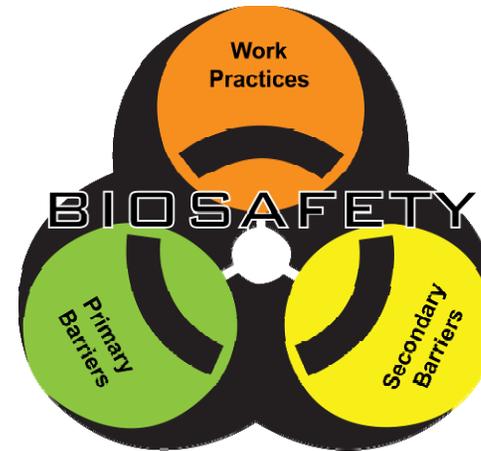
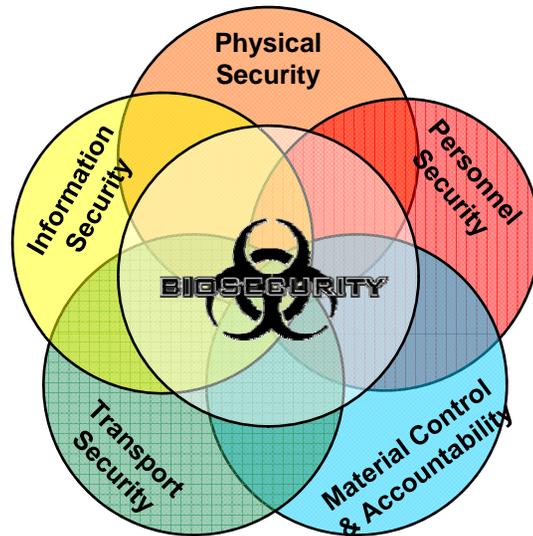




Risk Assessment



African Biological Safety Association (AfBSA)

“WORKING SAFELY AND SECURELY WITHIN BSL-2 LABORATORIES”

Reynolds M Salerno, PhD, Manager
International Biological Threat Reduction
Global Security Programs
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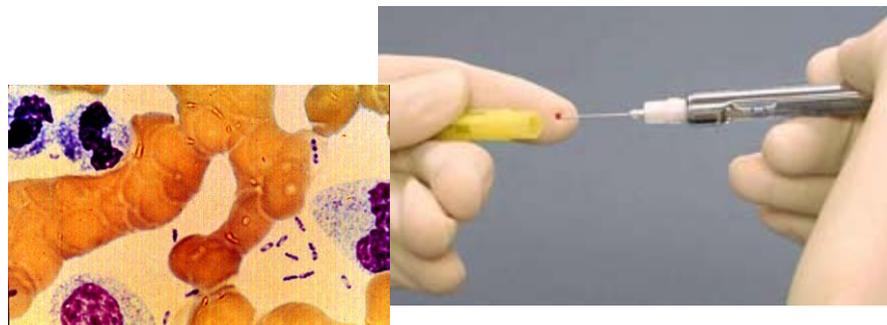
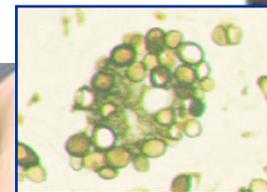
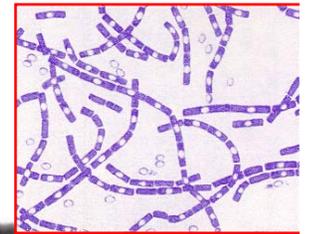
SAND No. 2008-0480P
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company,
for the United States Department of Energy's National Nuclear Security Administration
under contract DE-AC04-94AL85000.





Risk

- **Is a function of the likelihood an adverse event will occur**
 - Risk = Potential * Consequences
- **Laboratory work with pathogens will always involve some level of safety and security risk**
 - Distinguish between “acceptable” and “unacceptable” risks
 - Cannot protect against every conceivable adverse event
- **Resources for risk mitigation are not infinite**
 - Existing resources should be used efficiently



RISK
PERCEPTION

RISK
ASSESSMENT

RISK
MANAGEMENT



WATIS

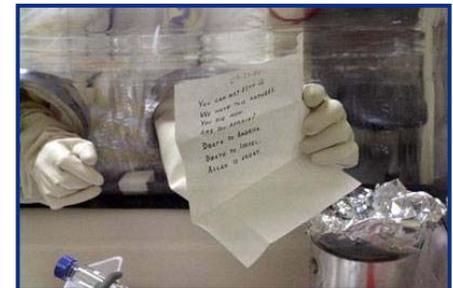
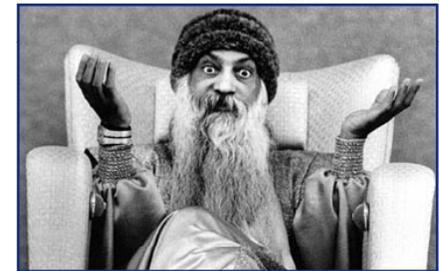


Class Discussion: Risk Perceptions

Biosafety Risks



Biosecurity Risks





Laboratory Biorisks

Risk = f (Likelihood, Consequence)

- **Likelihood**
 - For security assessments, the likelihood of the adverse event, often referred to as the Threat Potential, includes the Threat, because it is a deliberate event
 - For safety assessments, the likelihood of the adverse event does not incorporate the Threat, because it is an accidental event
- **Consequences**
 - Of infection from accidental exposure or malicious release
- **Risks**
 - To laboratory workers
 - Risk of accidental or deliberate exposure to community
 - Risk of accidental or deliberate exposure to animal community



Risk Assessment Principles

- **Define the problem**
- **The problem should drive the choice of method for the assessment**
- **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**





Class Activity: Brainstorming Risk Assessment Criteria

- On the worksheet, list criteria that you think would be important in the risk assessment
 - Identify whether each criterion impacts the likelihood (probability), consequences, or both for biosafety risks and for biosecurity risks
 - If you were doing a risk assessment, identify who you might have help you evaluate each criterion
- Example:**

Criterion	Biosafety			Biosecurity			Who would you ask for help in evaluating this criterion?
	L	C	Both	L	C	Both	
Biological Agents							
4. Morbidity		x			x		scientist
5. Mortality		x			x		scientist
6. Routes of Infection	x			x			scientist

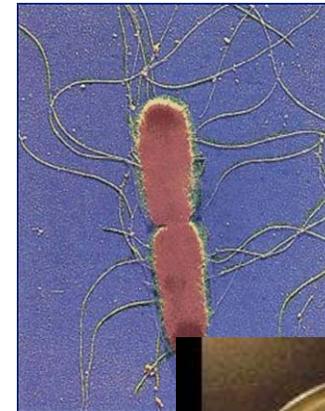


Biosafety Risk Assessment

- 1. Characterize biological agents and laboratory activities**
 - a. Evaluate the specific biologic agent hazards
 - b. Evaluate laboratory procedure hazards
 - c. Evaluate in-place hazard mitigation measures

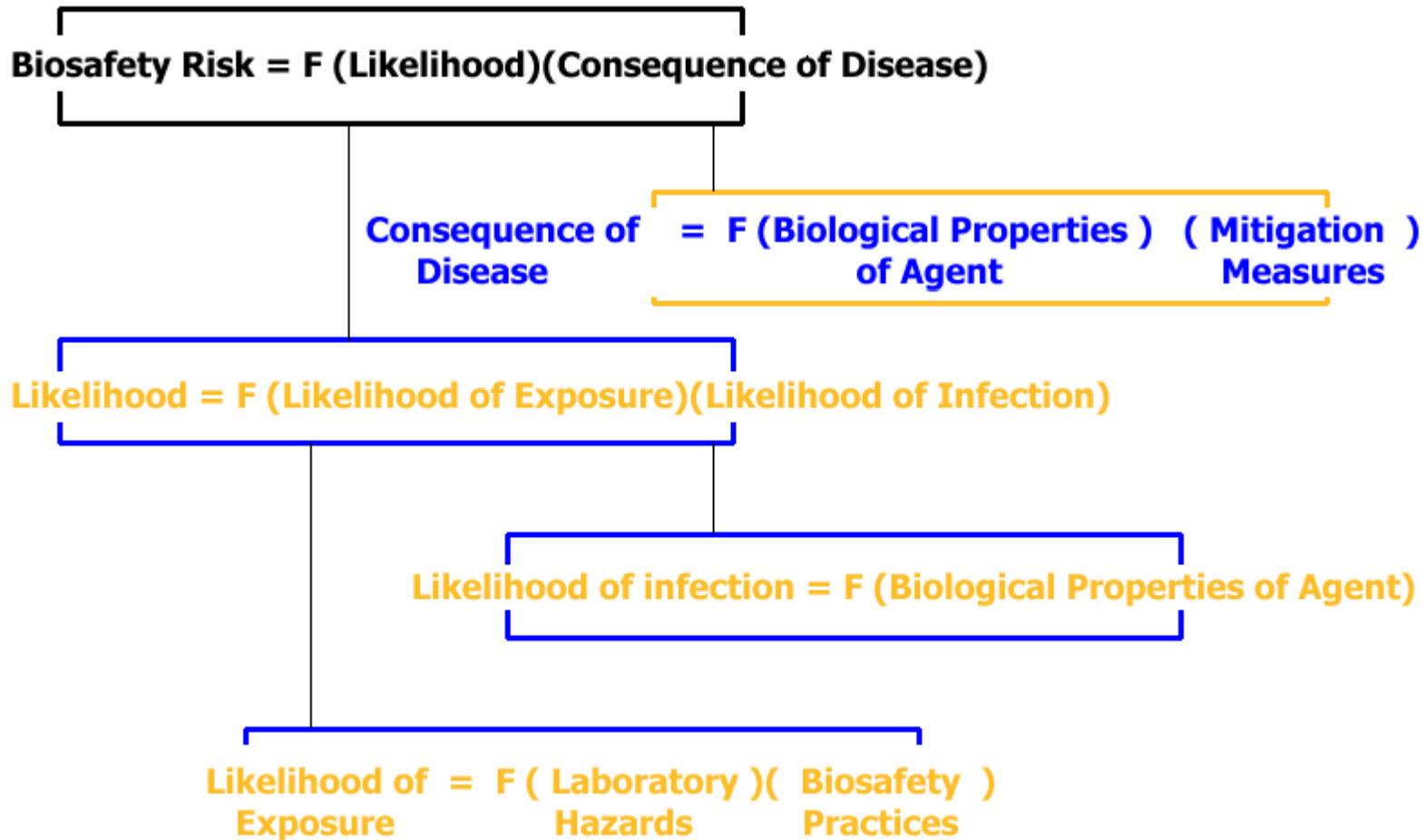
- 2. Evaluate scenarios**
 - a. Create scenarios consisting of the specific agent and specific laboratory procedures
 - b. Determine the likelihood of exposure based upon the procedure and the likelihood of infection based upon the agent as related to the method of exposure

- 3. Characterize the risk**
 - a. Evaluate the overall likelihood and consequences of each scenario
 - b. Determine acceptable and unacceptable risks; develop risk statement





Biosafety Risk Variables in More Detail





Biosecurity Risk Assessment

- 1. Characterize biological agents and threats**
 - a. Evaluate pathogens and toxins at a facility (asset assessment)
 - b. Evaluate adversaries who might attempt to steal those pathogens or toxins (threat assessment)

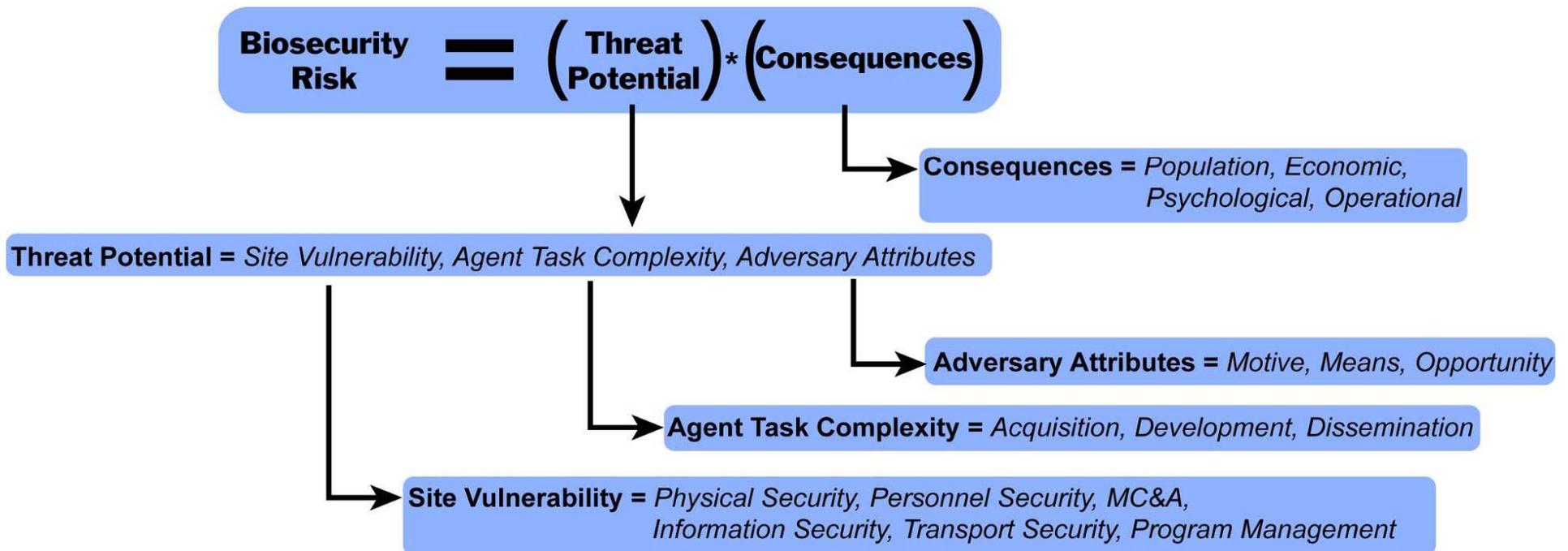
- 2. Evaluate scenarios**
 - a. Create scenarios consisting of “specific adversaries” attempting to steal and misuse a specific biological agent
 - b. Determine how the various scenarios could be perpetrated (vulnerability assessment)

- 3. Characterize the risk**
 - a. Evaluate threat potential and consequences of each scenario
 - b. Determine acceptable and unacceptable risks; develop risk statement





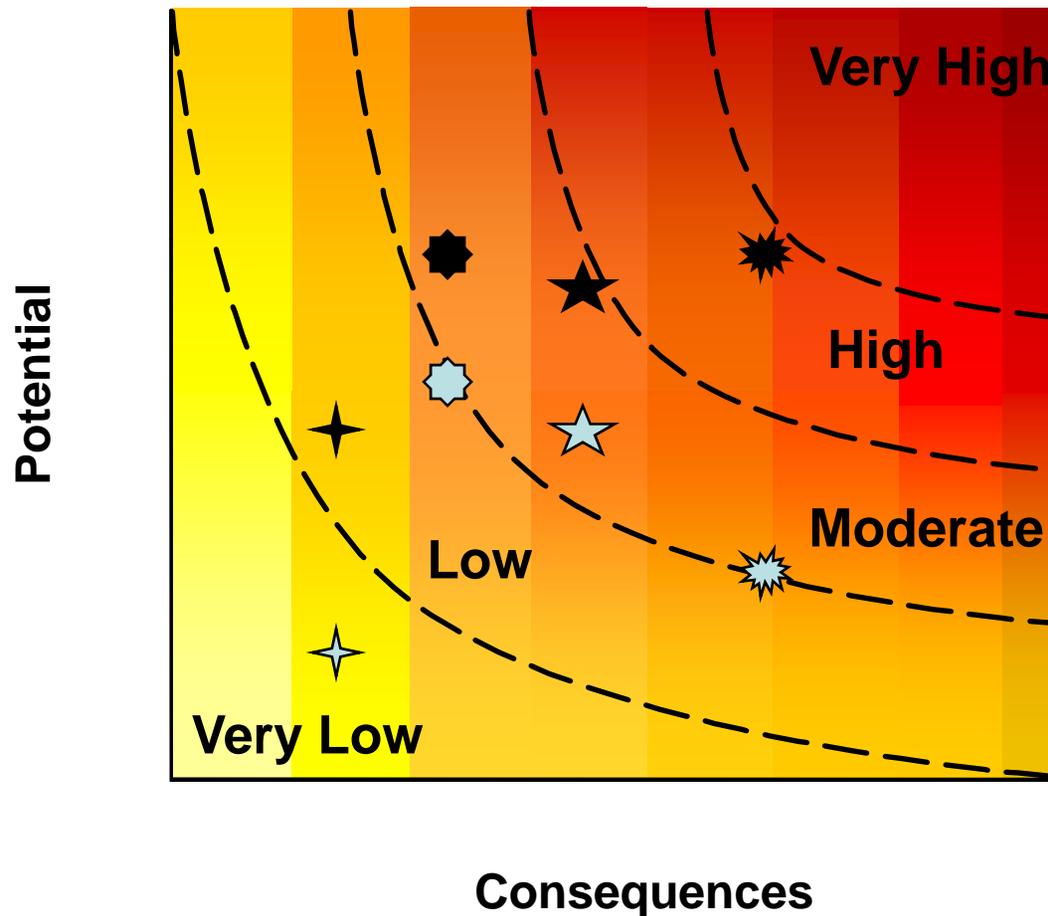
Biosecurity Risk Variables in More Detail



Reference: [Laboratory Biosecurity Handbook](#),
by Reynolds M. Salerno, Jennifer Gaudioso
CRC; 1 edition (June 20, 2007) ISBN-10: 0849364752



Characterizing Scenarios by Risk: Hypothetical Results



● Protect against unacceptable risk scenarios

● Develop incident response plans for acceptable risk scenarios



Risk Assessment Usually Not the Only Input for Risk Management

- **Mitigation strategies for risk are based on several factors:**
 - Science (the risk assessment)
 - Technical limitations
 - Economic constraints
 - Politics
 - Legal implications
 - Health
 - Social





Conclusions

- **Need to integrate biosafety and biosecurity considerations into decisions about laboratory operations**
- **Biological facility risk assessment provides an opportunity to concentrate resources on the highest risks**
 - Tiered system of protection based on risk assessment and risk management methodologies
 - Risk assessment is a fundamental resource allocation tool for making decisions about which risks need to be protected against
- **Parallels exist between safety and security risk assessment processes**
- **Risk assessment and risk decision are the critical foundations for the design of a laboratory biosafety and biosecurity program**

