BIOSAFETY AND RISK ASSESSMENTS

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Stacey Alexander ND HHS– Laboratory Services Section

OBJECTIVES

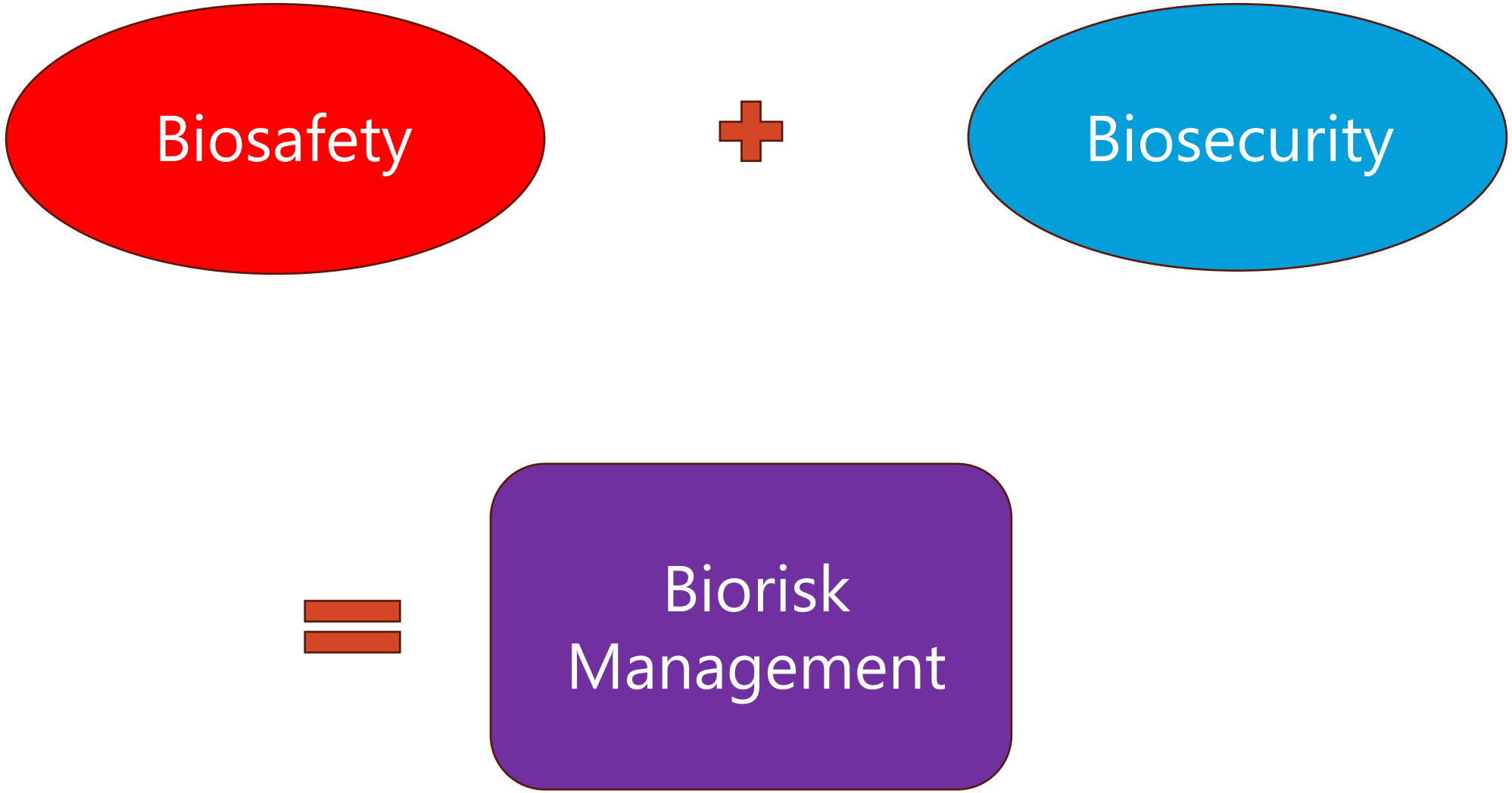
- Describe laboratory biosafety and biosecurity
- Describe the factors in a risk assessment
- Evaluating likelihood and consequences of hazards in the laboratory

BIOSAFETY

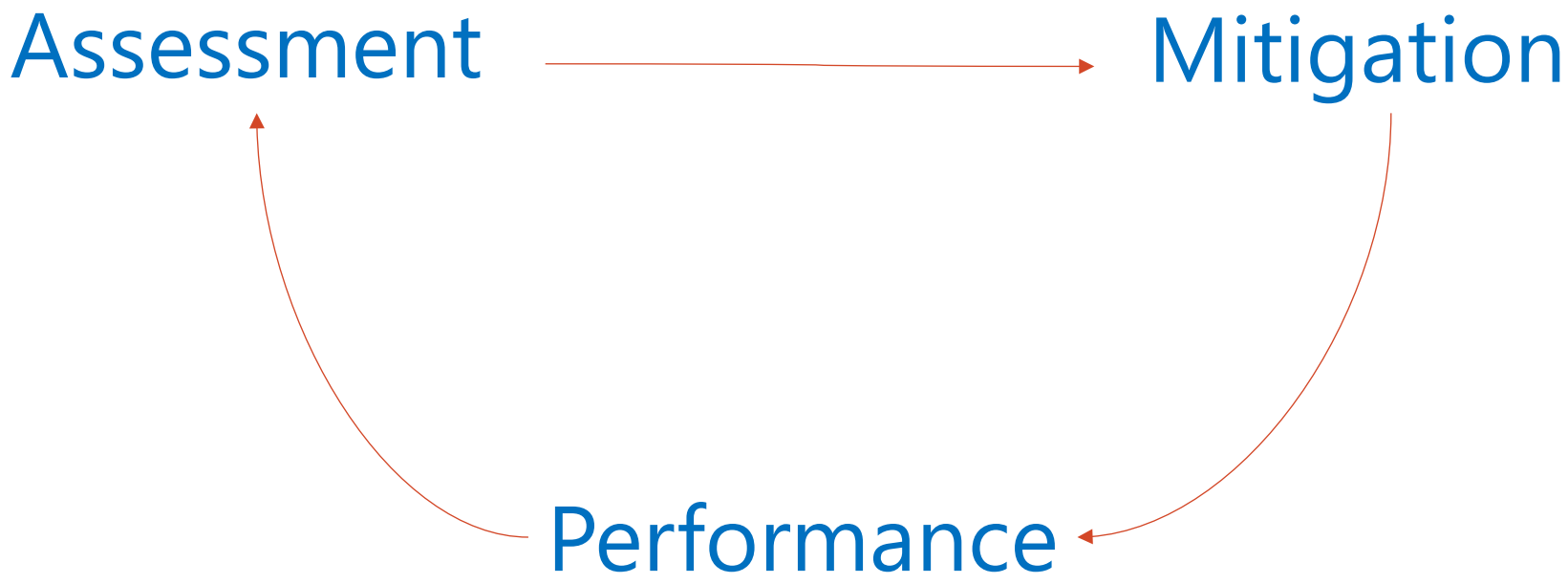
- Protect people from pathogens
- Biosafety in Microbiological and Biomedical Laboratories or the BMBL.
- The main principles for biosafety include containment and risk assessments.

BIOSECURITY

- Protect pathogens from dangerous people
  - Physical Security
  - Personnel Reliability
  - Information Security
- Plan is required by entities registered with the Select Agent Program


Biosafety
Biosecurity
Biorisk
Management

AMP MODEL APPROACH TO RISK ASSESSMENTS



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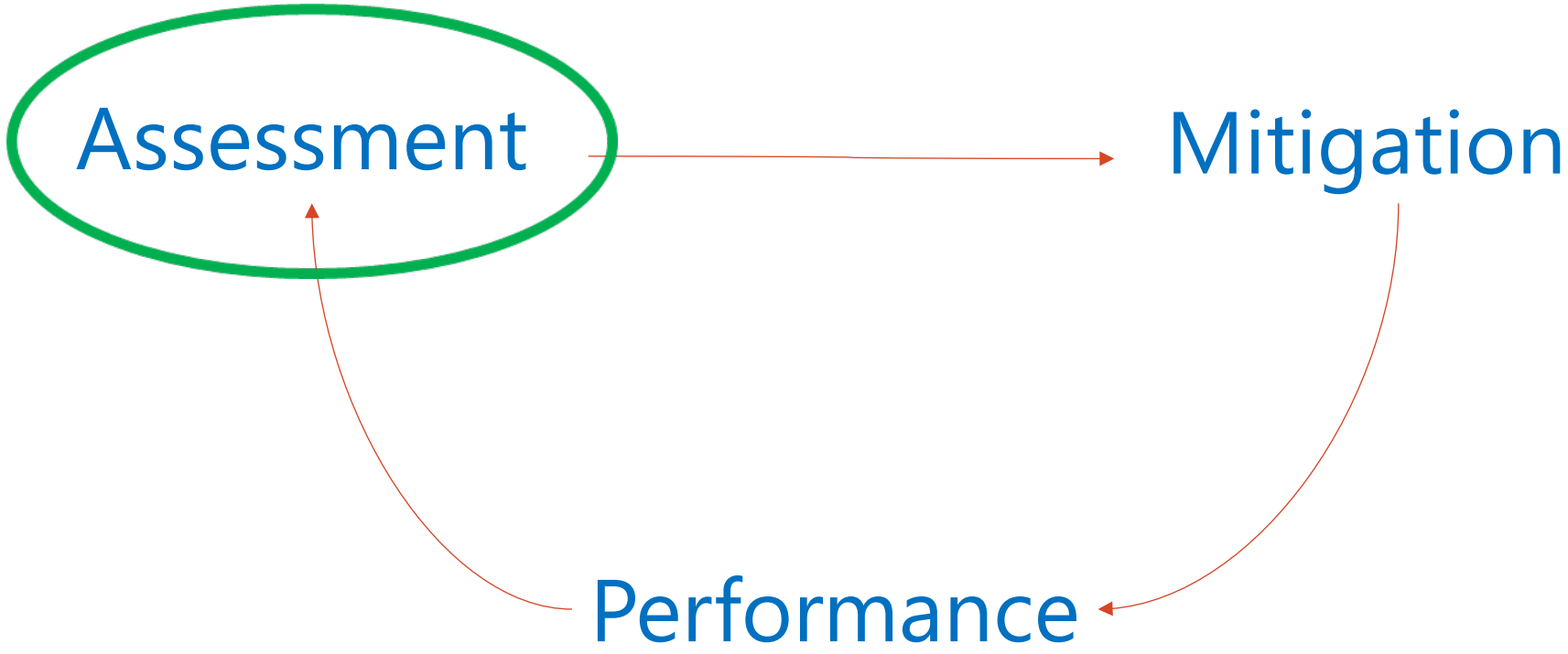


ASSESSMENT

- Risk Assessments – identify hazards and evaluate risk

- Share responsibility between principal investigators, scientists, researchers (or a risk assessment team), security professionals, and biosafety professionals.
- Perform assessments when there are new tasks or significant changes in how things are done.

- Use the results to choose the proper control measures to reduce risks as needed.

DEFINITIONS:

- Hazard – any situation, item or organism that could cause injury, illness or death

- Risk – The likelihood of an adverse event happening and probability of a consequence that could cause harm, injury, illness or death

DEFINITIONS

- Inherent Risk – risk in the absence of mitigation factors
  - Also known as initial risk, natural risk or raw risk

- Residual Risk – Risk remaining after protective or mitigation factors have been implemented

RISK ASSESSMENT CONSIDERATIONS

1. Agents
2. Environment
3. People

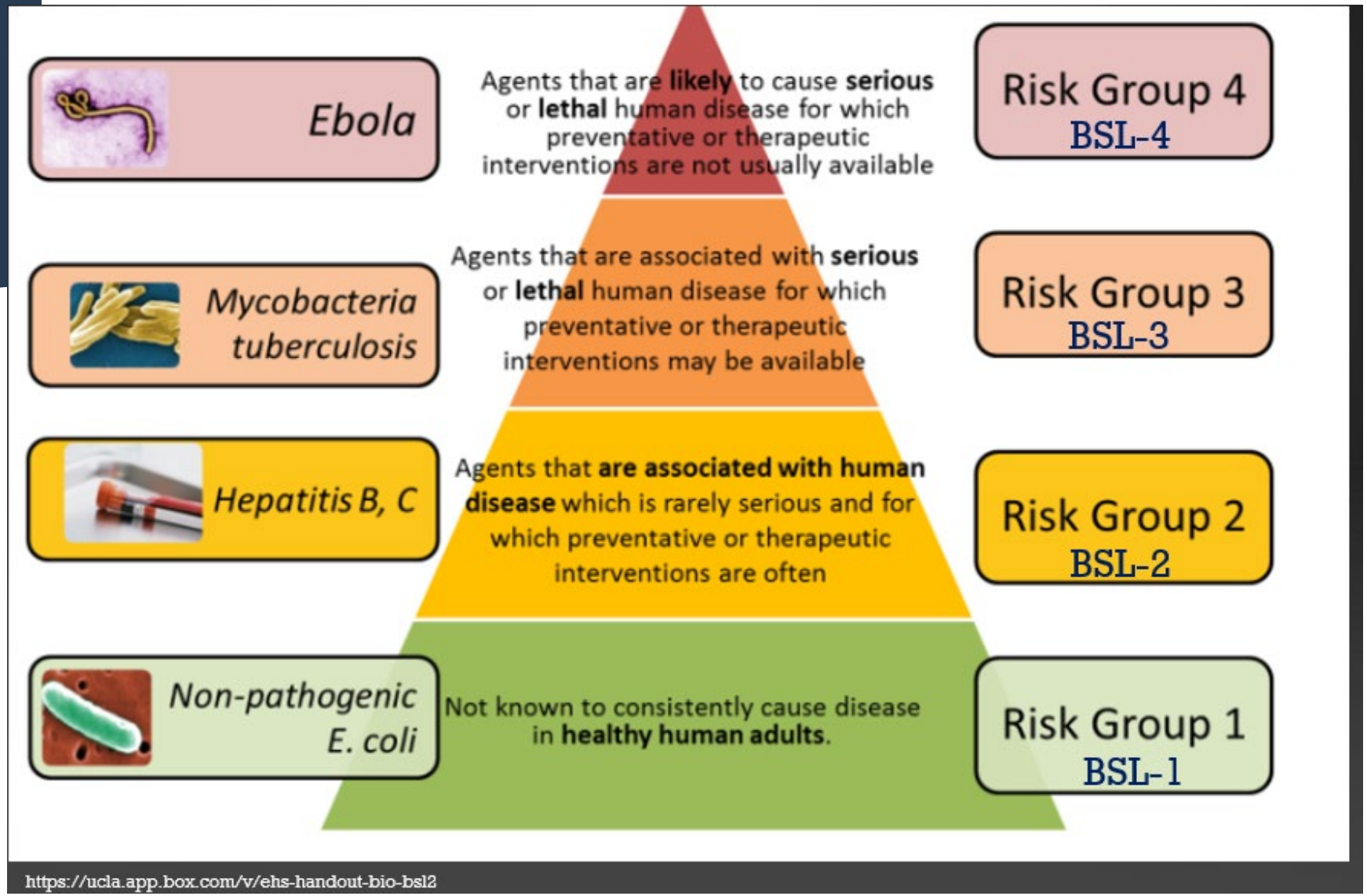
ENVIRONMENT

- Facilities
- Workflow
- Equipment
- PPE
- Waste management
- SOPs

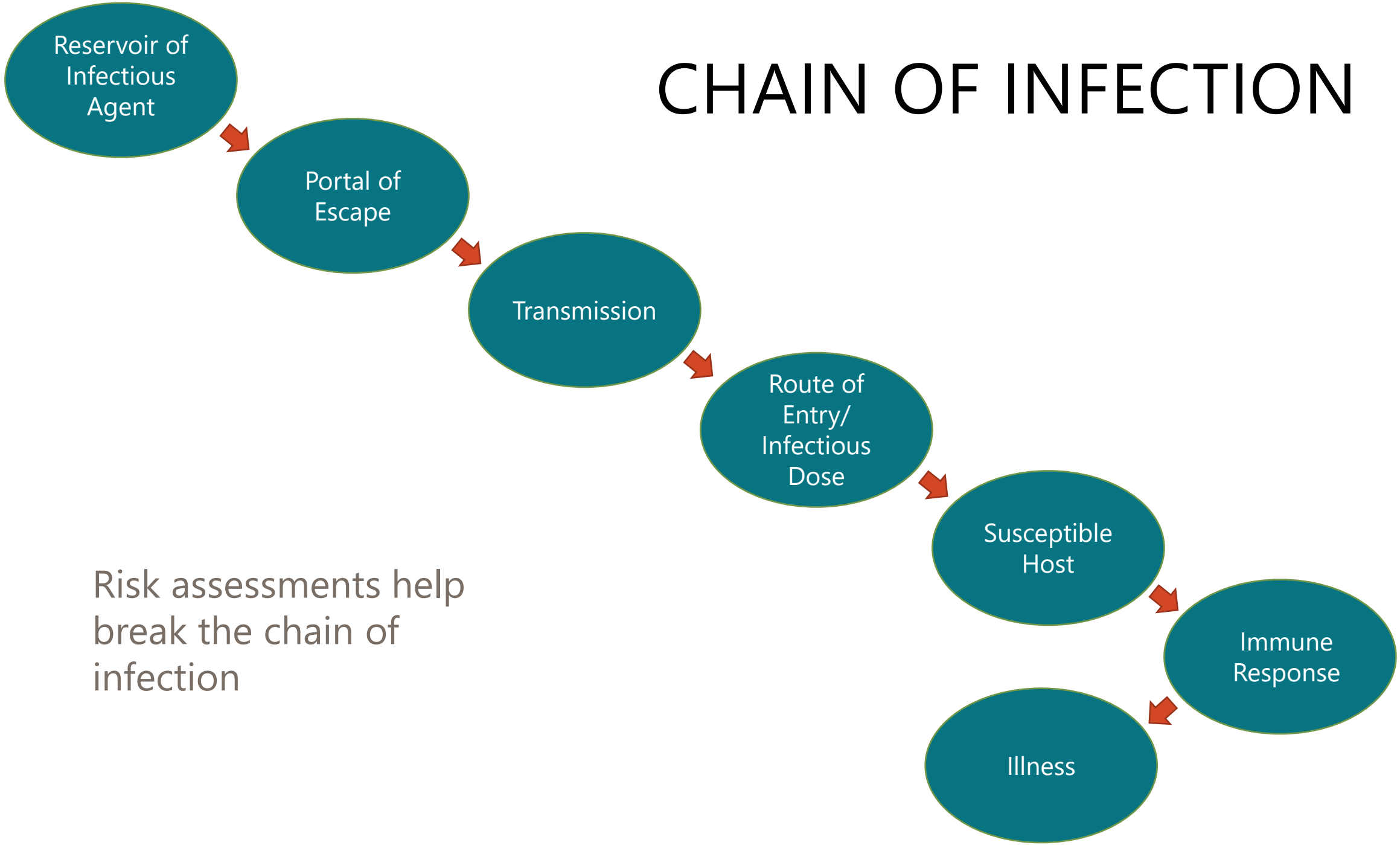
PEOPLE

- Immune Response
  - Pre-existing conditions or medical status
  - Pregnancy
  - Immunizations
- Behavioral Factors
  - Stress, fatigue
  - Perception of risk
  - Attitude toward safety
  - Competency (previous training and experience)

AGENT HAZARDS AND BIOSAFETY LEVELS



CHAIN OF INFECTION



Risk assessments help break the chain of infection

RISK ASSESSMENT MATRIX

Risk Matrix		Consequence				
		Insignificant	Minor	Moderate	Major	Severe
Likelihood	Almost Certain	Medium	High	Very High	Very High	Very High
	Likely	Medium	High	High	Very High	Very High
	Possible	Low	Medium	High	High	Very High
	Unlikely	Low	Low	Medium	Medium	High
	Rare	Low	Low	Low	Low	Medium

RISK ASSESSMENT MATRIX

Risk Factors	Degree of Laboratory Risk		
Agent Hazards	**Low to Moderate**	**Moderate to High**	**High**
Pathogenicity	Mild to moderate disease - Salmonella	Moderate to serious disease - TB	Severe Disease - Ebola
Virulence	Mild to moderate disease or low infectivity	Severe disease or moderate infectivity	Lethal disease or high infectivity
Infective dose	$>10^6$ IU (*Vibrio cholerae*)	10^6 – 100 IU (Influenza A virus)	<100 IU (*Francisella tularensis*)
Transmission	Indirect contact (contact with contaminated surfaces)	Direct contact (droplet, secretion contact with mucous membranes; ingestion)	Inhalation or percutaneous inoculation (needle stick)

RISK ASSESSMENT MATRIX

Risk Factors	Degree of Laboratory Risk		
Susceptibility to Disease	**Low to Moderate**	**Moderate to High**	**High**
Potential for Exposure	Visitor to the lab	Lab worker in the room where agents is handled	Lab workers who hand agents
Individual Susceptibility	Effective immunizations	Immunocompetent	Compromised immune status
Availability of vaccine or other prophylaxis	Yes	Less effective prophylaxis	No
Availability of effective treatment	Yes	Treatment offers some value	No

RISK ASSESSMENT MATRIX

Risk Factors	Degree of Laboratory Risk		
Protocol Hazards	**Low to Moderate**	**Moderate to High**	**High**
Agent concentration	$<10^3$ IU/ml	10^3 - 10^6 IU/ml	$>10^6$ IU/ml
Suspension Volume	<1 mL	1 mL - 1 L	>1 L
Generate aerosols	Streaking cultures	Pipetting	Centrifuging or vortexing
Protocol Complexity	Standard repetitive procedures	Periodic change in procedures	Frequent changes and complex procedures
Use of sharps	Reading slides	Things with protective devices – safety sharps	Necropsies

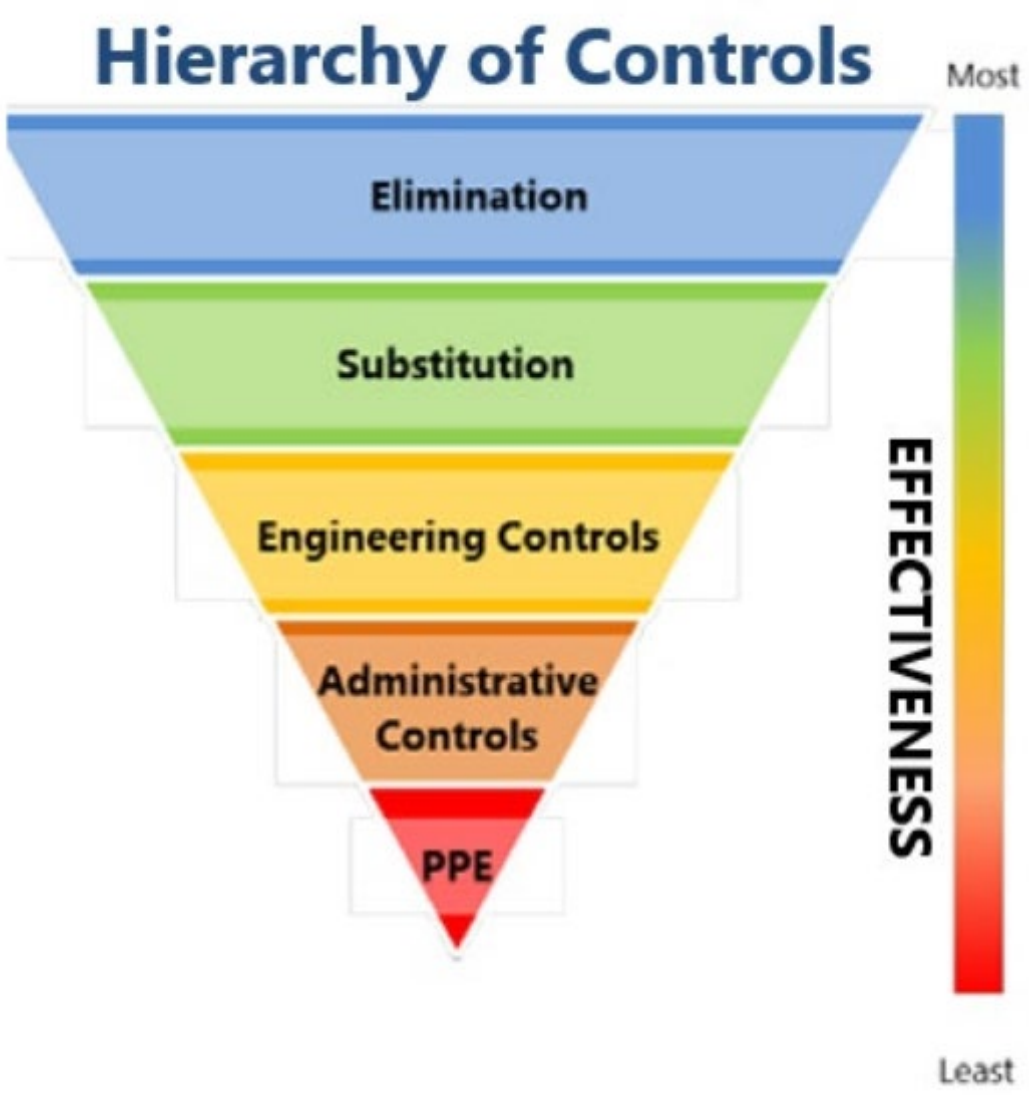
ACCEPTABLE RISK

Risk Matrix		Consequence				
		Insignificant	Minor	Moderate	Major	Severe
Likelihood	Almost Certain	Medium	High	Very High	Very High	Very High
	Likely	Medium	High	High	Very High	Very High
	Possible	Low	Medium	High	High	Very High
	Unlikely	Low	Low	Medium	Medium	High
	Rare	Low	Low	Low	Low	Medium

AMP MODEL APPROACH TO RISK ASSESSMENTS

RISK MITIGATION MEASURES

- The hierarchy of controls
  - eliminate it from the workplace or substitute a less hazardous technique, process, or material.
  - If elimination or substitution are not feasible options, engineering controls, administrative controls, and PPE must be used to provide the necessary protection.



MITIGATION FACTORS

- Containment Equipment (BSC)
- Facility Features
- SOPs
- Handwashing
- PPE
- Medical Surveillance
- Vaccinations
- Medical Treatment (ProphylaxisA)

MITIGATING RISKS: ENGINEERING CONTROLS

- This includes anything that is used to prevent exposure to the hazard or agent
  - Biological Safety Cabinets
  - Negative air pressure in rooms
  - Fume Hoods
  - Splash Guards
  - Centrifuge Safety Caps
  - Doors must lock and be self-closing

MITIGATING RISKS: ADMINISTRATIVE CONTROLS

- Administrative controls define hazards and describe how to minimize risk while completing procedures.
  - Standard operating procedures for tests
  - Training on procedures
  - Emergency response procedures
  - Signs stating laboratory BSL level

MITIGATING RISKS: PERSONAL PROTECTIVE EQUIPMENT (PPE)

PPE is the last line of defense for hazards

- Proper Lab Attire
  - Long pants
  - Closed toes shoes
- Minimum PPE
  - Lab coat (reusable or disposable based on procedure)
  - Gloves (wash hands after removal)
- Increased PPE based on procedures being performed
  - Respirator
  - Back closing gown
  - Double gloves based on procedure

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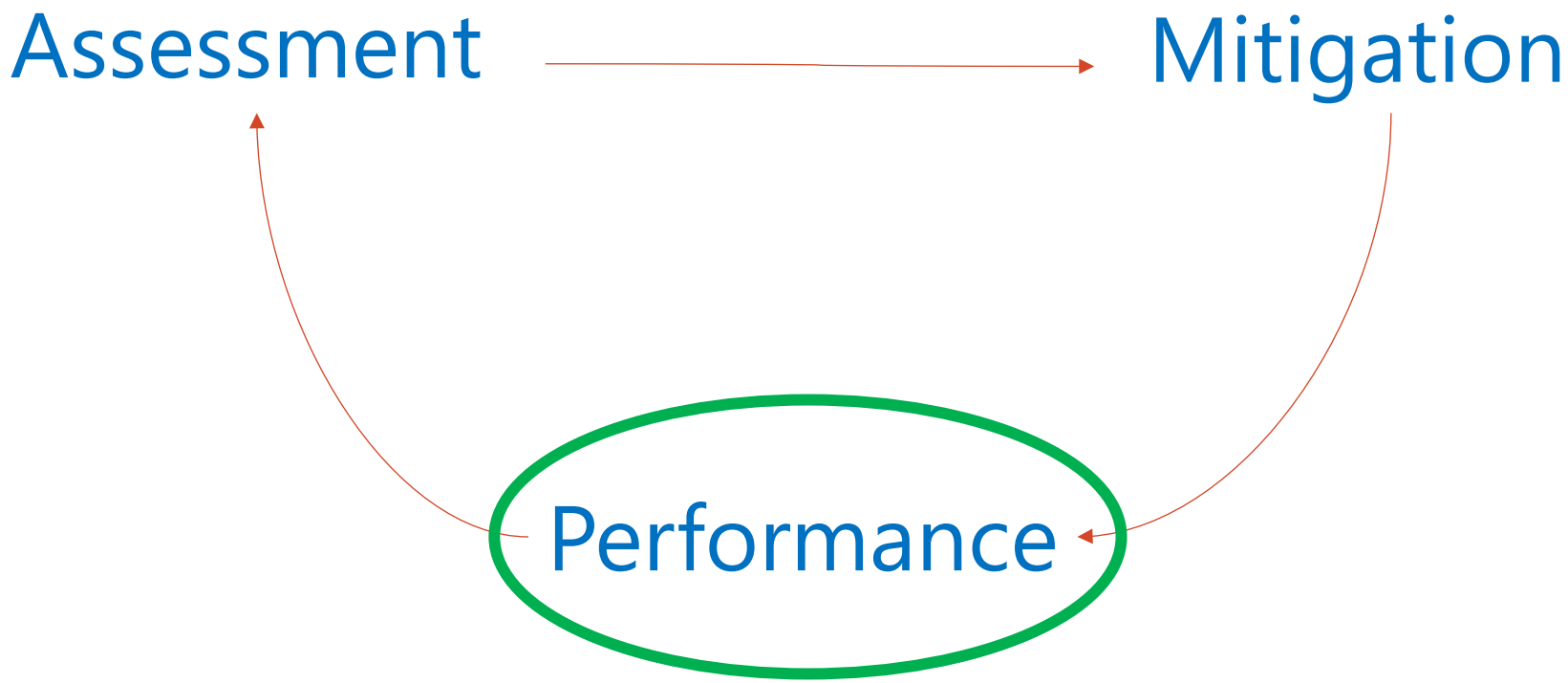

WHY DO WE CARE?

- Hundreds of thousand laboratorians work within a laboratory on any given day
- We want to prevent laboratory acquired infections and/or exposures
- Required by some federal programs (Select Agent Program)
- BMBL 6th ed states: “ongoing practice of biological risk assessments is the foundation of safe laboratory operations”

REFERENCES

- "Biosafety." *Centers for Disease Control and Prevention*. Centers for Disease Control and Prevention, 30 Mar. 2015. Web. 27 Mar. 2017.
- North Dakota Department of Health, “Bench Guide for Bioterrorism Agents.” 2005.
- "Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition." *Centers for Disease Control and Prevention*. Centers for Disease Control and Prevention, 13 Mar. 2015. Web. 27 Mar. 2017.

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