Biological Risk Assessment

for

Clinical Laboratories

Objectives

- Describe the concepts of risk assessment (Why and What?)
- Describe the basic steps of the risk assessment process (Who, When and How?)
- Perform a basic risk assessment exercise

Why Do Risk Assessments?

Approximately 500,000 US laboratorians work with or handle infectious materials and/or cultures every day.

Because of where you work and what you do…

Why Do Risk Assessments?

- To ***reduce*** and **minimize** the risk of exposure to workers and the environment
- But remember:

Risk is never zero!

Why Do Risk Assessments?

- Prevent laboratory-acquired infections (LAIs) from:
  - Direct contact (spills/splashes) to mucous membranes
  - Inhalation of aerosols
  - Percutaneous inoculation from cuts, sharps, vectors, non-intact skin
  - Ingestion
  - Indirect contact (contamination from fomites*)

*Fomite - an inanimate object (as a computer, doorknob, phone or work surface) that may be contaminated with infectious organisms and serve in their transmission

Definitions

Hazard is something that is intrinsically dangerous such as an object, a chemical, an infectious agent or a situation.

Risk is:

- the chance of injury or loss when exposed to a hazard.
- based on the probability of exposure and the severity of consequence from that exposure
- A prediction

Definitions

- **Risk Assessment (RA)** is a process that involves hazard identification and hazard control

- Risk assessment requires
  - knowledge of the hazards
  - understanding of the work, the environment, and the staff
  - management involvement and support

Definitions

Risk Assessment (RA) *overall* process:

1. Identify hazards
   - What may happen?
   - How may it happen?
2. Evaluate risks
   - How likely, how severe?
3. Determine controls to mitigate risk
   - To reduce risk if it is not acceptable
4. Implement controls
5. Review effectiveness of controls and adjust

RA Process


Review risk assessment
Identify hazards
Evaluate Risk
Mitigate Risk
Implement controls

Who Does Risk Assessments?

- *Ideally,* a multidisciplinary team
  - Laboratory staff
  - Management/supervisors
  - Health and safety specialists (biosafety, occupational health …)
  - Facility staff
  - Scientists with unique expertise & experience
    - Microbiologists, molecular biologists, chemists
    - Veterinarians
    - Others

When?
***Ideally,* at regular intervals**

- More frequently in problem areas
- When there is an incident, accident or exposure
- When changes occur
  - Move, renovation or new facility
  - New infectious agent or reagent
  - New piece of equipment, technique or procedure
  - New scientific information available

Risk Assessment Is Not New

- We conduct risk assessments all the time…

Steps of RA

1. Gather information and identify the potential hazard
2. Evaluate and prioritize the risk (likelihood and consequence)
3. Determine what additional safety precautions (controls) are needed to reduce the risk (mitigation)
4. Implement controls
5. Review and evaluate effectiveness, adjust

"Biosafety is an inexact science, and the interacting system of agents and activities and the people performing them are constantly changing."[1]

Every etiologic agent is different

Every laboratory is different

Every person is different

[1] Biological Safety: Principles and Practices, 4th Ed. Fleming DO, Hunt DL, eds., p. 81. Washington, DC. American Society for Microbiology, 2006

Risk Assessment: Interaction of Factors

Pathogen

People

Place, PPE, Procedures

Source: B. Johnson, Anthology of Biosafety, IV, 2001

Risk Assessment Considerations

Biological Agent

Environment

People

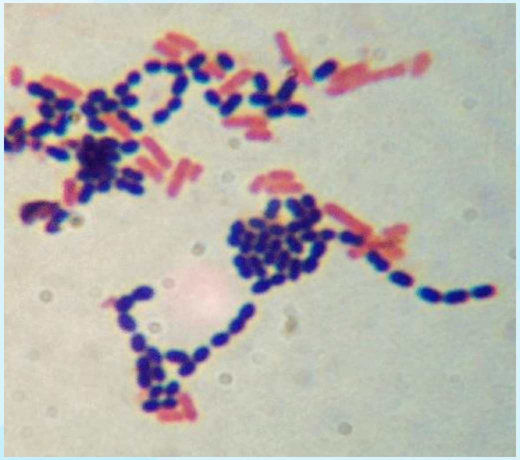
Bacteria, fungi, viruses, protozoa, algae, prions, recombinant organisms, cell lines, cell cultures, human/animal specimens, toxins…

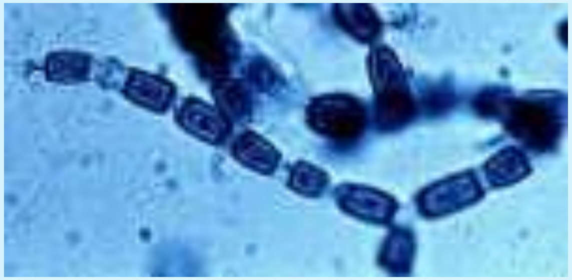
Agent Definitions

- Pathogenicity-the ability/capacity of an infectious agent to cause disease
- Virulence-the quantitative ability of an agent to cause disease, the disease-evoking severity of a pathogen (virulent agents cause disease when introduced in small numbers)
- Transmissibility/communicability- contagious, ease of spread between persons or species by contact with the sick or their fluids

Some Agent Factors to Consider

- Toxigenesis
- Stability in the environment
- Infectious dose
- Route of transmission
- Indigenous or rare
- Availability of data
- Availability of vaccine/treatment
- Host range (humans, animals, plants)
- Antibiotic resistance
- Resistance to disinfection





Agent: Route of Transmission

- Inhalation, ingestion, percutaneous, direct contact, indirect contact (fomites)

- Infection/disease can differ based on the route of transmission
  - *B. anthracis*
    - Inhalational anthrax
    - Cutaneous anthrax
    - Gastrointestinal anthrax

Infectious Dose- The number of microorganisms required *to* initiate infection can vary greatly with the specific organism and the route of transmission

Organism	Route	Dose
E. coli	ingestion	~10^8
E. coli O157:H7	ingestion	~10
N. meningitidis	inhalation, direct contact	unknown
Salmonella spp.	ingestion	~100-1000
Shigella spp.	ingestion	~10-180
Brucella spp.	inhalation, direct contact, ingestion	10-100* *By aerosol and subcutaneous routes in laboratory animals

Risk Assessment Considerations

Biological
Agent

Environment

People

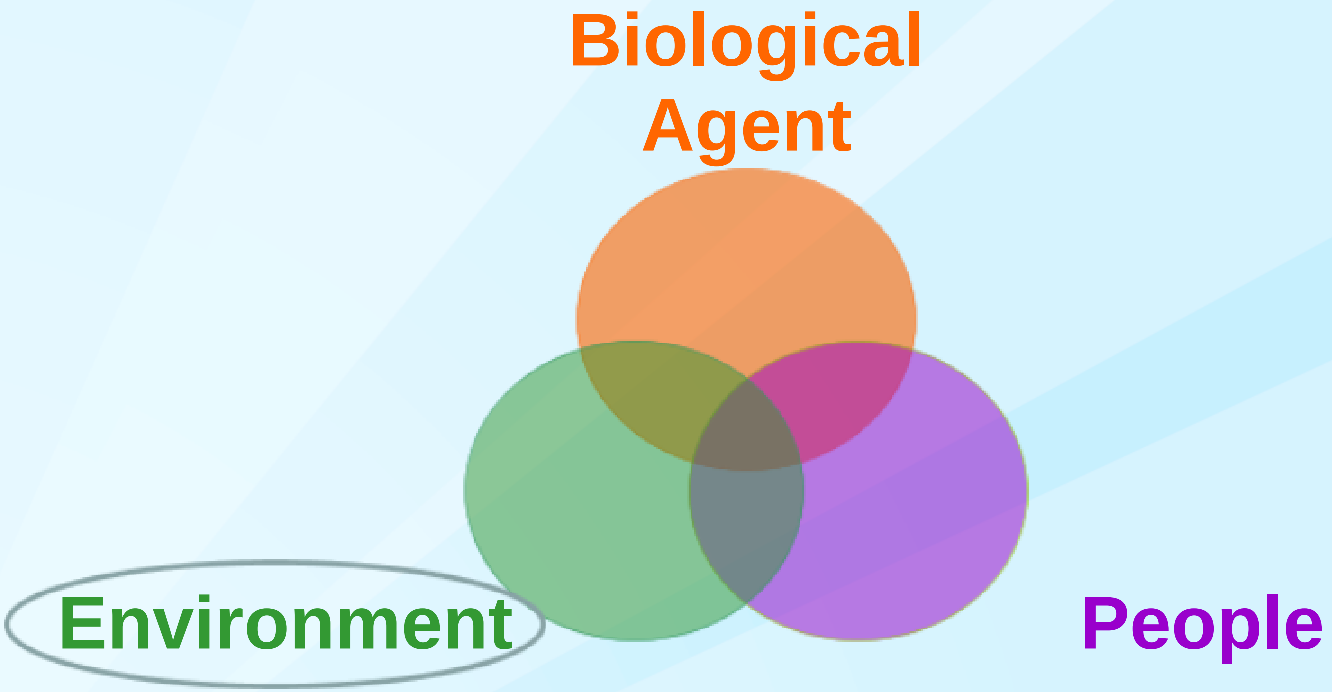
Host factors: Immune Status

-Age or life-stage
-Pre-existing conditions/medical status (stress, autoimmune disease, chemotherapy, non-intact skin, allergies, other infections/disease, medications, antibiotics)
-Pregnancy (Cytomegalovirus, HIV, Herpes simplex virus)
-Nutrition, diet
-Immunizations (HBV, Meningococcus, Pneumococcus)

Host: Behavioral Factors

- Stress, fatigue, mental status
- Cultural differences, age, habits
- **Perception** of risk
- **Attitude** toward safety
  - Follow procedures?
  - Use equipment/PPE as designed?
  - Take shortcuts?
- Competency
  - Education and experience
  - Trained?
  - Students, language barriers
- Dexterity or reaction time affected by medications or PPE?

Risk Assessment Considerations



Environmental Factors

Place (facility)

- research, clinical, industrial, public health, BSL-2/3
- workflow-is the lab crowded/cluttered?
- lab equipment (biosafety cabinet [BSC], animal cages, sharps, centrifuges, vortex, autoclaves …)
  - -is it available?
  - -does it protect or is it a hazard by itself?

PPE (hazard or protection?)

- appropriate PPE available?
- is it used?
- are people trained?

Environmental Factors (Procedures)

- hand washing-cracked skin?
- large volume, high agent concentration
- centrifuging, autoclaving
- sharps
- generating aerosols-anything that imparts energy to a suspension
- waste management
- inoculating biochemicals
- doffing procedures
- not using or improper use of BSC

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Risk Assessment

Very seldom is risk assessment a black and white issue

- Involves personal and social value judgments

- Everyone has different perceptions of risk and what is "acceptable"

Old woman or young girl?

Evaluate and Prioritize Risk-Example

Likelihood (probability) of occurrence

- Rare: could happen, but probably never will
- Unlikely: could happen but rare
- Possible: could happen but not likely
- Likely: could happen sometime
- Almost certain: expected to occur

Evaluate and Prioritize Risk-Example

Consequence (severity) of exposure

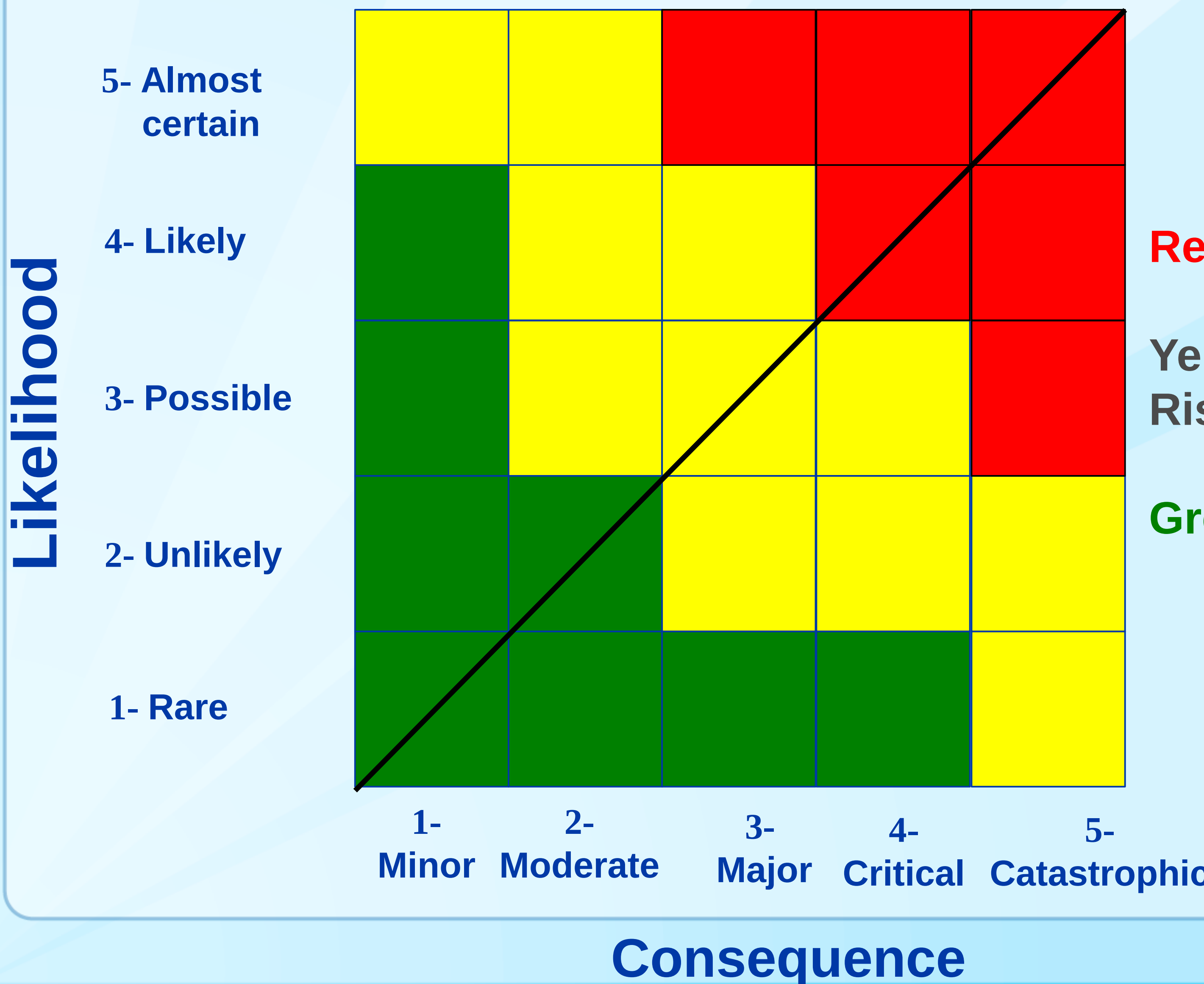
- Minor: Colonization, asymptomatic
- Moderate: Medical treatment or first aid
- Major: Infection and recovery
- Critical: Disease and sequelae
- Catastrophic: Death

Evaluate and Prioritize Risk-Example

- Performing Gram stain:
  - Potential Hazard: Aerosols from flaming slides — mucous membrane exposure
  - Likelihood: Possible
  - Consequence: Colonization; medical treatment
  - Risk: Moderate

- AFB culture work-up
  - Potential Hazard: Aerosols — inhalation
  - Likelihood: Likely
  - Consequence: Infection; medical treatment; disease
  - Risk: **High**

Risk Matrix-Example



Red = HIGH RISK

Yellow=Moderate Risk

Green= low risk

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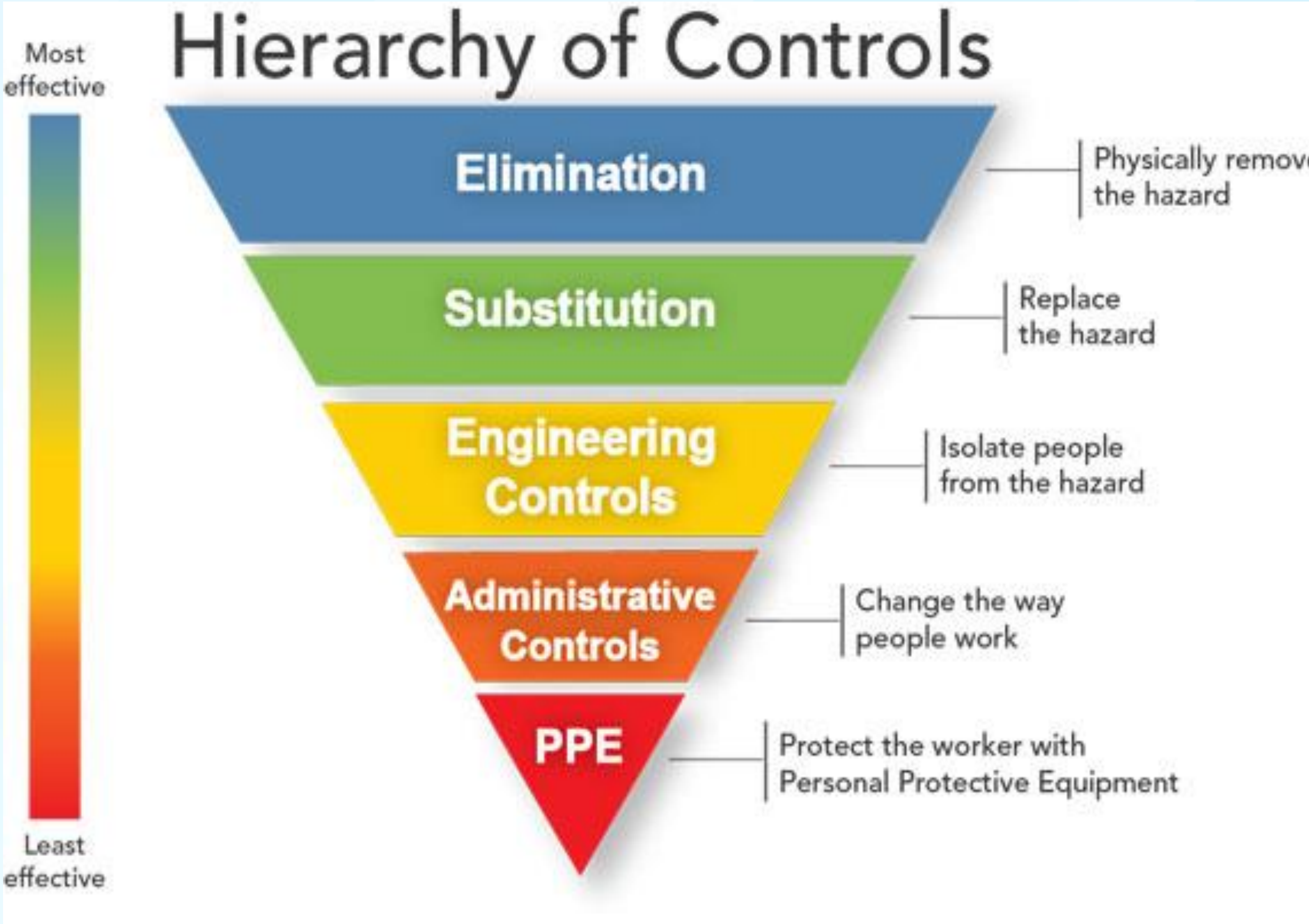
Hierarchy of Controls
Most effective
Least effective
Elimination
Substitution
Engineering Controls
Administrative Controls
PPE
Physically remove the hazard
Replace the hazard
Isolate people from the hazard
Change the way people work
Protect the worker with Personal Protective Equipment

Some Engineering Controls

- Safety Equipment (BSC, sharps containers, centrifuge safety cups, eyewash, sealed rotors)

-Facility Design (directional airflow, lockable doors, hands-free faucets)

Some Administrative Controls and Work Practices

- Training
- Signage
- SOP’s and site-specific safety manuals
- Medical surveillance program (including a process to address unusual absences, sickness, and injury)

- Frequent hand washing
- Appropriate use of PPE
- No mouth pipetting
- Limiting use of needles and sharps
- Minimizing aerosols

PPE

- PPE is your *last* resort, after all other mitigation steps have been taken
- Proper technique for donning and doffing PPE is as important as having the correct PPE-staff must be trained!
- *More PPE is not always better* (decreased dexterity and sensitivity, uncomfortable, hot)
- PPE can vary on what you are doing and where you are doing it-depends on risk assessment!
- Institutions must establish policies for adherence

Routes of Transmission	Mitigation Strategies
inhalation	BSC, respiratory protection, centrifuge safety cups
ingestion	No mouth pipetting, gloves, hand washing
percutaneous	Safer sharps, sharps containers, cover compromised skin
direct contact with mucous membranes	Gloves, hand washing, face protection
indirect (fomites)	Disinfecting surfaces, spill procedures, designated clean and dirty areas

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Review and Evaluate Effectiveness

-Review incidents, accidents, illnesses

- Encourage and support non-punitive reporting

-Identify causes/problems, make changes, follow-up training

- Document and maintain records

-Conduct routine lab inspections

-Repeat RA when incidents or changes occur

Perform a Risk Assessment

- In order to simplify the entire process and make it more practical for laboratorians, a **Job Hazard Analysis** framework can be used to break down a complex process into individual steps.

- Each step is then evaluated separately, and mitigation controls can be determined and implemented at each step of the process.

OSHA Job Hazard Analysis

- “A technique that focuses on job tasks as a way to identify hazards before they occur.
- Ideally, after you identify uncontrolled hazards, you will take steps to eliminate or reduce them to an acceptable risk level.”
- https://www.osha.gov/Publications/osha3071.html

Job Hazard Analysis Steps

- Break procedure down into individual components
- Determine hazard(s) associated with individual component* (hazard ID)
- Identify way to deal with each hazard (hazard control)

*5 P’s: pathogen, people, place, PPE, procedures

Job Hazard Analysis-Example

Procedure or Process	Principal Steps (Procedure)	Health Hazards (Pathogen)	Safety Equipment/ Engineering controls (Place)	Administrative Controls and Work Practices (Personnel)	Recommended PPE
Slide Catalase Test	1. Touch colony of organism with stick or plastic loop 2. Put on slide 3. Add Hydrogen Peroxide 4. Observe for bubbles	Pathogen (?) Aerosol generation Chemicals Sharps	Perform this test in a tube, BSC, or use other engineering controls. Sharps containers	Proper BSC usage; safe sharps handling; aerosol containment; SOPs and demonstrated competency	Gloves Lab coat Face shield (optional if using a bench shield or BSC)
Hematology differential	1. Label slide 2. Open tube 3. Place drop of blood on slide 4. Swipe to make diff 5. Air dry 6. Stain	Sharps Aerosol generation Auto-inoculation Spill Chemicals	Use automated system, splash shields, absorbent pads, tube holders Sharps containers	SOPs and demonstrated competency; Safe sharps handling; Aerosol containment Splash shield	Gloves Lab coat Face shield (optional if using a bench shield or automated system)

Don't Forget:

- There is some risk in everything we do-we can reduce it, but not eliminate it
- To ask questions
- Your staff, their training and competency
- To evaluate, review and adjust

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