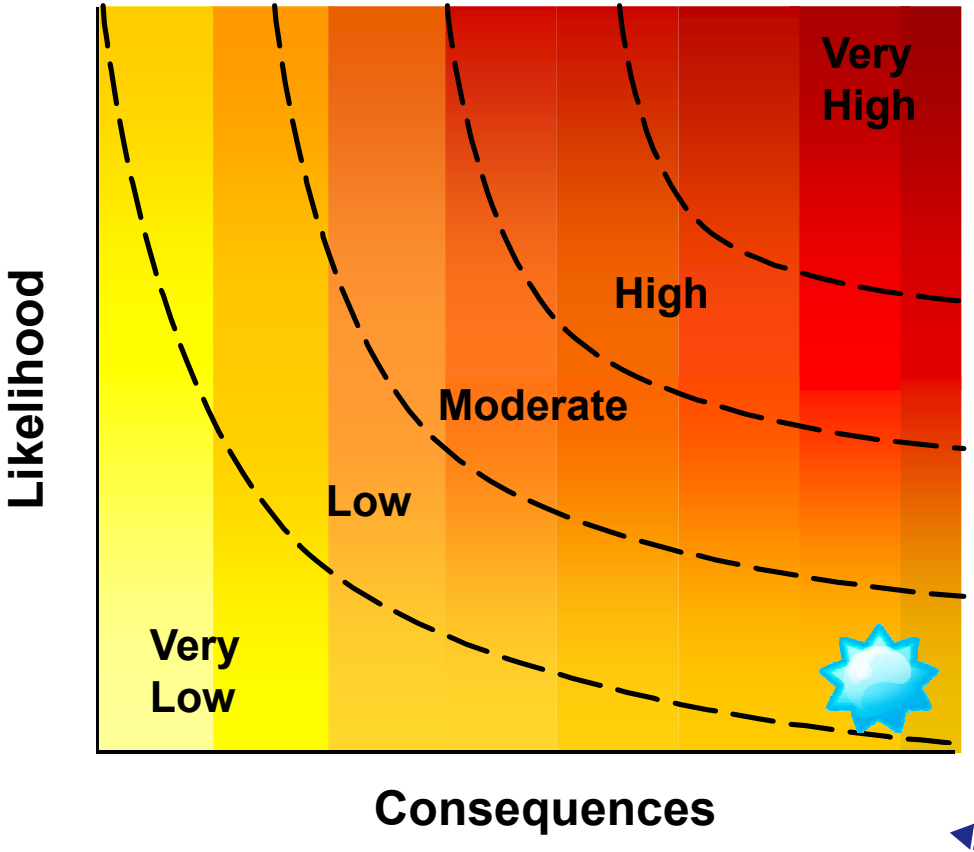
Risk = f(L,C)

You are at the zoo, looking at an adult tiger which is well fed, has a mild temperament and is restrained in a secure tiger enclosure.



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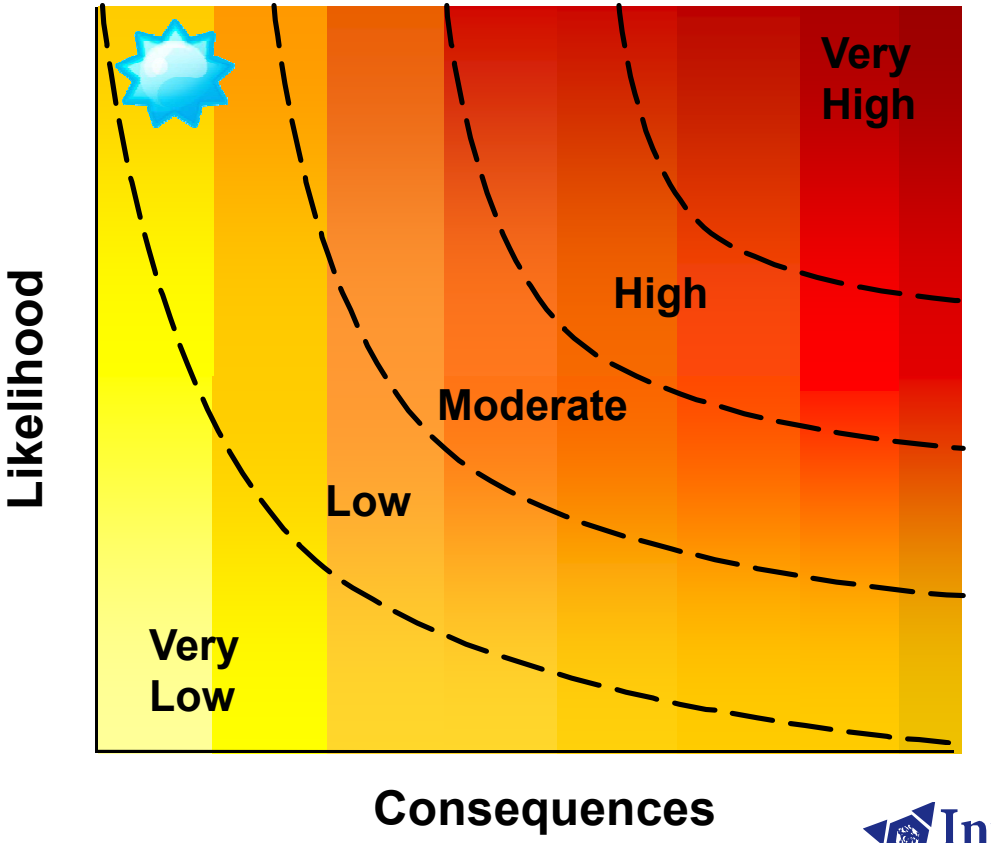
Risk = f(L,C)

You are holding a baby tiger with a playful temperament



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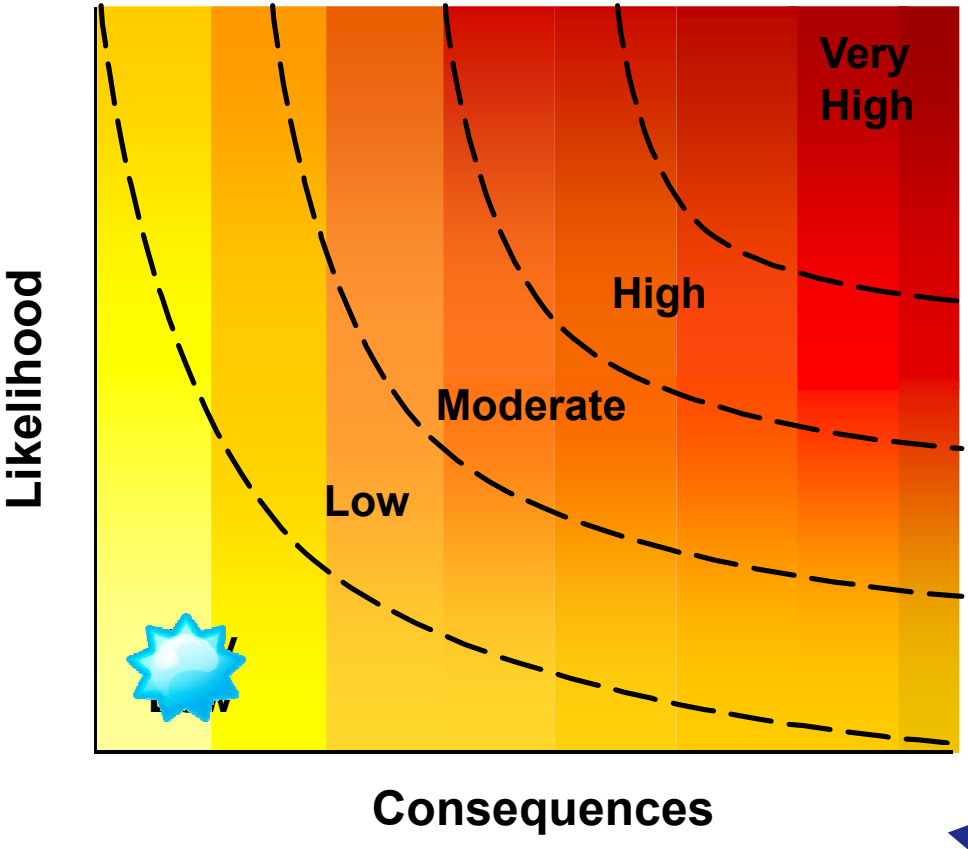
Risk = f(L,C)

You are at the zoo looking at a toothless older adult tiger which has been declawed, raised in a zoo, and well fed. It has a mild temperament and is restrained in a secure tiger enclosure.



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Risk Assessment Principles

Define the problem

Think about how the factors would change if you were assessing the risk of someone stealing a tiger?

The risk assessment method should be as simple as possible

Elaborate when needed

Those conducting risk assessments should be explicit about uncertainties

Risk assessment methods can incorporate one or more approaches

Group Exercise

Laboratory Biorisk Assessment (Step 1)

Example 1: A laboratory researching resistance factors for *Mycobacterium tuberculosis*

Work in your group to determine:

What are the risks you need to assess?

Take 10 minutes to list on your flip chart at least five risks associated with this research

Group Exercise

Laboratory Biorisk Assessment (Step 2)

Example 1: A laboratory researching resistance factors for *Mycobacterium tuberculosis*

Pick one of the risks:

What are the key factors needed to conduct a risk assessment?

- Write down one factor per sticky note
- Characterize each factor as one that affects likelihood, consequences or both (put and "L" or "C" next to the factor)

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Group Exercise

Laboratory Biorisk Assessment (Step 3)

Example 1: A laboratory researching resistance factors for *Mycobacterium tuberculosis*

For each factor:

Identify if it is low, medium or high

- Use another color sticky note, write either low, medium or high and place it next to the factor
- Mark unknowns
- Mark any key factors

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Group Exercise

Laboratory Biorisk Assessment (Step 4)

Example 2: A clinical laboratory conducting diagnostic tests for diarrheal diseases

Using the same factors from the previous scenario:

- Use another color sticky note, write either low, medium or high and place it next to the factor
- Mark unknowns
- Mark any key factors

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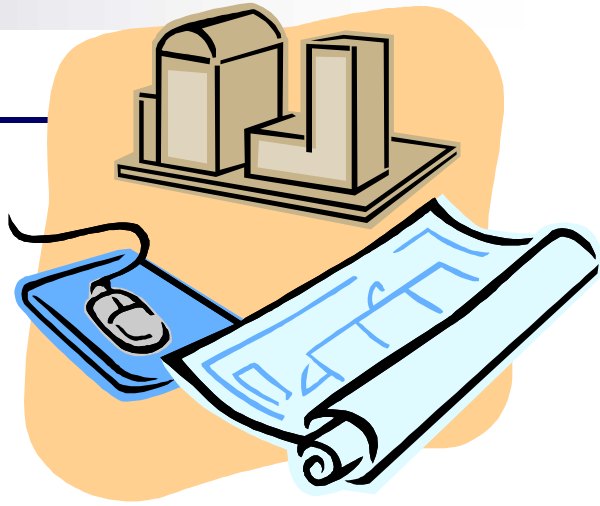
Do the factors you defined for Example 1 work to assess biorisks for Example 2?

Is conducting a risk assessment simple? Why or why not?

What are some of the benefits to a structured process for conducting a biorisk assessment?

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

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Biosafety RAM

Risk = f (Likelihood, Consequence)

Risks

- To laboratory workers (Researchers, Animal Care staff, engineers, technicians, custodial staff, etc.)
- Risk of accidental exposure to community
- Risk of accidental exposure to animal community
- Risks of secondary exposure to human and animal community

Biosafety RAM

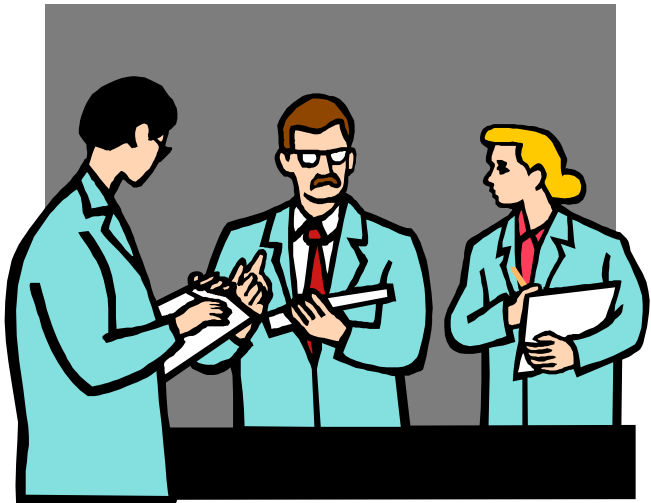
Risk = f (Likelihood, Consequence)

Likelihood

- Likelihood of infection by the agent
- Likelihood of exposure through an infectious route based on the procedures and work practices

Consequences

- Of disease from accidental exposure



LDRD
LABORATORY DIRECTED RESEARCH & DEVELOPMENT

Likelihood of Infection

Routes of infection of the agent (and infectious dose via that route)

- Inhalation
- Ingestion
- Contact
- Percutaneous
- Vector-Borne

Infection mitigation measures (existence of prophylaxis)

Likelihood of exposure

Potential of inhalation exposure to laboratory workers and to the community

- Procedures
- Mitigation measures

Potential of ingestion exposure to laboratory workers and to the community

- Procedures
- Mitigation measures

Potential of percutaneous exposure to laboratory workers and to the community

- Procedures
- Mitigation measures

Potential of contact exposure to laboratory workers and to the community

- Procedures
- Mitigation measures

Consequence of disease

Agent properties

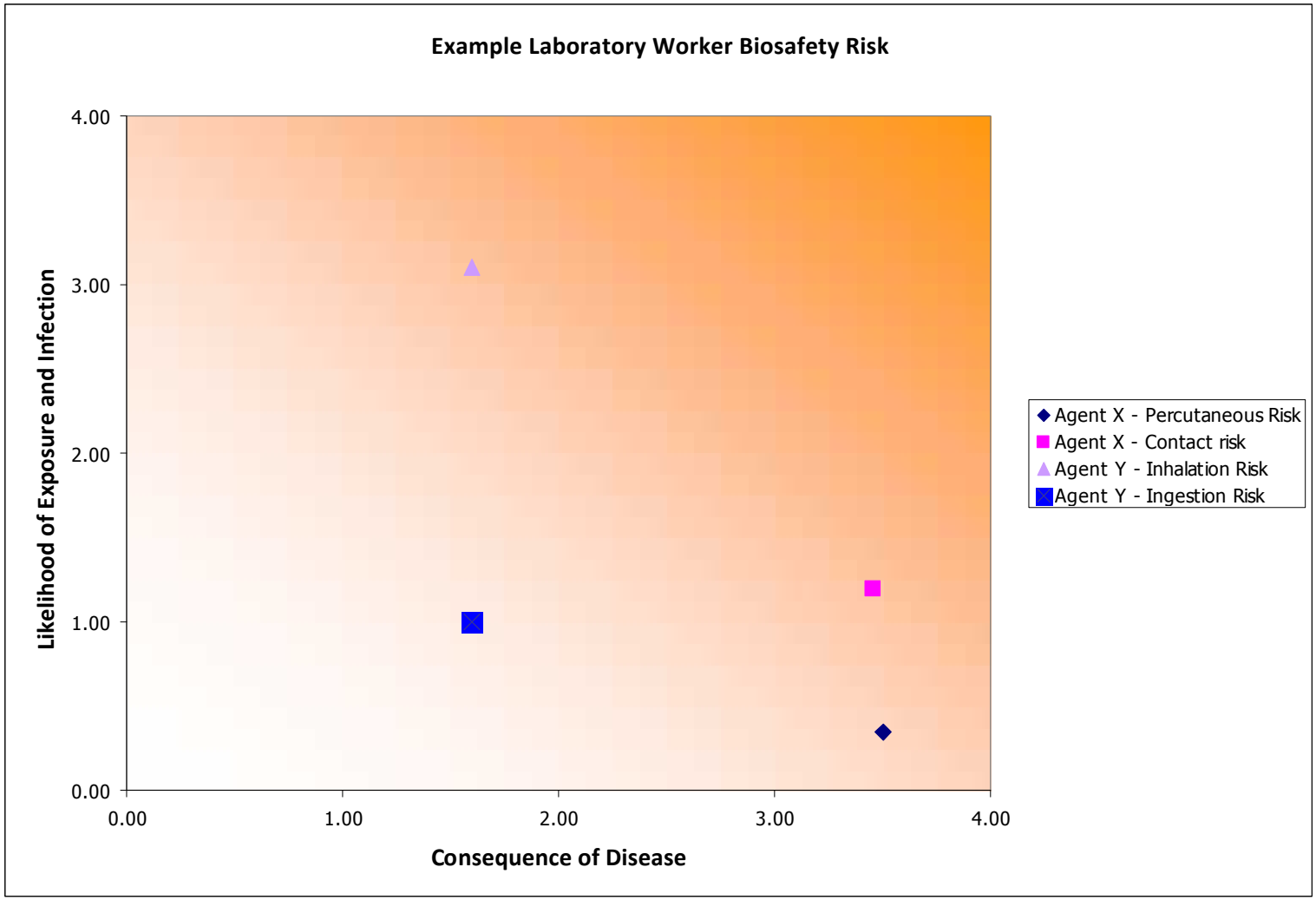
Morbidity

Mortality

Consequence mitigation measures

Potential for secondary transmission

- Communicability (host to host)
- Transmissibility (route of infection between hosts)



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Biosecurity RAM

Risk = f (Likelihood, Consequence)

Likelihood

- The likelihood of theft from a facility and the likelihood an agent can be used as a weapon

Consequences

- Of a bioattack with the agent

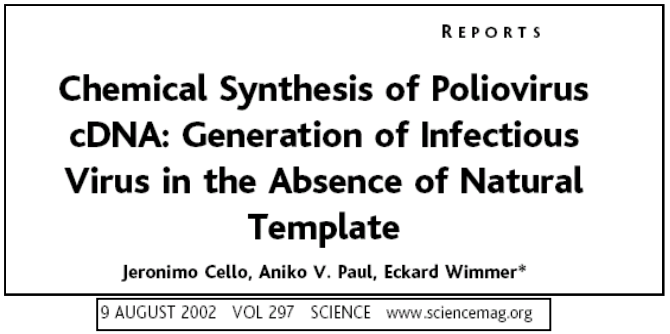
Risks

- Persons in area of attack
- Persons in larger community from secondary exposure
- Animals in area of attack
- Animal in larger community from secondary exposure

Characterize the Biological Agents

Agents potential as a biological weapon

- **Biological Agent Properties**
  - Transmissibility
  - Stability
  - Awareness of agent's BW potential
- **Production and dissemination**

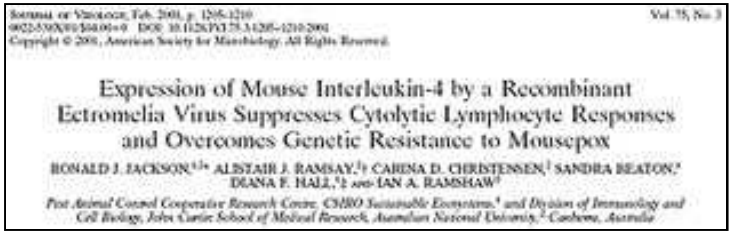


REPORTS

Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer*

9 AUGUST 2002 VOL 297 SCIENCE www.sciencemag.org



Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

RONALD J. JACKSON, ALISTAIR J. RAMSAY, CARINA D. CHRISTENSEN, SANDRA BEATON, DIANA F. HALL, AND IAN A. RAMSHAW

Consequences of a bioattack with agent

- **Disease consequences**
- **Socioeconomic consequences**
- **Secondary exposure consequences**

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Characterize the Adversaries

Adversary Classes

- Should be defined in design basis threat
  - **Terrorist**
  - **Extremist**
  - **Criminal**

Insiders

- Authorized access to the facility, dangerous pathogens, and/or restricted information
- Distinguish Insiders by level of authorized access
  - **Site**
  - **Building**
  - **Asset**

Outsiders

- No authorized access

Characterize the Facility

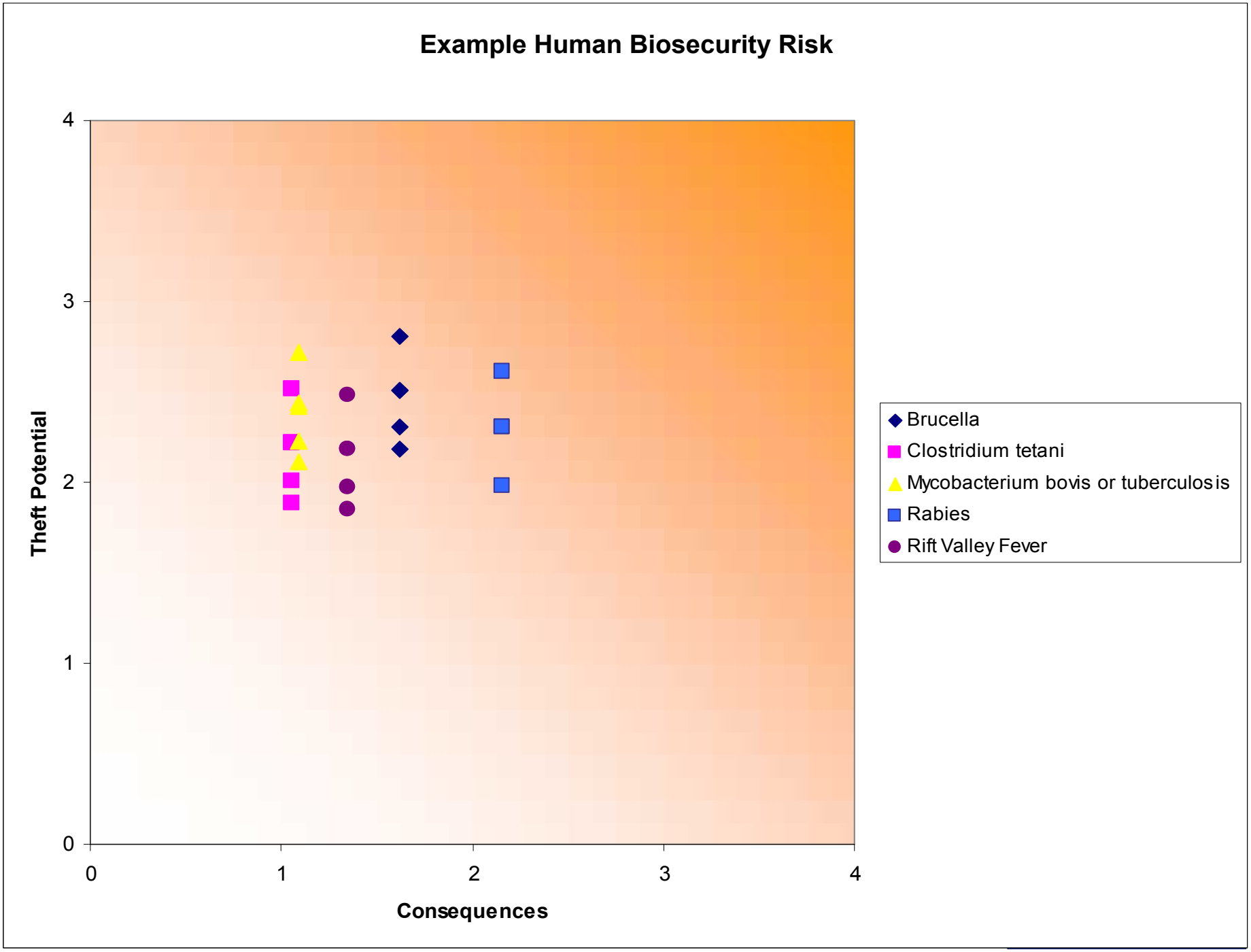
Identify "specific adversaries"

- Operational Means
- Opportunity

Identify "specific assets"

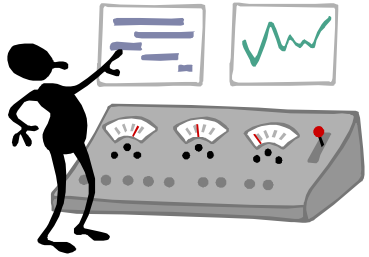
- Uniqueness of asset at facility
- Location of asset
- State of asset (e.g. in long-term storage, in active research, type of research, quantity, …)

Facility vulnerabilities


Example Human Biosecurity Risk
Theft Potential
Consequences
0
1
2
3
4
Brucella
Clostridium tetani
Mycobacterium bovis or tuberculosis
Rabies
Rift Valley Fever

Technical Risk Assessment

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



Technical Risk Assessment

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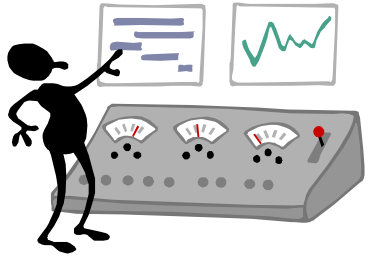
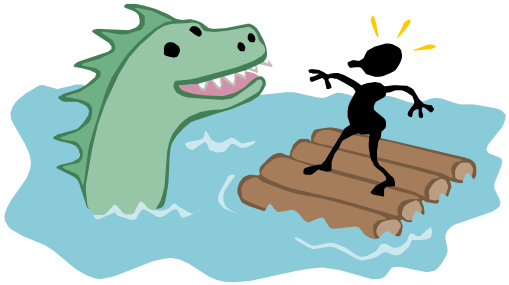


- Concern assessments are generally based on risks ‘perceived’ by management and/or the general public and include perceived social, cultural and political concerns



Risk Assessment vs. Concern Assessment

Are concern assessments important in assessing biorisks? Why or why not?

Work in your group and identify what factors you should consider for conducting a concern assessment?

10 Minutes, identify as many factors as you can. Put one factor per sticky note

Characterizing the factors

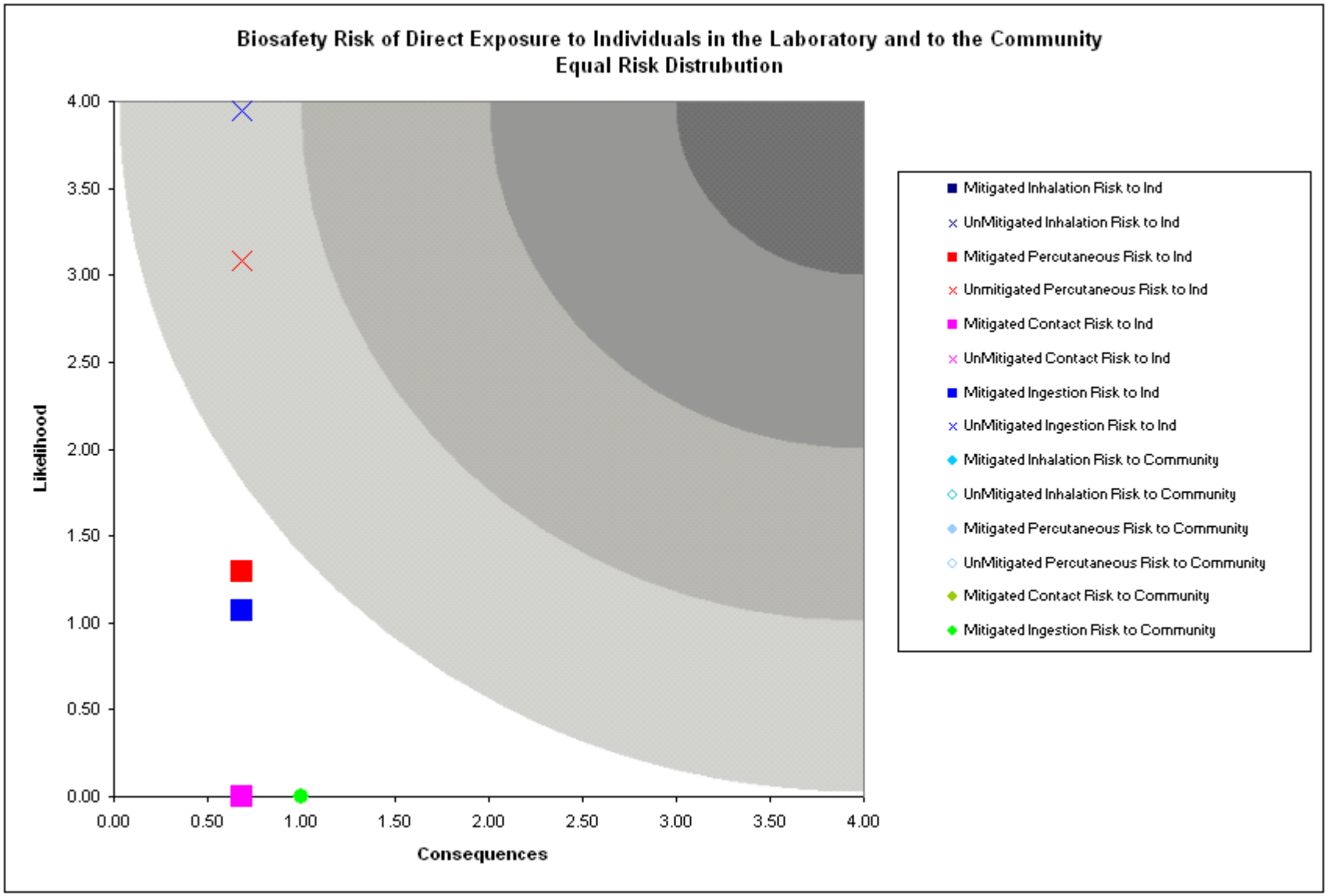
- **Factors that characterize the public's dread regarding the situation**
- **Factors that characterize the publics ability to know or understand the situation**

Create two categories on your flip chart: "Dread" and "The Unknown"

Place each factor under one of these categories.

Risk Acceptance

- How should the concern assessment be reflected in the technical risk assessment? Which, if either, is more important?
- How much risk mitigation is enough?
- How should you balance safety risks vs. security risks?
- Do the assessments help to determine level of acceptance?



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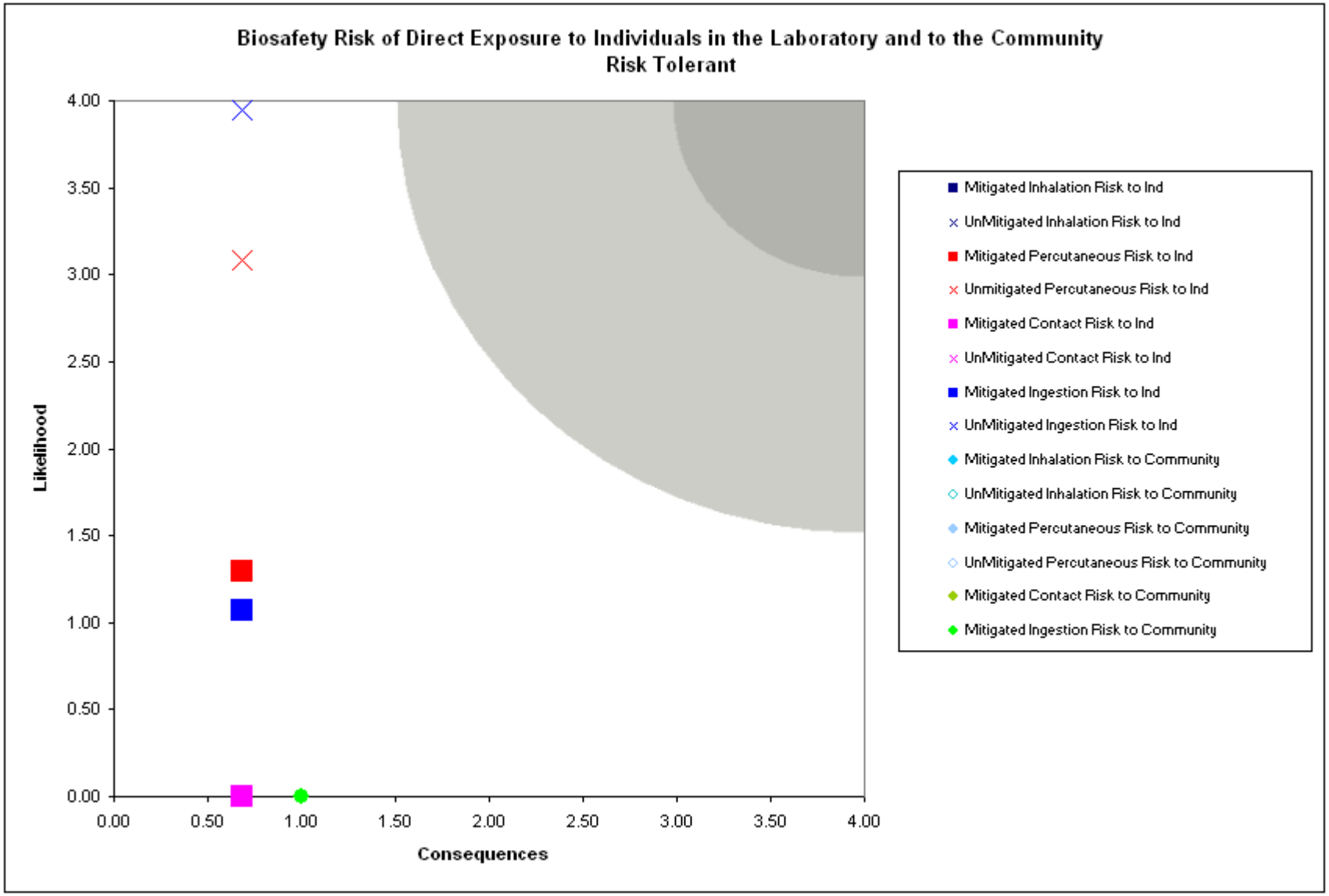

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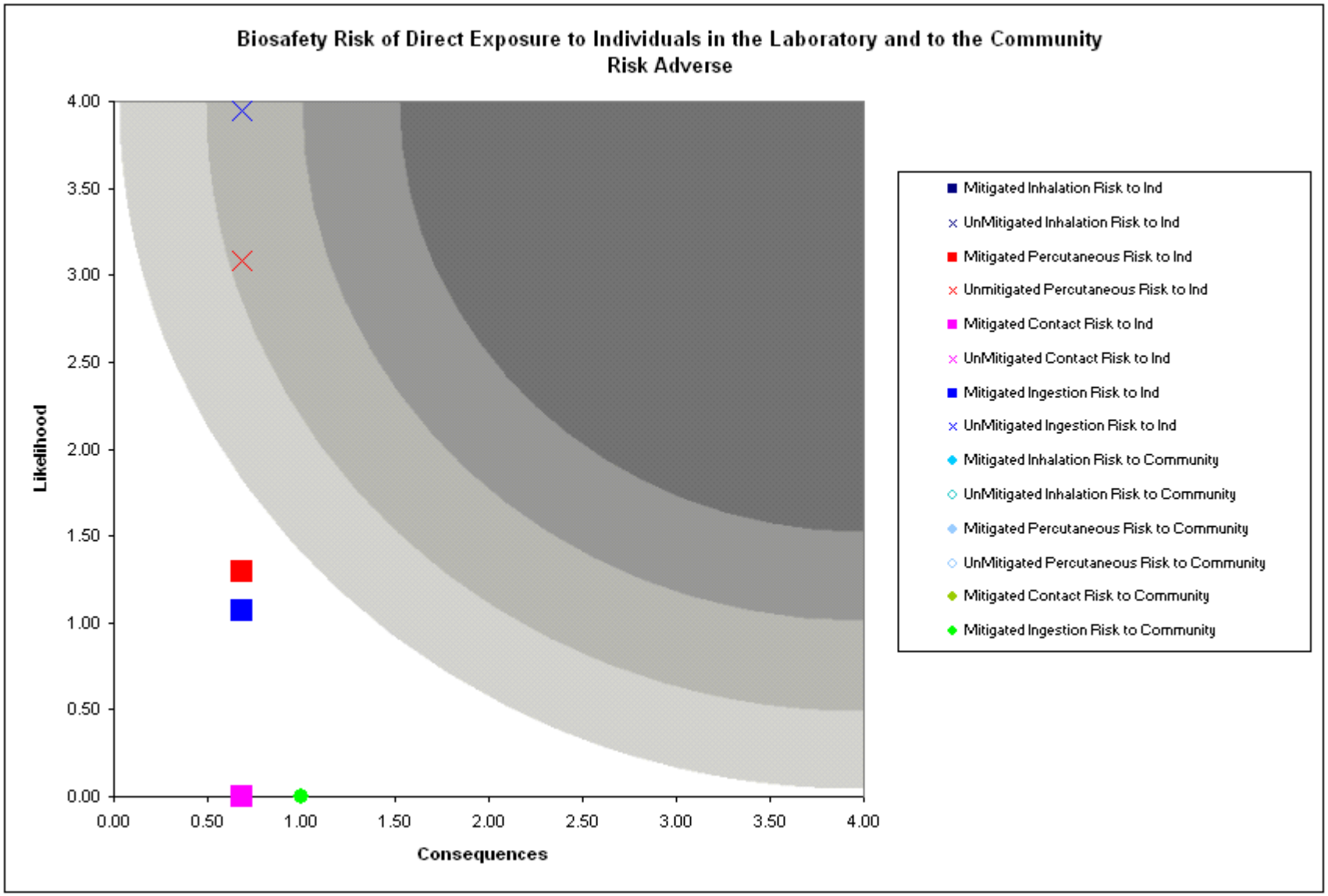
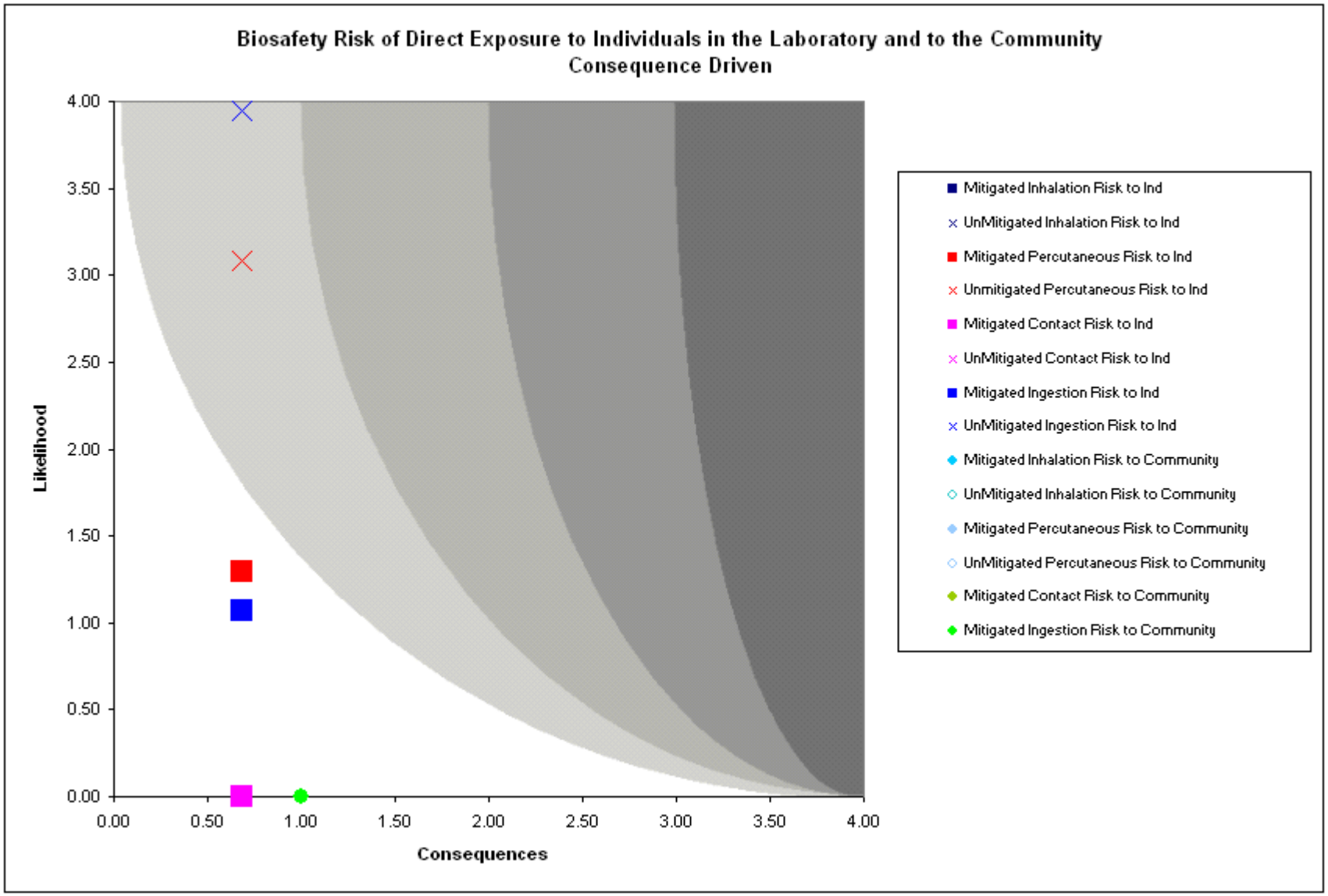

Biosafety Risk of Direct Exposure to Individuals in the Laboratory and to the Community
Risk Adverse
Likelihood
Consequences
0.00
0.50
1.00
1.50
2.00
2.50
3.00
3.50
4.00
Mitigated Inhalation Risk to Ind
UnMitigated Inhalation Risk to Ind
Mitigated Percutaneous Risk to Ind
Unmitigated Percutaneous Risk to Ind
Mitigated Contact Risk to Ind
UnMitigated Contact Risk to Ind
Mitigated Ingestion Risk to Ind
UnMitigated Ingestion Risk to Ind
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



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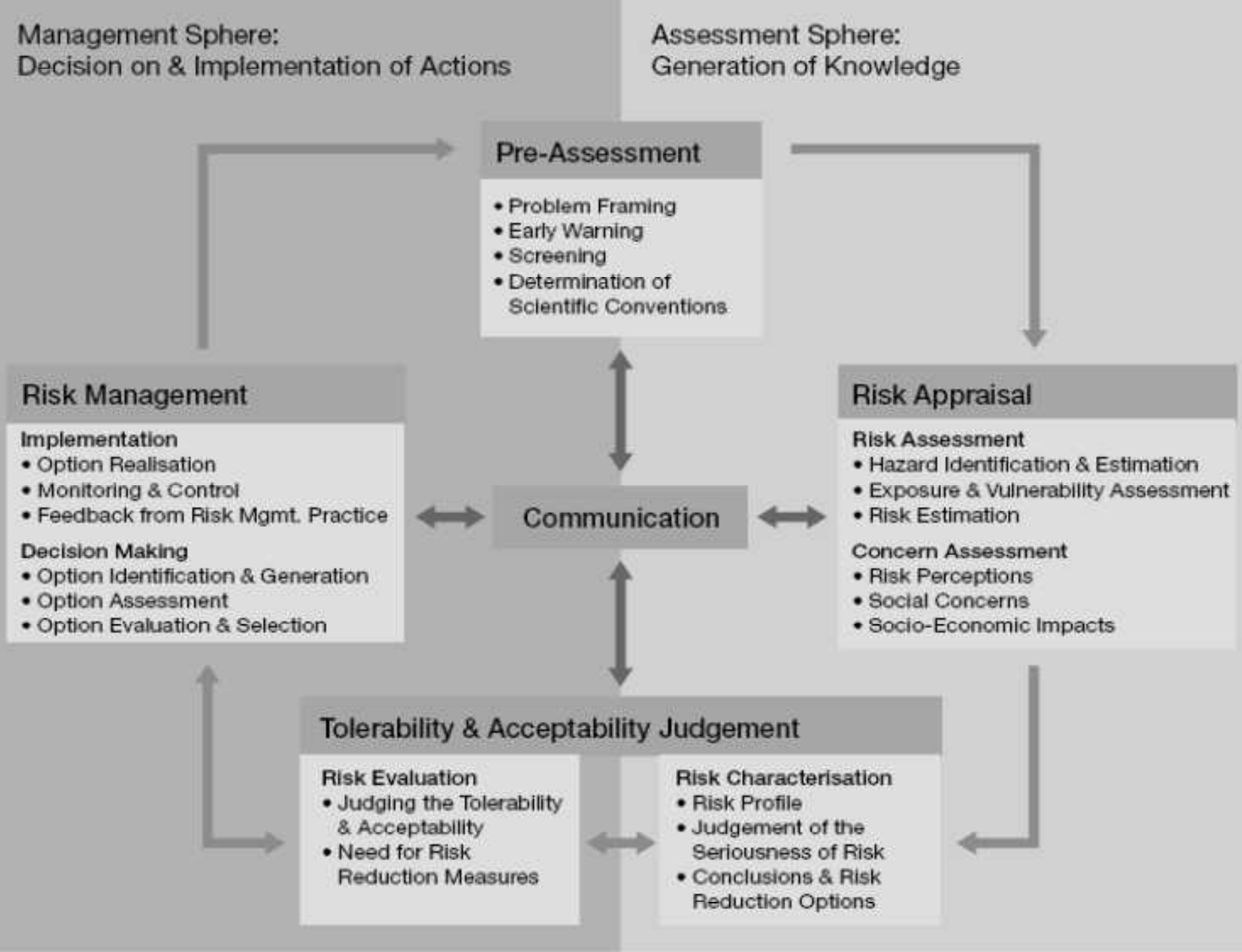
Management Sphere:
Decision on & Implementation of Actions
Assessment Sphere:
Generation of Knowledge
Pre-Assessment
• Problem Framing
• Early Warning
• Screening
• Determination of Scientific Conventions
Risk Management
Implementation
• Option Realisation
• Monitoring & Control
• Feedback from Risk Mgmt. Practice
Decision Making
• Option Identification & Generation
• Option Assessment
• Option Evaluation & Selection
Communication
Risk Appraisal
Risk Assessment
• Hazard Identification & Estimation
• Exposure & Vulnerability Assessment
• Risk Estimation
Concern Assessment
• Risk Perceptions
• Social Concerns
• Socio-Economic Impacts
Tolerability & Acceptability Judgement
Risk Evaluation
• Judging the Tolerability & Acceptability
• Need for Risk Reduction Measures
Risk Characterisation
• Risk Profile
• Judgement of the Seriousness of Risk
• Conclusions & Risk Reduction Options

Conclusions

What is AMP? And why is assessment important?

What is risk?

What are the benefits of a systematic, standardized risk assessment process?

What is a concern assessment and why would you do one?

How can your risk assessment help to communicate risk acceptance?

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AfBSA Biorisk Assessment Pre-Conference Course

Course Introduction:

This biorisk assessment training aims to develop the understanding of a systematic and standardized methodology for assessing biosafety and biosecurity risks, this process will allow the assessments to be repeatable and quantifiable. This workshop will include presentations and discussions on methodologies and models for standardizing biorisk assessments. At this workshop, participants will discuss the principles of risk assessment and how risk should be defined in the context of bioscience. The differences between actual risk and concern (or perception) will also be addressed. Additionally, there will be a detailed review of how the various factors used in assessing risk are related to each other and their overall importance in assessing risk. Workshop attendees will have a chance to review and conduct biorisk assessments.

Course Objectives:

- Understand the principle of AMP and specifically the value of assessment
- Define risk
- Define/Build a risk model (For biosafety and/or biosecurity)
- Compare the differences between technical assessments and concern assessments
- Communicate the issues around risk acceptance

Schedule:

- Welcome, Introductions, Course overview
- Introduction to Biorisk
  - Discussion: What does Biorisk mean? Why is a risk assessment important?
  - Presentation: Introduction to AMP
- General Risk Assessment
  - Small Group Exercise: Conduct and present a risk assessment on the presented scenario
  - Discussion: Defining Risk
- Biorisk Assessment
  - Small Group Exercise: Conduct and present a risk assessment on the presented laboratory scenario
  - Discussion: Structure of risk assessments
- Methods and models
  - Discussion: Value of Structured Assessments
  - Presentation: Introduction to BioRAM
- Concern Assessment vs. Technical Assessment
  - Small Group Exercise: Identify concern factors
  - Discussion: Risk Acceptance
- Conclusion/Wrap-up

AfBSA Pre-conference Risk Assessment Workshop Facilitator Guide

March 7 and 8, 2011

Sandia National Laboratories
International
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CBEP
Cooperative Biological Engagement Program

Course Description

Overview

Brief Description

This biorisk assessment training aims to develop the understanding of a systematic and standardized methodology for assessing biosafety and biosecurity risks, this process will allow the assessments to be repeatable and quantifiable. This workshop will include presentations and discussions on methodologies and models for standardizing biorisk assessments. At this workshop, participants will discuss the principles of risk assessment and how risk should be defined in the context of bioscience. The differences between actual risk and concern (or perception) will also be addressed. Additionally, there will be a detailed review of how the various factors used in assessing risk are related to each other and their overall importance in assessing risk. Participants will be introduced to the Biosafety and Biosecurity Risk Assessment Model (BioRAM). Workshop attendees will have a chance to review and conduct biorisk assessments.

Objectives

Organizational Objectives

To improve security of pathogens in laboratories

Instructional Objectives

To provide an opportunity for a WHO BRM ATP graduate to gain experience through a partnered/mentored approach

Create excitement and awareness of biorisk assessment among participants

Create a feeling of trust between the students and IBTR to help enable other engagement opportunities

Key Messages

1. *Biorisk is the combination of the probability of the occurrence of harm (likelihood) and the severity of that harm (consequences) where the source of harm is a biological agent or toxin.*
2. *AMP is a Biorisk Management Strategy*
3. *Biorisk encompasses both biosafety and biosecurity*
4. *Risk assessment is a key part of Biorisk Management because it drives (determines) the mitigation efforts.*
5. *Building a risk assessment model based on risk as a function of likelihood and consequences.*
6. *The benefits of a structured risk assessment process: facilitates risk assessment; it is reproducible and repeatable; you can compare results; it allows you to evaluate the impact of mitigation measures; provides quality control documentation; allows you to communicate risk easier.*
7. *BioRAM is one method that can be used to do a structured risk assessment.*
8. *Technical risk assessments rely on scientific data/observations but are only part of the risk evaluation. A technical risk assessment should also be coupled with a*

concern assessment that is based more on perceived risks by management and/or the general public.

9. *The risk assessment process (risk governance) involves: Pre-assessment; Risk Appraisal (Technical risk assessment and concern assessment); Risk Acceptance (Evaluation and Characterization); Risk Management*

Student Objectives

Know – Risk assessment is critical part of the Biorisk Management process; Biosafety and Biosecurity is relevant to my work; Basics of the AMP model

Feel – Curious about how to improve safety at my facility; energized and excited about learning more about the AMP model; anxious to try BioRAM to assess risks in my workplace

Do – Create a basic biorisk assessment model for my work. Identify what is next for me to do in improving safety/security at my worksite

Evaluation Strategy

Evaluation of this course will be measured by a Level 1 satisfaction evaluation survey at the end

Learning Level and Scope

Goal of the course in terms of Bloom's Taxonomy (knowledge, comprehension, application, synthesis, or evaluation). Participants should understand the importance of doing a risk assessment (comprehension) and understand that risk is a function of likelihood and consequences (knowledge) and be able to develop their own basic models for risk assessment (application). They should be able to perform a basic risk assessment in their own labs (application) and know the difference between a technical risk assessment and concern assessment (knowledge).

What the course will and WILL NOT address/cover: the course will not go into detail on specific risk assessment models (e.g. WHO risk groups, BioRAM). While the course introduces the AMP model, it only the "A" portion and does not provide any further information on M and P (other than a basic definition). The course does not demonstrate how mitigation affects risk.

Target Audience

This course is designed for 15 to 20 people with some laboratory or biosafety experience and is part of a set of preconference courses for AfBSA conference.

Prerequisites

Some knowledge of laboratory biosafety or experience working in a research laboratory

Instructional Environment

Instructional Method

Course will be taught using many small group discussions. In my experience African students tend to be more biased toward reflectors (due to their schooling) especially those coming from former British colonies. Therefore ample time must be given for thinking, reflecting, and white space. The AMP model, BioRAM and use of risk graphs will appeal to theorists. For pragmatists, groups will work together to develop a basic risk assessment model for TB research and a basic clinical lab. Each of these group discussions will provide plenty of opportunities for activists to jump in.

Preferably no more than six people per group and three to four groups are ideal. The following group exercises are employed:

- Develop a group definition of Biorisk
- Develop/define the AMP model as a group
- Identify risk factors for tiger attack
- Characterize (create natural groupings) for tiger attack factors
- Characterize (as likelihood or consequence) tiger attack factors
- Develop a risk assessment model for TB research lab
- Apply the model that they created to a clinical setting: diagnosing diarrheal disease

The course is approximately 50% facilitation and 50% teaching.

Class Layout

Requires several clusters of tables to facilitate these discussions

Instructional Materials

- *10 large sticky note pads of four (or five if possible) different colors*
- *10 small sticky note pads of two different colors*
- *4 or 5 flip charts (one for each group)*
- *Large sharpies*
- *Projector and computer with BioRAM loaded*
- *Extra tape*
- *4 or 5 'prizes' for students*

Student Handouts

- *Agenda*
- *Course objectives*
- *Workbook*
- *Additional handouts*

Pre-course Preparation

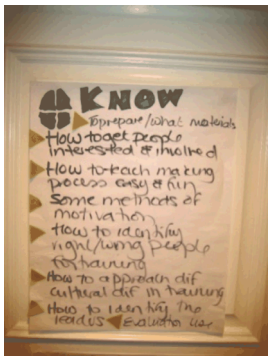
1. Arrange the tables and chairs so that there is space to put stuff up on the walls and people can move around. Depending on the number of participants, you will want to arrange the tables into

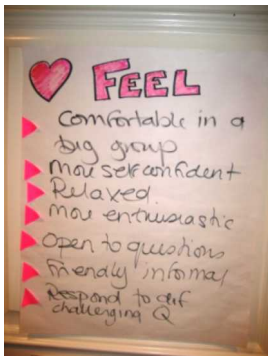
four or five groups. You should strive for no more than six participants per group. Place a flip chart for each group,

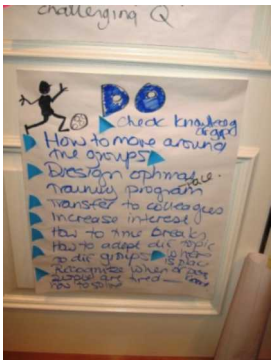
2. Create a learning environment by posting quotes, interesting pictures, and a "Welcome" sign and post it to the wall. (VAK attack)

(*example welcome sign*)

3. Create flip chart pages with "Know" "Feel" and "Do" titles. Use a variety of colors and simple graphics (see pictures below)







4. Create flip chart pages with "Assessment", "Mitigation", and "Performance"
5.

Course Outline/Schedule

	Time	Topic	Instructional Method	Slide #	K M #	T/F
		Pre-Work	Describe any work that you will ask the students to do before the class			
10	09:00	Welcome & Introductions		1		T
20	09:10	Course Objectives – Know, Feel, Do (Nemawashi)	Reflection, then plenary activity to address Know, Feel, Do – post-its	2		T/F
10	9:30	Introduction to Key Message #1 Defining Risk	Small group exercise#1 Part 1: What are risks working in a lab?	3		F

10	9:40		Small group exercise #1 Part 2: What does Biorisk mean?	4		F
5	9:45		Instructor presentation of CWA definition of Biorisk	5	1	T
10	9:55	BREAK				
15	10:05	Activity to reinforce KM #1 and introduce KM#2.	Small group exercise #2 Part 1: *How you identify and manage risks, how to you know it is working?*	6	1	F
10	10:20	Biorisk AMP Model	Instructor presentation	7-10	2	T
10	10:30	Activity to reinforce KM#2	Small group exercise #2 Part 2: Put answers from part 1 into AMP model	11	2	F
5	10:35	Why is risk assessment so important?	Plenary discussion	12	4	F
5	10:40	Why risk assessment	Instructor presentation	13	3,4	T
30	10:45	Introduction to KM#5. Risk is a function of L and C	Small group exercise #3 Part 1: Identify factors in risk of tiger attack	14	5	F
10	11:15	BREAK				
15	11:25	Building a RA model (KM#5)	Small group exercise #3 Part 2: Grouping the factors	15	5	F
15	11:40	Building a RA Model	Small group exercise #3 Part 3: Identifying factors according to L and C	16	5	F
20	11:55	Reinforce KM#5	Instructor presentation: Graphing risk as a function of L and C	17-22		F
60	12:15	LUNCH BREAK				
5	1:15	Review of RA principles	Instructor presentation	23		T
10	1:20	Developing a RA model for a laboratory biorisk scenario	Small group exercise #4 Part 1: Mtb research; what are the risk factors?	24	5	F
20	1:30	Developing a RA model for a laboratory biorisk scenario	Small group exercise #4 Part 2: Identify the factors for one of the risks. Determine if the factors drive likelihood or consequences or both	25	5	F
10	1:50	Developing a RA model for a laboratory biorisk scenario	Small group exercise #4 Part 3: Rate the factors as low, medium, or high	26	5	F
20	2:00	Developing a RA model for a laboratory biorisk scenario. Student presentations and debrief	Group discussion		5	F
10	2:20	BREAK				
10	2:30	Use the new model for another scenario (Clinical lab diarrhea)	Small group exercise #4 Part 4: Use the same factors from part 2 to rate new scenario, low, medium, high	27	5	F
20	2:40	De-brief KM #5	Plenary discussion: What? So what? Now what?	28	6	F
30	3:00	Introduce BioRAM	Instructor presentation	29-40	7	T
10	3:30	BREAK				
15	3:40	technical vs. concern assessments	Plenary discussion: Are concern assessments important in assessing Biorisks or not. Small group exercise #5 Part 1: identify factors to consider when conducting a concern assessment.	42-43	9	F
10	3:55	Concern assessment factors	Small group exercise #5 part 2: categorize the factors under “dread” and “unknown”	44	9	F
15	4:10	Risk Acceptance	Small group discussion and report back	45		F
10	4:25	Review of risk acceptance curves	Instructor presentation	46-49		T
5	4:35	Risk Governance	Instructor presentation	41	8	T
15	4:40	Summary and review	Map the course on cards. Q & A	50		F
5	4:55	End of Day wrap up and course evaluations				

Course

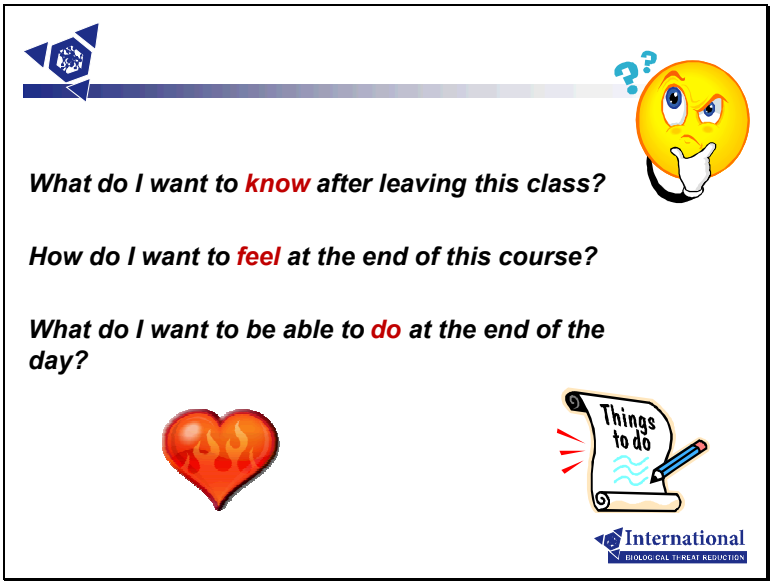
Welcome, Introductions - 10 Minutes

Instructor Introduction – short introduction of instructor including name, facility representing

Student Introduction – Student's names and facility they represent

Hand out the course agenda and course objectives pages. Review the agenda and the objectives, answer any questions.

Know, Feel, Do (Nemawashi) - 20 Minutes



DIRECTIONS:

Prepare "Know", "Feel", "Do" flip chart pages before the course.

Allow five minutes for everyone to reflect on the questions above and write down their answers to the posted questions.

Start with "Know". In plenary, ask the students to provide their answers. Write them down on the flip chart. Make sure that each "unique" answer is captured. As they give their answers, you may need to temper expectations if needed and align (nemawashi) the participants with the objectives of the course. Make sure that everyone gets a chance to voice at least one.

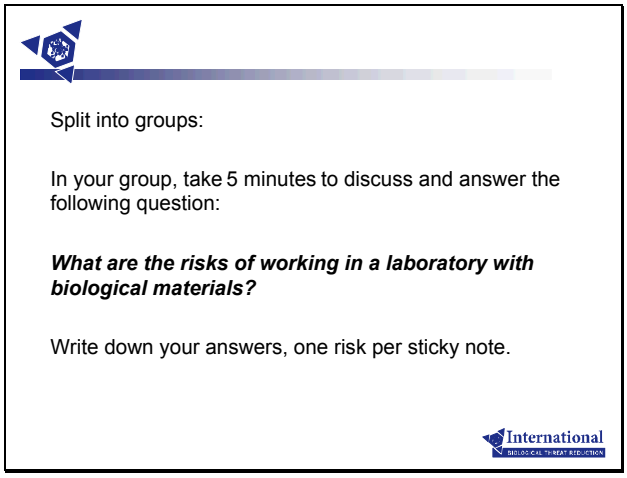
Continue in the same process with "Feel" and "Do"

You should spend approximately five minutes for each topic (15 minutes total) to capture all of the unique thoughts. Tape the three pages to the wall.

Introduction to Biorisk – 10 minutes
Facilitates key learning message 1: *Students should be able to define biorisk*

Small group activity #1 – Part 1

10 minutes



DIRECTIONS:
Each group take one sticky note pad and a pen
Take five minutes and write down one item per sticky note
"What are the risks of working with biological materials?

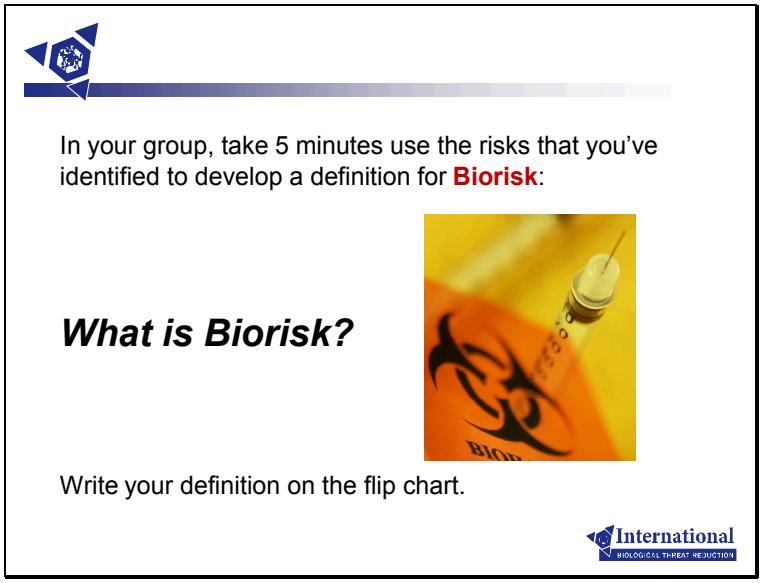
Capture the sticky notes at the front on a single flip chart. Place congruent answers over the top of each note so that as many of the "unique" risks as possible are captured.

Expected Answers:

Expected Answers: Personal risk (infection, contamination), laboratory acquired infections; physical injury: chem, rad, electrical, burns, cuts, needlesticks, slip, trip, falls and other physical hazards; cross-contamination; environmental release/contamination; theft; misuse of biohazardous agents; loss of containment; risks associated with animals: bites, scratches, allergies.

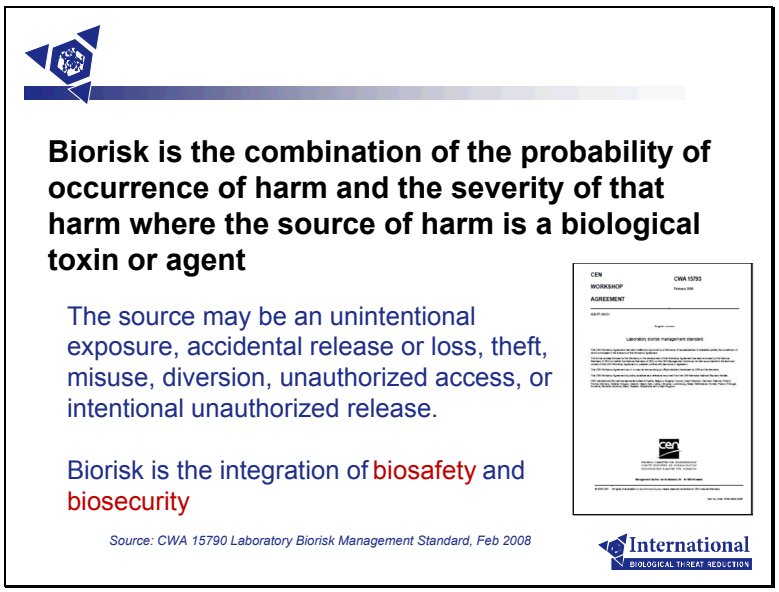
Small group activity #1 – Part 2

10 minutes



DIRECTIONS:

Using the risks they've identified, they should work together as a group to create a definition for biorisk. Each group should spend another 5 minutes developing their definition and writing it on their flip chart. Give each group an opportunity to present their defintion to the rest of the class (another 5 minutes)



This is the definition from the CEN biorisk management standard and here so students have a formal definition for their notes.

Key item is to highlight the integration of safety and security in this definition of biorisk.

You can also use this slide to introduce the CWA and talk about it a little. Through general inquiry, you can determine if the participants are familiar with the standard and provide a little more detail on its origins and purpose.

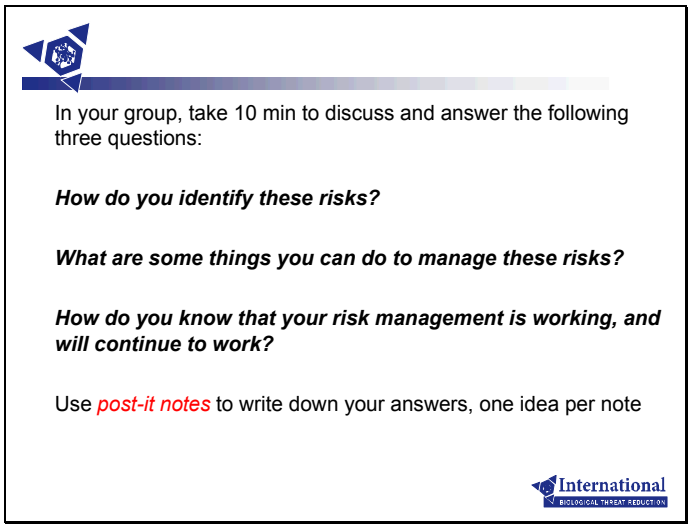
Note: Be sure to validate participants definitions and find common ground between what they came up with and the CEN standard. Also you may want to point out the language of "probability" (likelihood) and "severity" (consequences) as this will start to get them thinking about risk as a function of likelihood and consequences.

BREAK (this is a natural point to take a 10 minute break)

Activity to reinforce Key Message #1 – Know the definition of Biorisk and introduce Key Message #2 – AMP is a strategy to manage Biorisk.

Small group exercise #2 – Part 1

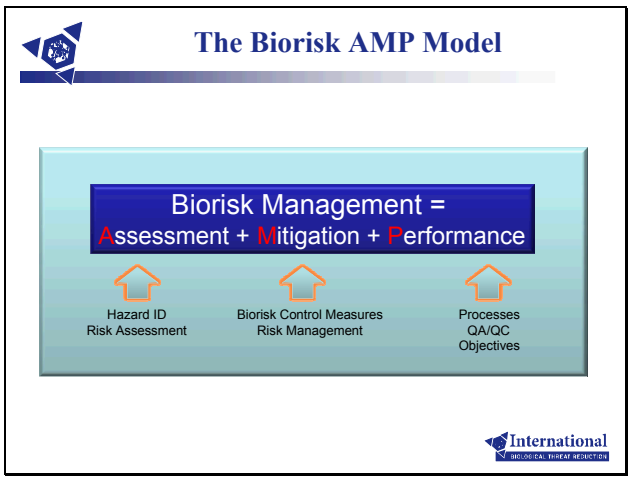
10 minutes



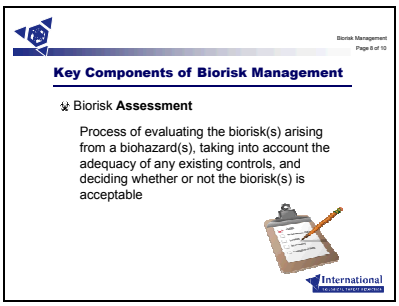
For this exercise, each table (or group) should use a distinct color of post-it notes. Be sure to circulate to ensure that they are putting down only one concept or idea per note.

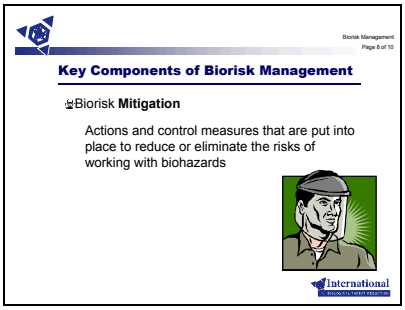
Allow 10 minutes for the groups to discuss and write down their answers

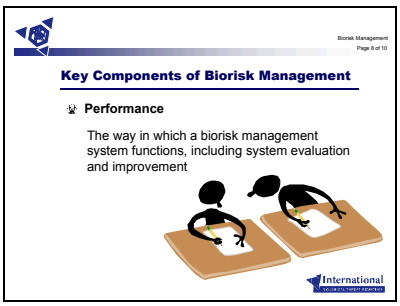
Eventually, all of these notes will end up on three flip charts (Assessment, Mitigation, Performance) at the front of the room. Having each group with an identifiable color will allow you to distinguish one group from another when all of their answers are mixed together. For now, have the groups keep their notes to themselves.



This is the AMP model, Risk management is made up of the assessment, mitigation measures and performance. Take a few minutes to present this model and answer any questions. Use the next three slides to discuss the A, M, and P parts in more detail.



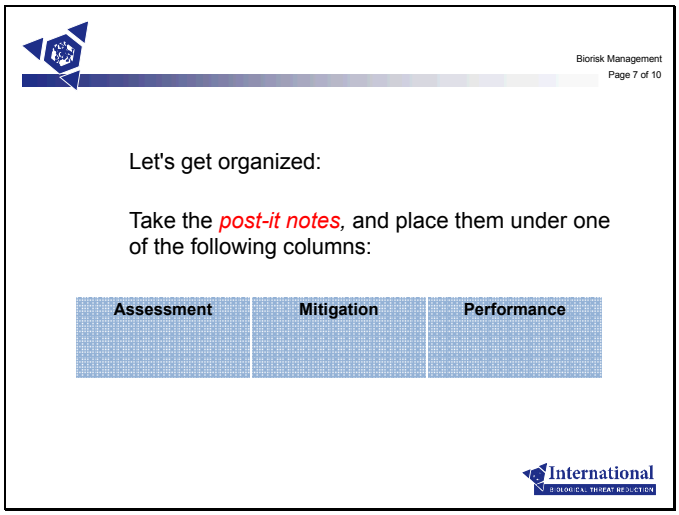




Activity to reinforce KM#2 - *AMP is a Biorisk Management Strategy*

Small group exercise #2 – Part 2

10 minutes



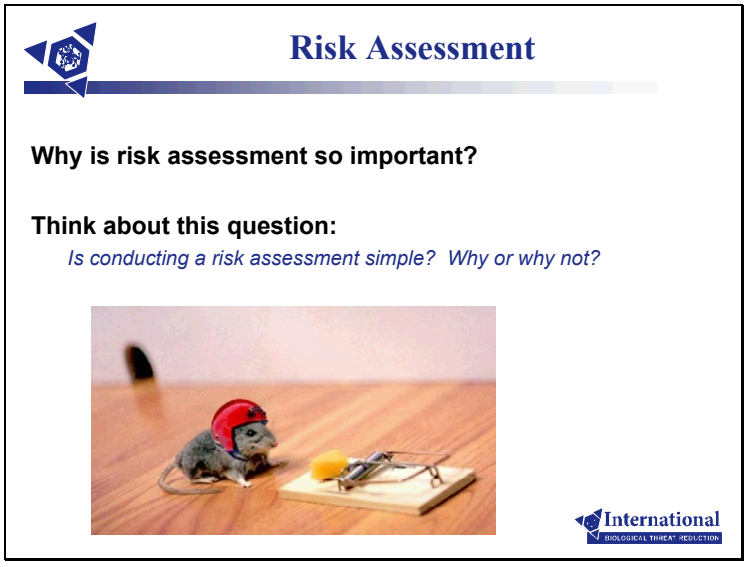
DIRECTIONS:
You will need to arrange three flip charts title with the following: “Assessment” on one chart, “Mitigation” on another, and “Performance” on the third. Have them place their post-it notes from Part 1 of the exercise on the appropriate flip chart.

Explain that they have just created a management system.

It is expected that there will be many more notes on the mitigation chart. If there happens to be a lot of notes under the mitigation section and fewer under assessment and performance you can ask the participants why this is true and try and guide them to the answer that **“typically, people focus on mitigation, and less emphasis is placed on assessment and performance”.** Explain that while this presentation is focused on the assessment part of the model, they need to be aware that it is an important part of a management system. And this will lead to the next question and slide.

Why is risk assessment so important?

5 Minutes



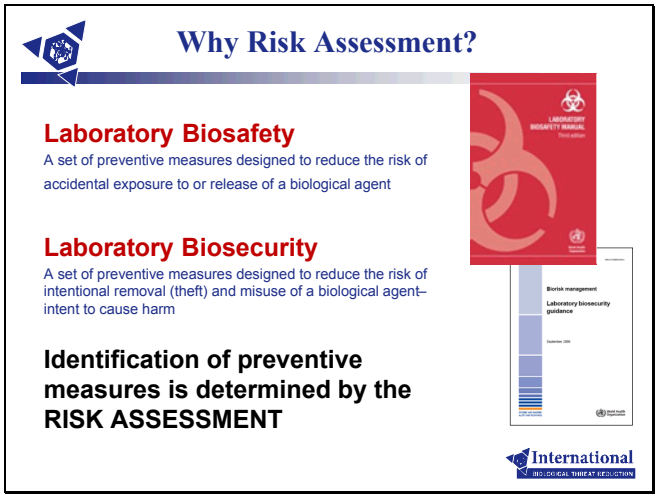
This question should be asked to the full group and one or two answers identified and put on white board of flip chart.

Point to the second question as something they should start to think about, **but don’t have them answer it yet.**

Formal definition of Biosafety/Biosecurity and one rational why RA is so important. Key message #3 and #4: *Biorisk encompasses both biosafety and biosecurity; RA informs risk mitigation decisions.*

Instructor presentation.

5 Minutes



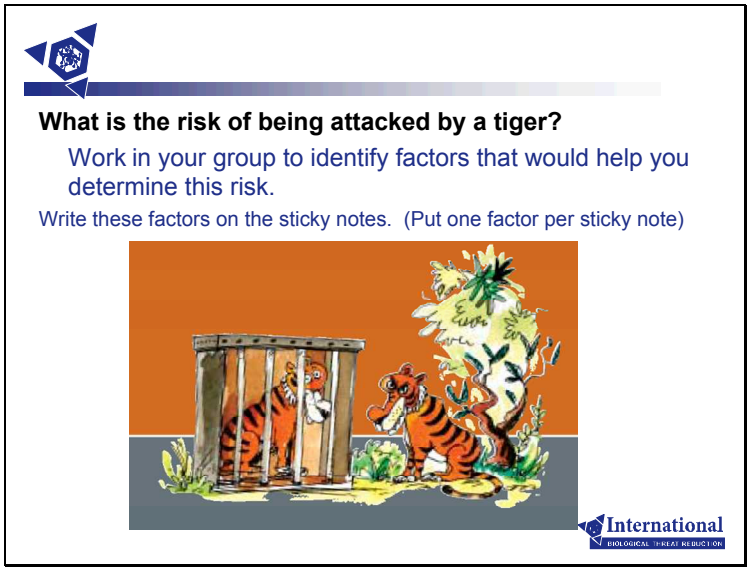
This slide is to provide a formal definition of biosafety and biosecurity and one rational for risk assessment being important.

This slide is provided for their notes and can be reviewed quickly. Ask if there are any questions. Emphasize that one very important reason why we do RA is that it drives/determines what the appropriate mitigation measures are. In other words, you could implement the wrong mitigation. For example, all the expense and maintenance required for a BSC might not be appropriate for research with HIV.

Introduction to Key message #5: *Risk is a function of Likelihood and Consequences.*

Small group exercise #3 Part 1: Identify factors in risk of tiger attack

30 minutes



DIRECTIONS:

Depending on dynamics, this may be a good time to change groups, mix people up to work in different teams and to change their learning environment/context. You can have them count off numbers (1-4 or 5 depending on the number of groups that you have) in their current groups and then have them move to new tables.

Have them work in their groups. This activity is designed to "force" the students into creating a risk assessment model, and it also will highlight risk as being a function of likelihood and consequences, the identification of risk factors, and ways to categorize the factors.

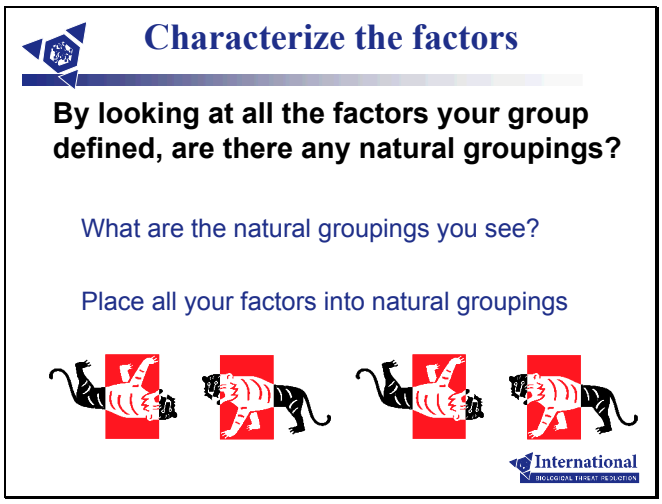
Students need sticky notes and each group will need a flip chart to place them on.

Students should work on this for about 30 minutes

BREAK (This is a good point to take a 10 minute break)

Small group exercise #3 Part 2: Group factors in risk of tiger attack

15 minutes



DIRECTIONS:

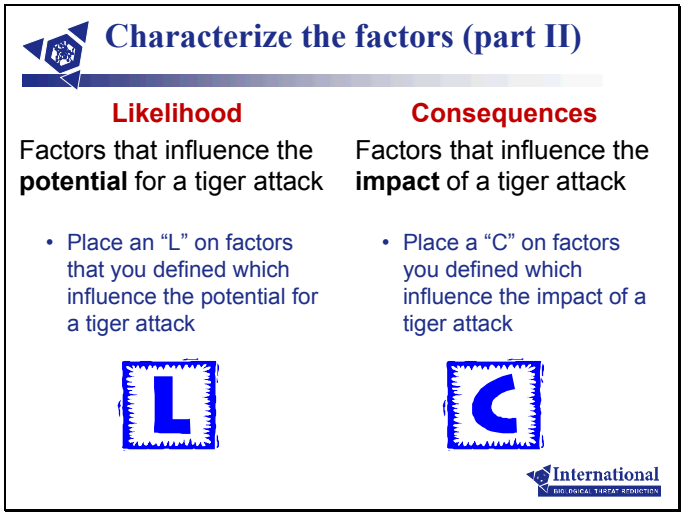
Ask participants to categorize the factors into groups, e.g. tiger factors, environmental factors, etc. They need to identify these natural groups and place the factors into those groups. This could be done on their flip chart or on the wall. Make sure that they have a heading for each group.

Taking turns, have each group briefly summarize their findings for the rest.

This should take about 15 minutes

Small group exercise #3 Part 3: Characterizing factors according to likelihood and consequences.

15 minutes



DIRECTIONS:

Ask participants to now identify each factor as a likelihood factor, a consequence factor, or both. They can do this simply by writing an "L" or "C" next to the factor. Alternatively you can have them put an "L" or "C" on several smaller sticky notes and place these next to the factor (this will allow them to change them on the fly if needed during group discussions).

Students should see that a natural group will likely include factors which influence both likelihood and consequences and some natural factors may only influence one. E.g. the tiger factors will influence both

If participants are having trouble deciding whether a factor influences likelihood or consequences, remind them that some factors will affect both. Another way to help visualize this is to provide a temporal setting with the following:

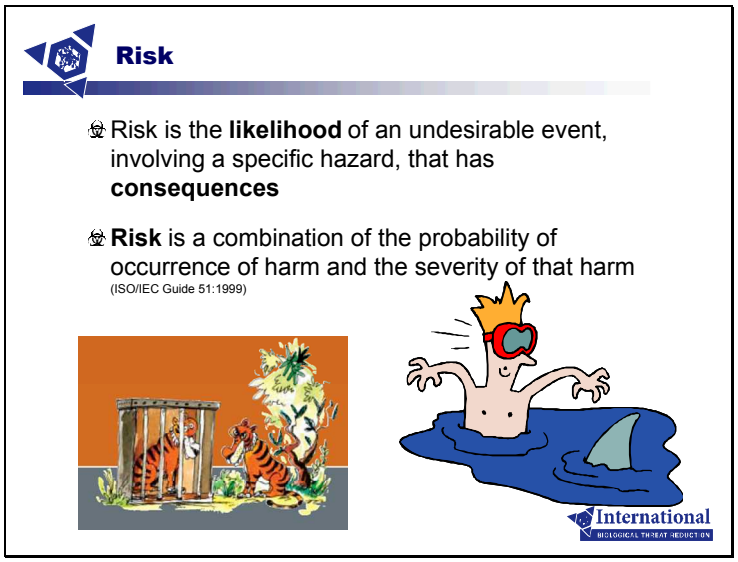
If you imagine a point on a timeline that represents an undesirable event, likelihood factors influence everything leading up to the event. Once the event has occurred, consequence factors influence everything after.

This activity will help to define risk as a function of likelihood and consequences. This should take about 15 minutes

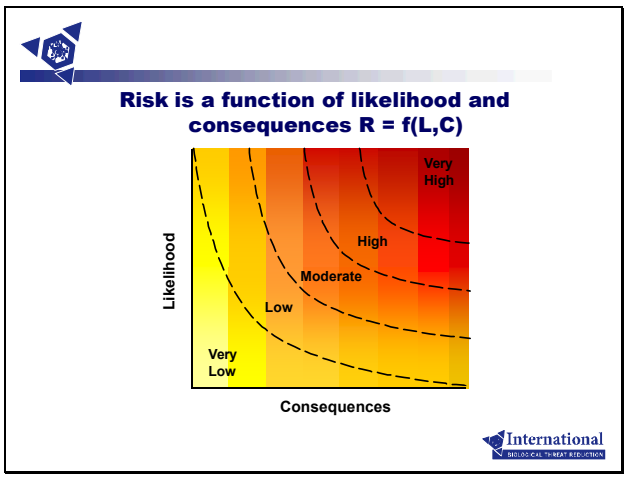
Reinforce Key message #5: *Risk is a function of Likelihood and Consequences.*

Instructor presentation

20 minutes

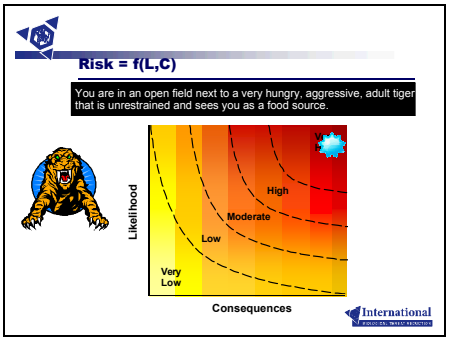


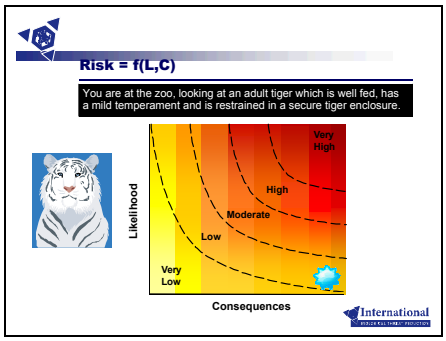
This slide formally defines risk. The second definition comes directly from the CWA. The importance here is for participants to begin to understand that Risk is a function or likelihood and consequences and must account for both.

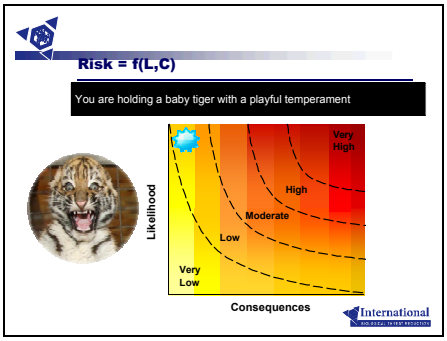


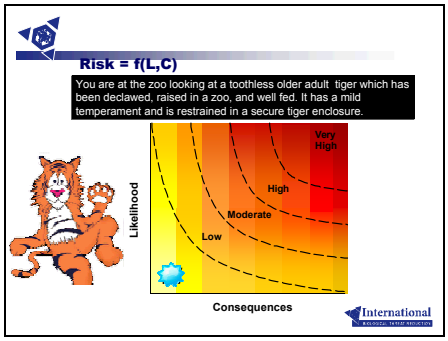
This slide is meant to introduce the concept of a graph and how it can be used to visualize risk as a mathematical function of L and C.

The next four slides further develop this concept by looking at the tiger scenario in four exaggerated situations. One where both L and C are high, one where L is low and C is high, a third L is high and C is low and a final slide where both are low. As each scenario is presented to the class, you should query the participants as to where they would graph the risk. They should pretty quickly come to the appropriate consensus at which time, advancing the slide produces the “star”, in the location where everyone should have already come to consensus on where it should be.









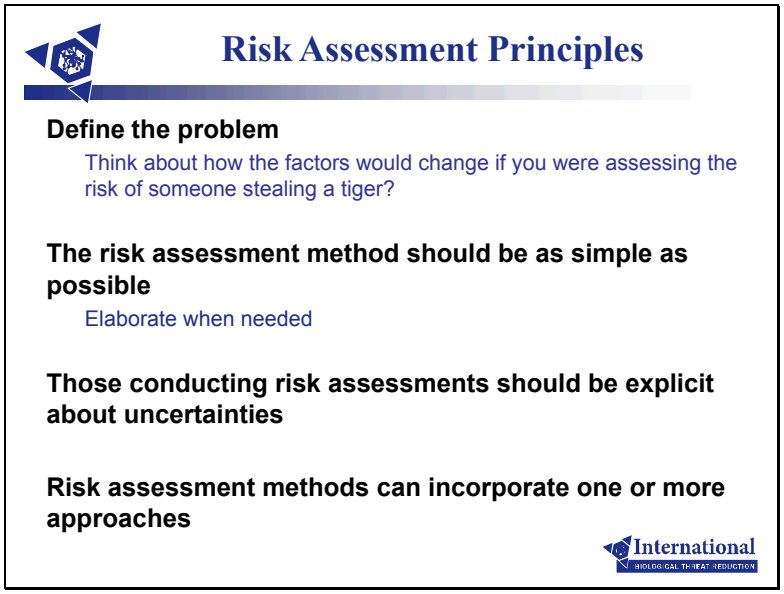
Ask if there are any questions. Spend a few minutes debriefing and asking questions to confirm comprehension.

BREAK (This is a good point to stop for lunch) – 1 hour

Review of RA principles.

Instructor presentation

5 minutes



These are the key principles and steps for risk assessment. Not only do you need to cover a broad range of issues, and ask many different questions, but you need to organize your assessment according to likelihood and consequences. A structured process for assessing risks is key.

Defining the problem is really the identification of what risk you are assessing. You need to differentiate the risks and assess each one separately.

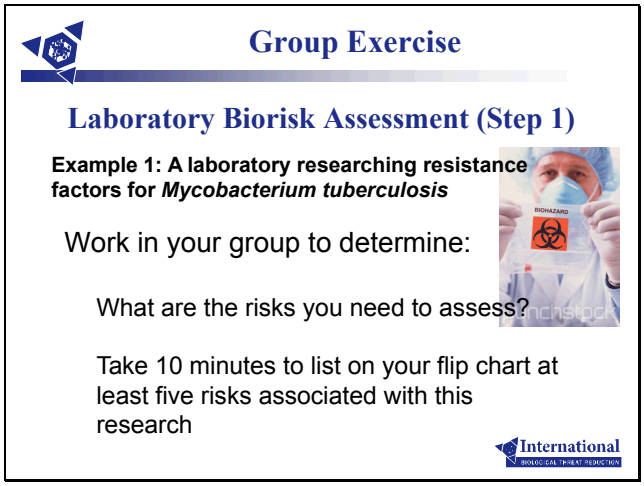
Simple is best as if the risk assessment gets too complex it's hard to do, hard to understand, and may not be of any value. You need to have clear questions about likelihood and consequences.

You need to have access to information about the situation. It is critical to document what you don't know. It is okay to have items you don't know as long as you have them documented.

Developing a RA model for a laboratory biorisk scenario.

Small group exercise #4 Part 1: Identifying risks associated with Mtb research.

10 minutes



DIRECTIONS:

Present a simple scenario to the participants: A laboratory is working to indentify antimicrobial resistance factors for Mtb. If they ask questions about the research like "Where is the lab located?", "What strains are they working with?" "Will they be culturing TB in large quantity?", etc. Point out at this time, they should just identify a series of risks associated with this type of research it should be similar to what they did at the beginning of the class: "What are risks associated with working in a laboratory with biological material?" However, this time they know a little more about the biological material that is being manipulated.

Circulate to make sure that they are listing "risks" not factors related to likelihood and consequences.

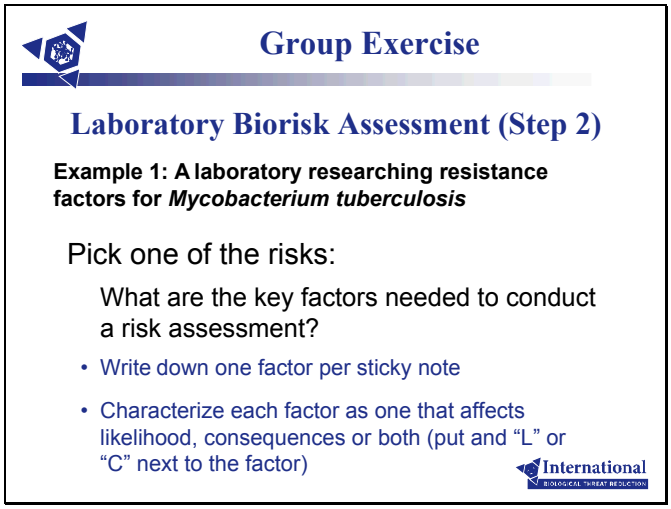
After 10 minutes (or if you see that each group has come up with a good list) move on to step 2. You should not need to spend much time debriefing at this point but you may point out a few key risks.

It is unlikely that groups came up with any risks that relate to security, you may want to point this out and ask them why they left these out? Try to guide the group to the conclusion that we tend to assess what we know and this can add bias that we need to be aware of.

Expected answers: Risks include things like: laboratory acquired infection (lab workers); accidental release (loss of containment) of the agent; creation of a more virulent or antibiotic resistant strain; theft of the agent from the facility; intentional misuse; spread to the community (accidental exposure of the community to an agent from the lab); secondary spread to the community; physical injury burns, slips, trips, falls, ergo and other lab accidents not associated with bioagent; risk associated with animal research (e.g. bites, scratches, allergies); etc.

Small group exercise #4 Part 2: Identifying and characterizing risk factors associated with Mtb research.

20 minutes



DIRECTIONS:

Have each group work on a different risk if possible. You may need to make assignments.

This is the most time consuming step in the exercise and students should be given lots of time to discuss and come up with at least 10 or more factors.

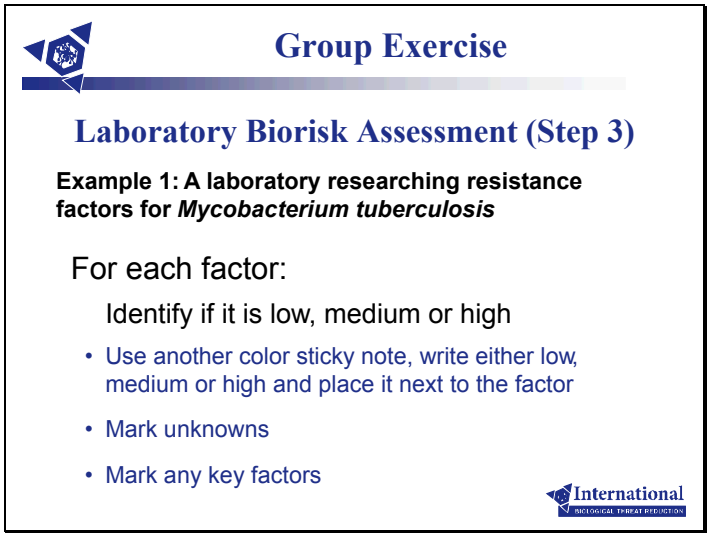
Expected answers: Factors include things like: Use of PPE (this could be broken into several: use of gloves, use of a respirator, use of a lab coat, eyewear, face shields, masks, etc.); Agent factors (morbidity, mortality, virulence, length of disease, infectious dose, route of infection, ease of transmission or transmissibility, stability of the agent in the environment, availbility and use of vaccine); type or form of the agent; concentration used; types of procedures performed (potential for aerosol generation); amount of sharps in use; Facility factors (work surfaces, HVAC system, presence of operable windows, doors, public access, security, primary and secondary barriers, engineering controls, use of BSCs, sealed centrifuges); Practices and procedures (GLP, waste handling, frequency of decontamination, handwashing procedures); Use of animals (number, types of manipulation, use of primary animal housing); Material control and accountability program, shipping and receiving practices, equipment maintenance program, incident response plans, occupational medicine program; Training program, management oversight; environmental factors (presence or availability of the agent in the environment), herd immune status; individual factors (how careful/careless is the researcher, stress factors and pressure to perform, level of training, immune/health status).

Circulate to ensure that they are characterizing the factors (as L or C) as they go, they should be putting one factor per sticky note. If they are having trouble, remind them of the tiger scenario and the natural groupings that they used (environment, tiger, person, etc.) and factors that they came up with.

After 20 minutes (or if you see that each group has come up with a good list) move on to step 3. You should not need to spend much time debriefing at this point but you may point out a few key factors.

Small group exercise #4 Part 3: Putting it together, Identifying and characterizing risk factors associated with Mtb research.

20 minutes

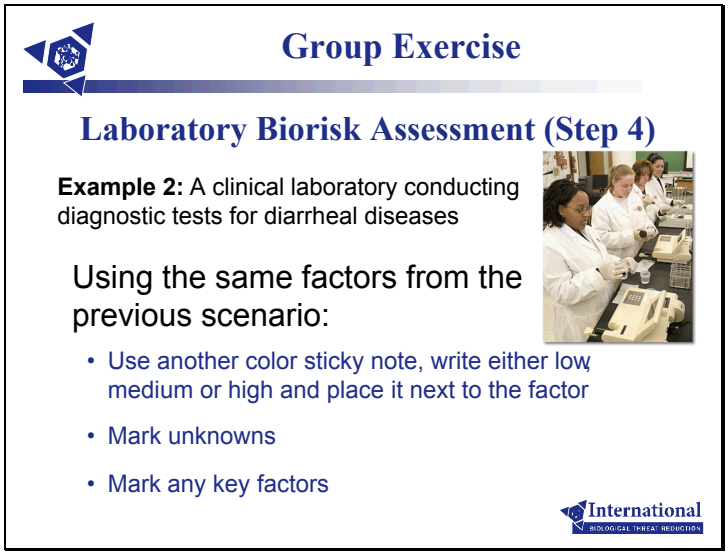


Using one color of small sticky note, they should place one next to each factor and put an L, M, or H on the note, preferably on the left hand side of the factor (step 4 will use a different color sticky on the opposite side of the factor). Allow the participants to work on this for about 10 minutes and then have each group present their findings to the rest. Have each group rate the overall risk for this research as low, medium or high. They should be able to justify their decision based on their RA model. Note that some factors will drive risk up and some factors will drive risk down (e.g Use of a BSC)

10 minutes should be allowed for the groups to rate their factors then each group should be given two or three minutes to present their findings. They should begin by explaining the particular risk that they evaluated, the factors they reviewed, any assumptions and then present an overall risk for the research in simple terms such as “Low”, “Medium” or “High”

Small group exercise #4 Part 4: Using the model in another scenario, identifying and characterizing risk factors associated with diarrheal research.

10 minutes



The L, M, H stickers from the previous step should be on the left of each factor. Now they put L, M, H stickers (preferably a different color) on the right side of each factor to assess the same risk in a clinical lab.

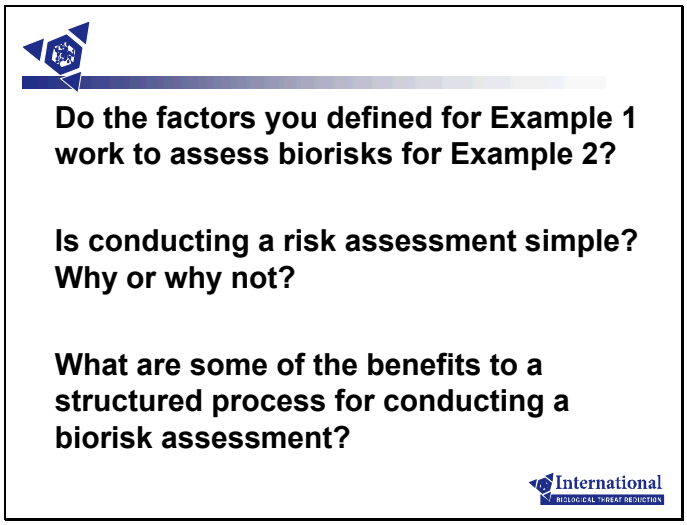
Depending on time, you may have each group present their findings. Alternatively, you could skip the debrief and go directly to the next slide.

Debrief: Developing a RA model for a laboratory biorisk scenario. *What? So What? Now what?*

Key Message #6 - *The benefits of a structured risk assessment process.*

Plenary discussion

20 minutes



What? So what? Now what? End of activity discussion, to the full group –

What did we just learn? (Expected answer: a systematic way or model to do RA; some of the things that need to be considered when doing a RA?)

Did the factors defined for one work for the other? Why, or why not?

Is conducting an assessment simple? Has your answer changed? Why did it – if it did? Why didn't it if it didn't?

What are some benefits to a structure process for RA?

If there is time, you could organize a small group discuss for this last question and have each group report back to the main body their answers.

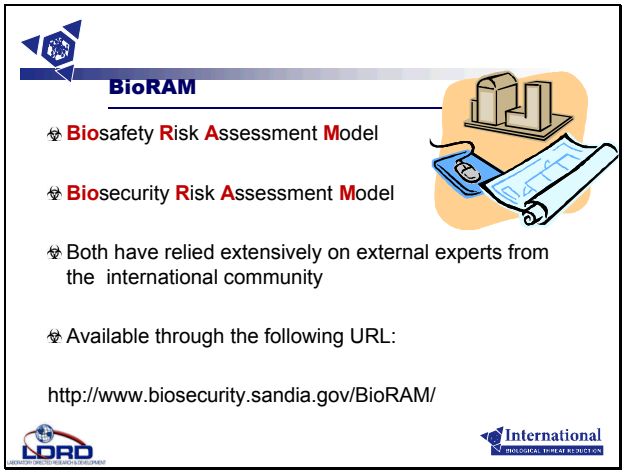
Expected answer: it is simpler, you can compare results, you can identify key factors driving risk, you can identify your unknowns, it allows you to compare risks over time in a consistent way, it allows you to evaluate the impact of various mitigation measures, facilitates risk assessment process, repeatable, reproducible, provides quality control documentation, allows you to communicate risk easier, etc…

Will you be able to use this model or something similar in your own labs? What would you change? How can you use what you've learned back at home?

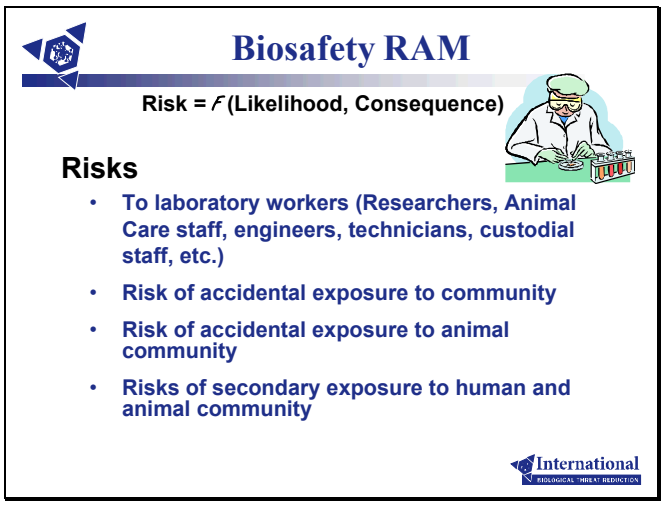
Introduce Key Message #7 – *BioRAM is one method for doing a structured, peer-reviewed, risk assessment.*

Instructor presentation

30 Minutes

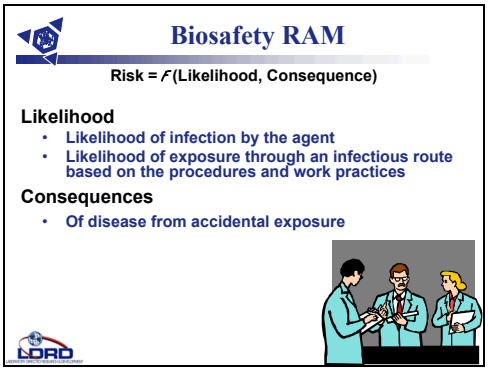


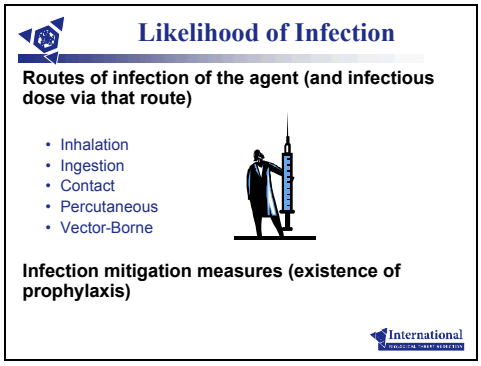
Explain that now they have developed a RA model of their own, we would like to introduce them to a model that was developed at Sandia with input from hundreds of Biosafety/Biosecurity experts from around the world.

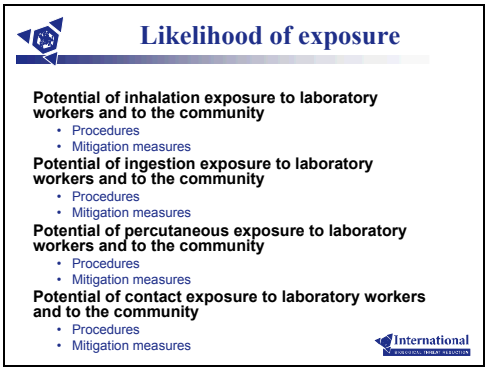


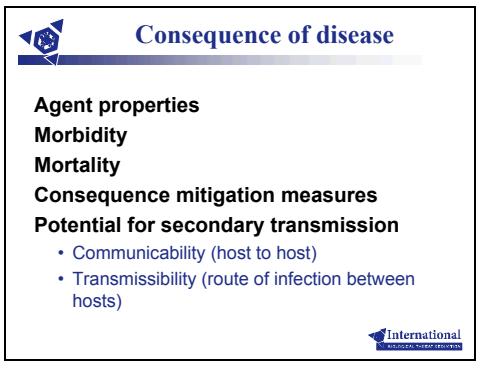
This is a short summary of the Sandia National Laboratories IBTR Biosafety RAM project. This project has defined four key risks that need to be assessed and has defined likelihood and consequences for each. This project was developed jointly with international biosafety experts.

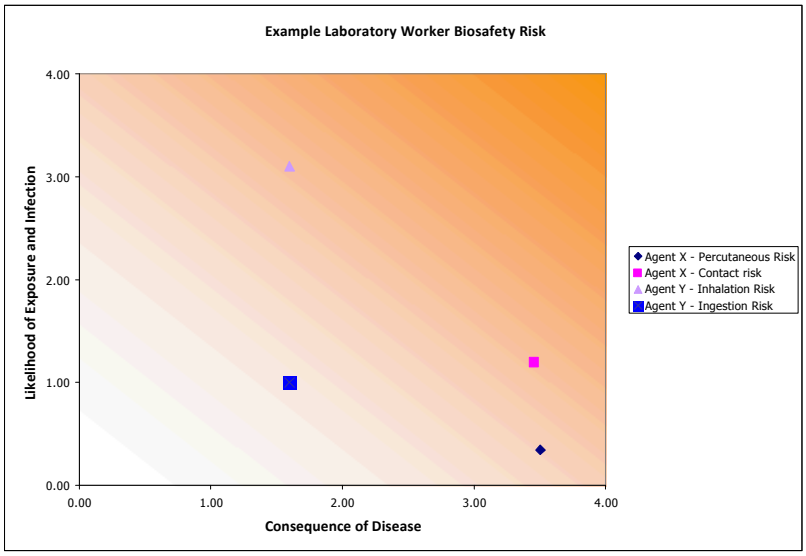
The next four slides provide more detail and should be quickly reviewed.









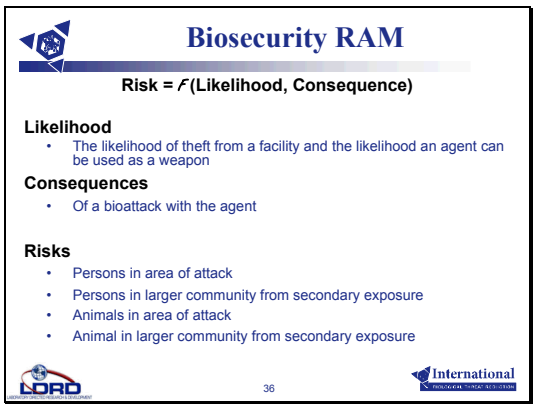


International BIOLOGICAL THREAT REDUCTION

This is the graphical results of the project. You can see several results for one experiment. The risk is calculated uniquely for the person in the lab and the community outside. The risk of 2nd exposure is also calculated uniquely.

Plotting risk 2D helps to determine if consequences or likelihood are driving the risk.

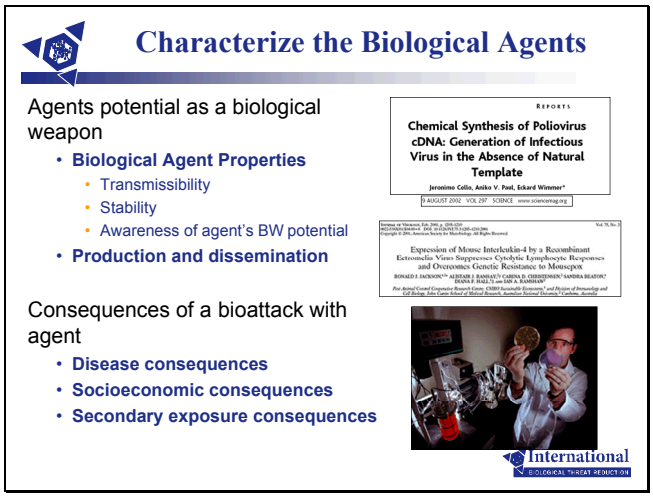
You may ask a person or two in the class to try and explain what the dots mean. For example: the dark blue diamond in the bottom right represents risk of a percutaneous exposure to Agent X. This likelihood of exposure through this route is very low but the consequences of exposure to this agent are very high.



This is a short summary of the Sandia National Laboratories IBTR Biosecurity RAM (or BioRAM) project. This project has defined four key risks that need to be assessed and has defined likelihood and

consequences for each. This project was developed at SNL but has been reviewed and updated by an international group of collaborators.

The next four slides provide more detail and should be quickly reviewed.

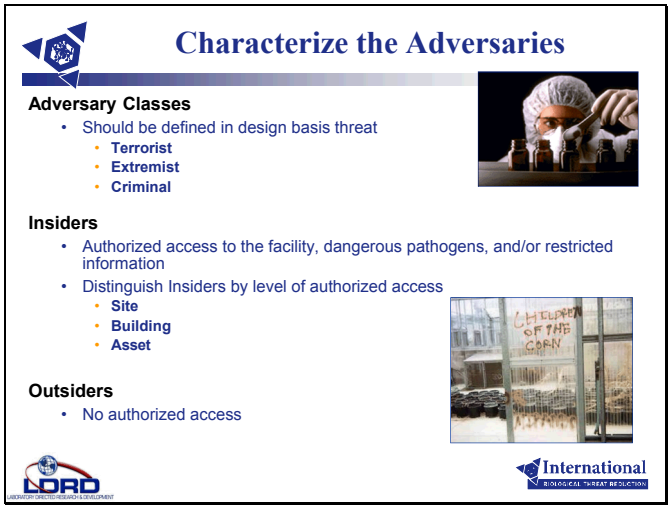


This slide defines elements of likelihood and consequences based upon the agent.

While characterizing biological agents for Biosecurity Risk Assessments, you have to do so from the point of view of the adversary.

What would an adversary find attractive about a particular agent?

RUN THROUGH SLIDE



This slide defined the elements of the adversaries that influence likelihood.

And of course, we have to think about our potential adversaries.

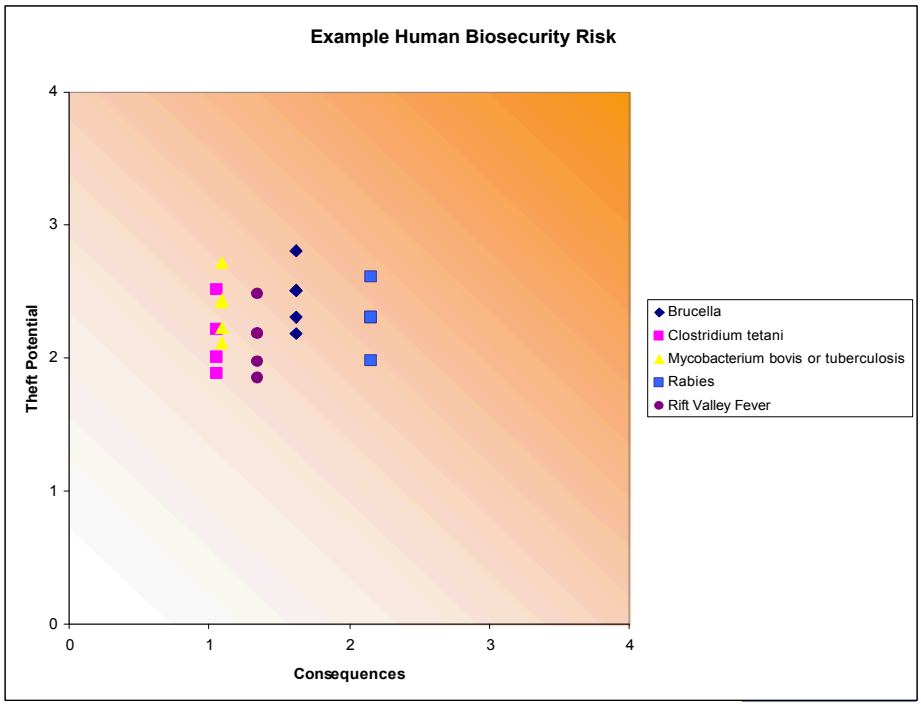
How do we characterize them? By their motives:

1) **Terrorists** – seeking to cause indiscriminate harm for ideological reasons
2) **Extremists** – seeking to cause focused harm for ideological reasons
3) **Criminals** – no ideology, seeking to cause focused harm, such as murders and blackmail

OR, by their access to your facility

1) Insiders
2) Outsiders

This slide defines elements of the facility which also influence likelihood.



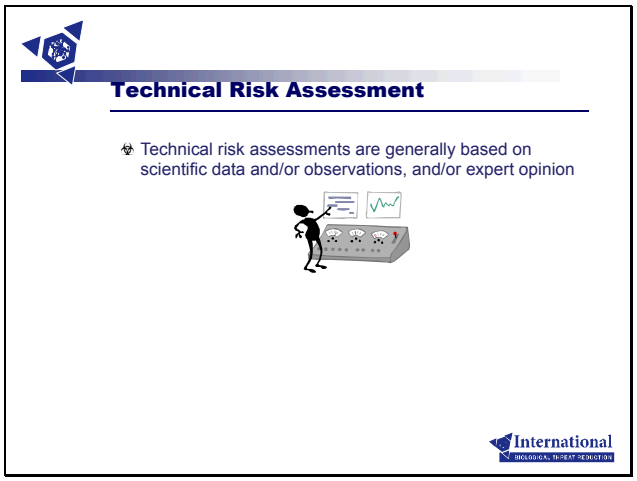
These are example results for several agents and several adversaries.

BREAK (This is a good point to take a little longer break of 15 minutes)

Introduce Key Message #8 – *Technical risk assessment vs. concern assessment*

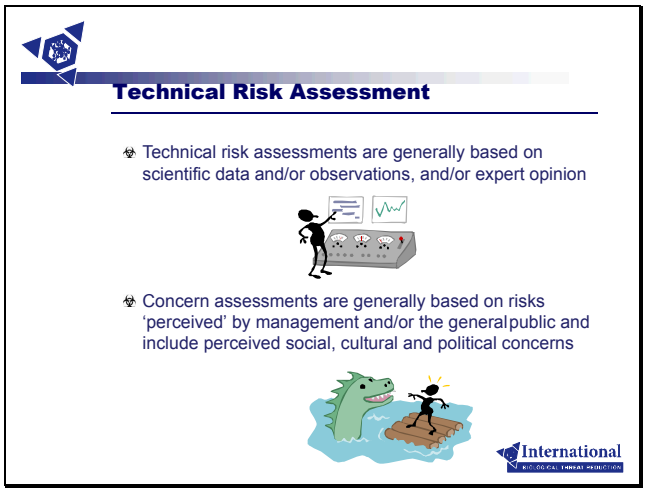
Instructor presentation and plenary

5 Minutes



Point out that during the past several hours we have been doing technical risk assessments. After reviewing the scientific literature, pouring over facility designs, going over SOPs, spending hours doing BioRAM paperwork,etc. . . . ask: **" What might be missing from this technical risk assessment?"**

Expected response: Perceived social, cultural, political concerns

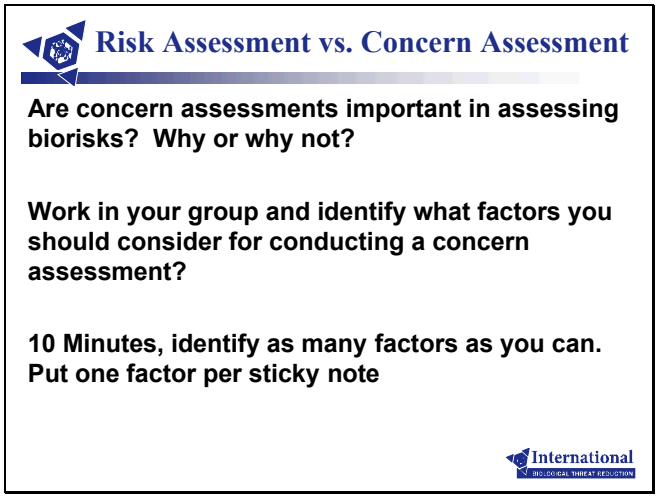


Use this slide to define technical risk assessments and concern assessments.

An example of a biorisk concern would be something like Marburg. In the US, we work with it in a BSL4, because it is not endemic and the public fears the disease; if we only did a technical assessment, however, we would see it is not that different than HIV technically – which in the US we work with at BSL2 (and in some places BSL3.)

Small group exercise #5 Part 1: identify factors to consider when conducting a concern assessment.

15 Minutes

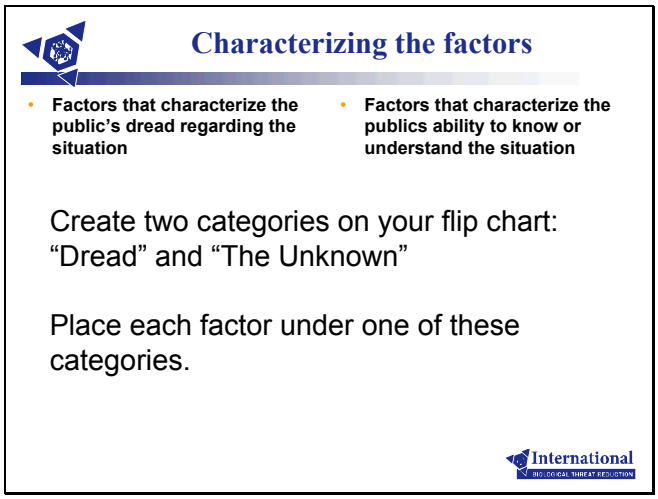


First have them answer in plenary "are concern assessments important, why or why not?"

Then have them work in small groups for about 10 minutes to identify factors they should consider in conducting a concern assessment. They should write down the factors, one per sticky note.

Small group exercise #5 Part 2: Categorize the factors

10 Minutes



Have the students use a flip chart to place the factors under "dread" or "unknown"

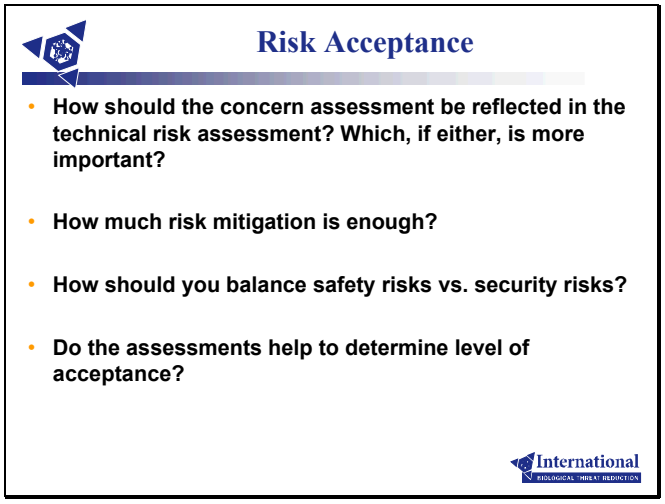
This will be difficult activity. The main goal is to get them thinking a little bit about the concern assessment and what factors they should be considering.

Give each group a couple of minutes to present their findings and chart.

Risk Acceptance

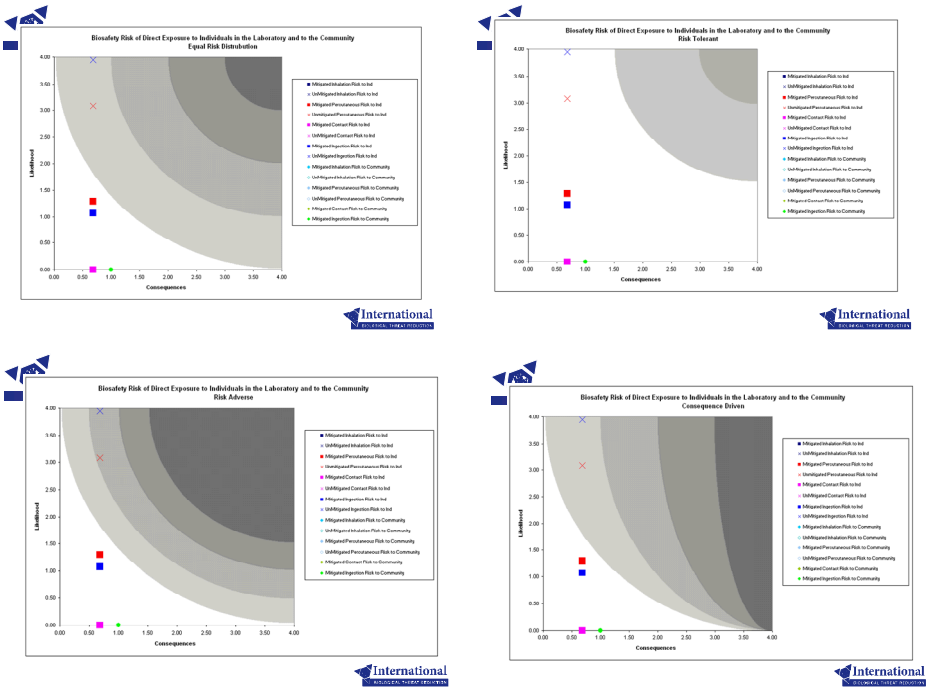
Small group discussion and report back to bigger group

15 Minutes



Have the students discuss these questions in their groups and present their thoughts. They should be able to work for about 10 min on this. Then pick a spokesperson for their group to report back. Alternatively, in the interest of time, one question could be assigned to each group to answer back to the entire body.

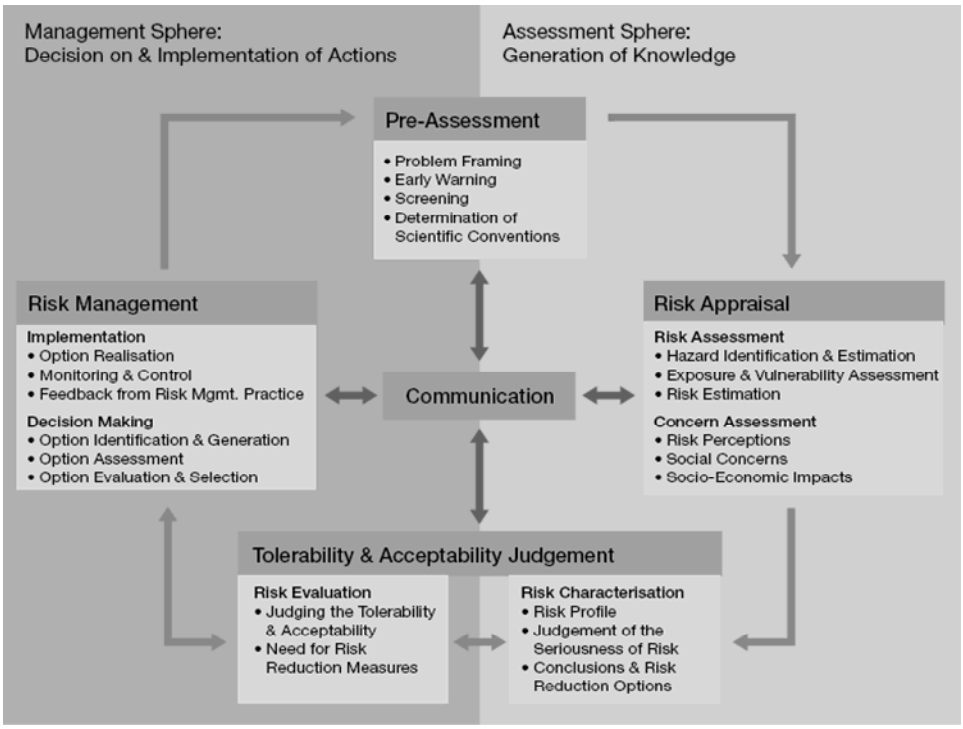
The next four slides are graphical examples of the same technical risks with different “acceptance curves”. These are to illustrate the difference between technical risk and risk characterization/evaluation; these also can be used to highlight the use of graphs with acceptance curves in risk communication.



Introduce Key Message #9 – *Risk Governance*

Instructor presentation and plenary

5 Minutes



This slide comes from the International Risk Governance Council.

This chart walks through all the stages of risk governance – pre-assessment, appraisal, characterization-evaluation, and risk management and summarizes what we have learned.

The A in AMP is part of the pre-assessment, the appraisal and part of the characterization.

The M in AMP is part of the characterization – evaluation, and the Management.

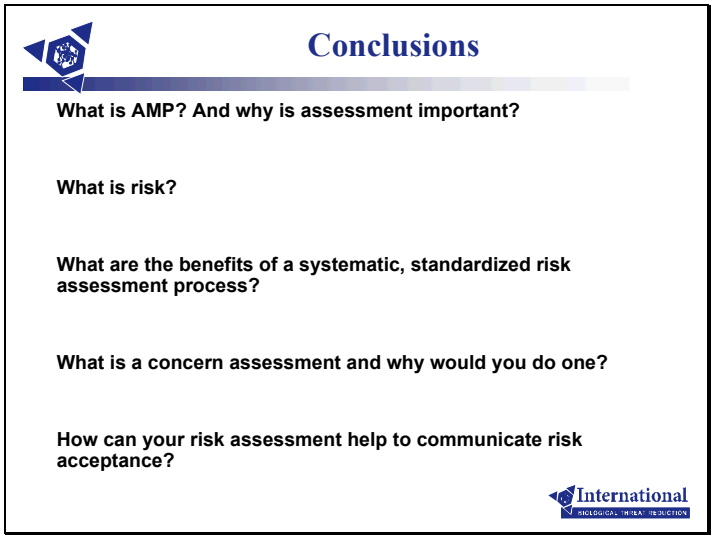
The P in AMP is part of the Management and the Pre-Assessment.

The risk appraisal has two parts, the risk assessment and the concern assessment.

Summary and Review

Small group discussion and report back

20 minutes



To conclude this presentation, each group should answer each of these questions for the full class. These questions match the learning objectives. If time is a concern then one question may be assigned to one group rather than all the questions.

Expected Answers: AMP is Assessment, Management, and Performance. Assessment is important to identify mitigation measures and can help to determine effectiveness of the mitigation.

A standardize, systematic risk assessment process allows for comparison of risks, insures you are always assessing the same thing – in order to see a delta over time, helps to communicate risk, helps to determine mitigation measures, helps in determining risk acceptability.

A concern assessment addresses public perception – its need is very dependant upon the situation, but it should be at least thought about.

Risk assessments can help to communicate risk by visualization, to identify risk drivers, etc….