



“Is it Magic, or Simply a Great Biosafety Plan?”

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Objectives



At the conclusion of this intermediate-level instructional session, attendees will be able to:

1. Summarize the components of a comprehensive biosafety plan
2. Explain how a comprehensive biosafety plan serves as the backbone for developing a strong biosafety culture
3. Discuss how you can use and, if needed, adapt your biosafety plan to prepare to safely handle an emerging or re-emerging pathogen

What is Magic?

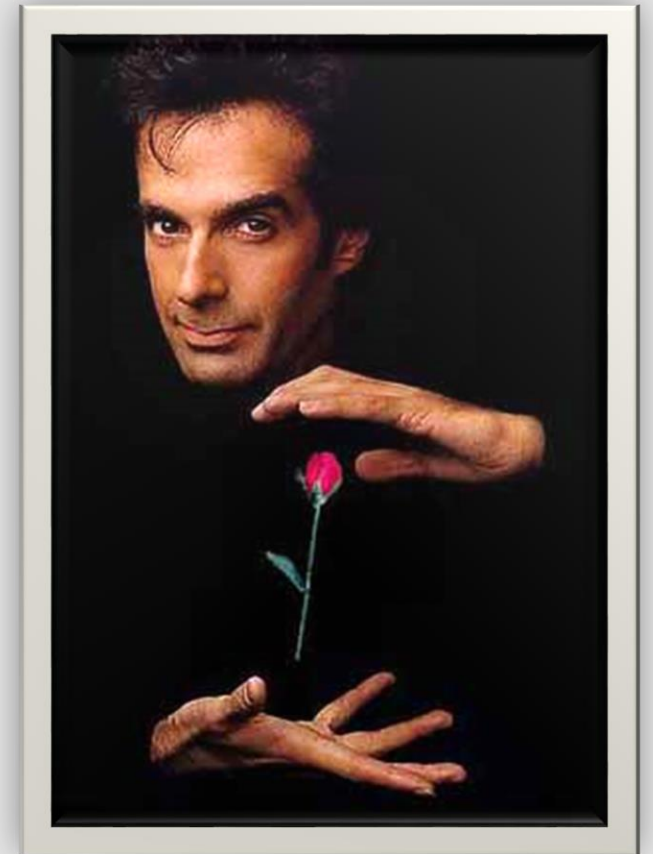
What do you think of when you hear the word **magic**?



Harry Potter?



Or perhaps a magician?





So, is it magic?

Or is magic something that happens when all the pieces align and something beautiful and amazing happens?

Solar Eclipse

Where the Moon fully/partially obscures Earth's view of the Sun

Partial Eclipse = Earth within Moon's Penumbra shadow.
Total Eclipse = Earth within Moon's Umbra shadow.

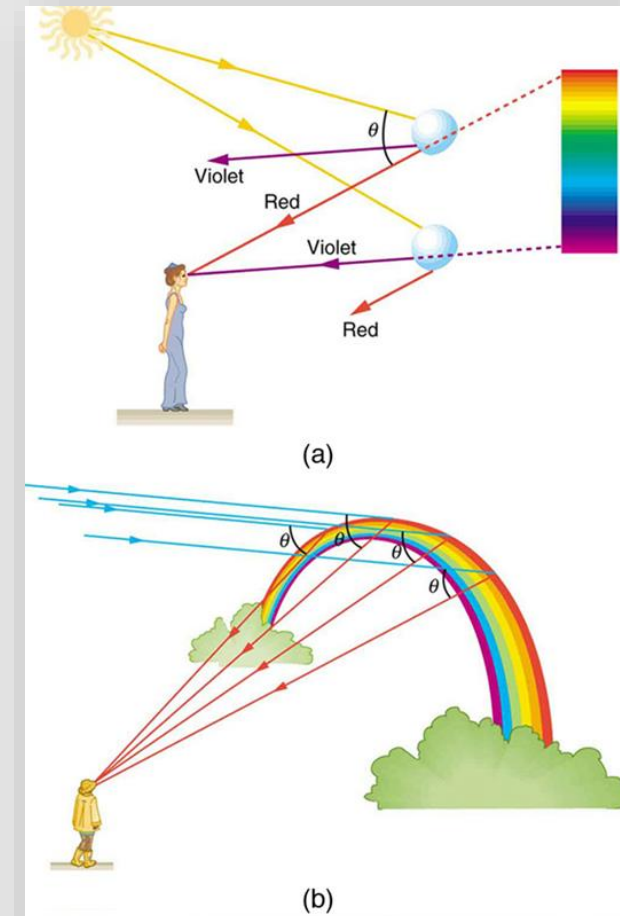
Obscures our future vision so we can clearly see the NOW
Profound Opportunities to not be a victim of the PAST
Quantum Leaps into more conscious ways of living/being

Moon's Orbit

Total Eclipse (Umbra)

Partial Eclipse (Penumbra)

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Is it magic?

In the case of biosafety, it may be most like the athlete who adopts the team culture, trains hard and follows the plan to achieve the performance that receives the prized gold medal.



What is the goal?

- If the goal is to be ready to safely handle all emerging or re-emerging pathogens that threaten public health, in a manner that protects staff and prevents laboratory associated infections (LAIs)...
- Then the training and preparation we do now, each and every day in our laboratories matters!

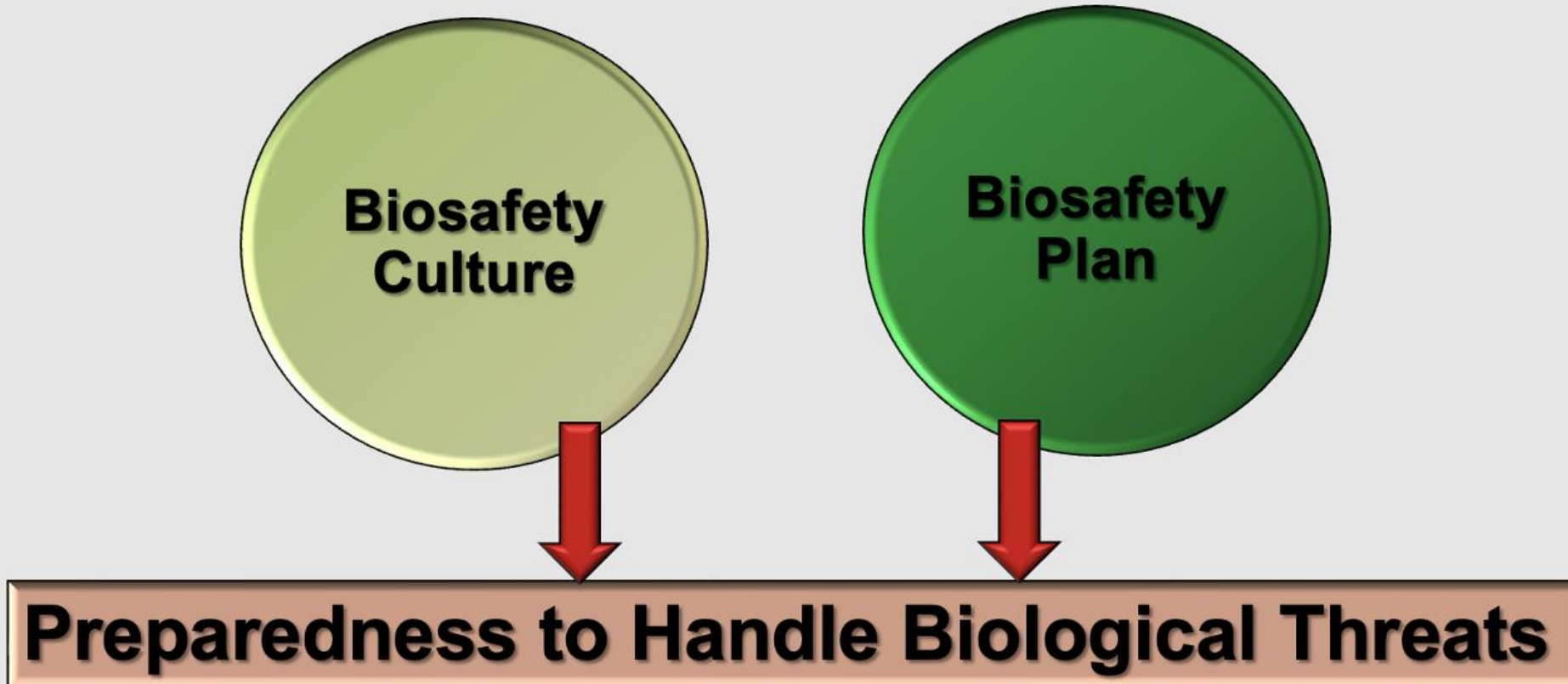


We are prepared to handle Biological Threats!



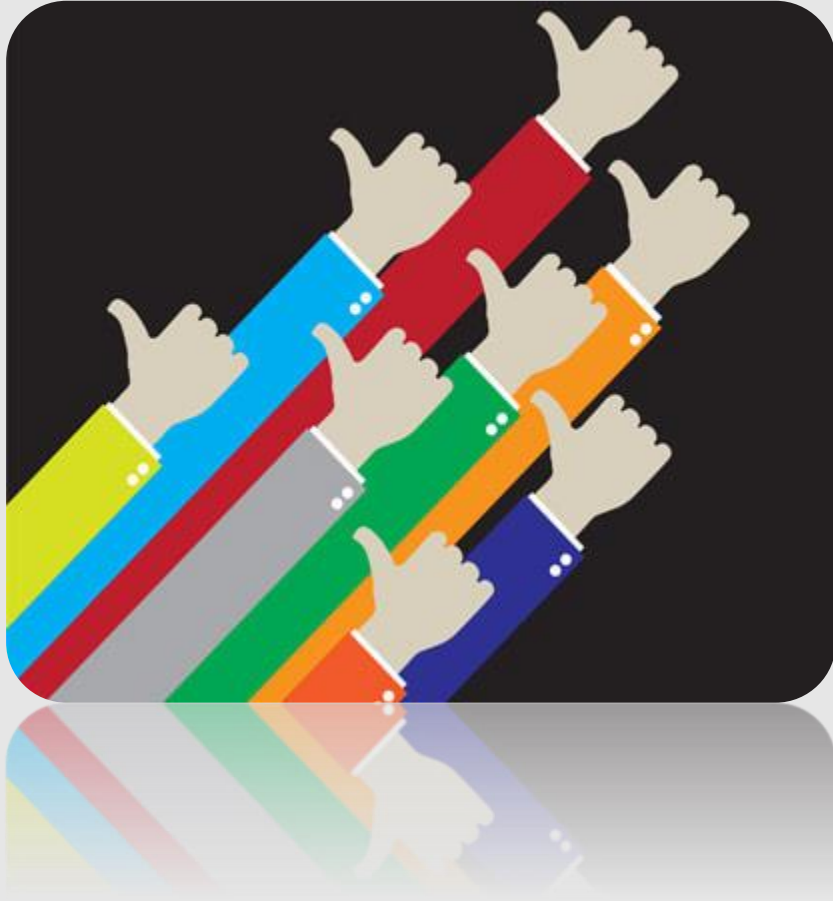
Where Do We Start?

It all begins with our biosafety culture and our biosafety plan!





Biosafety Culture

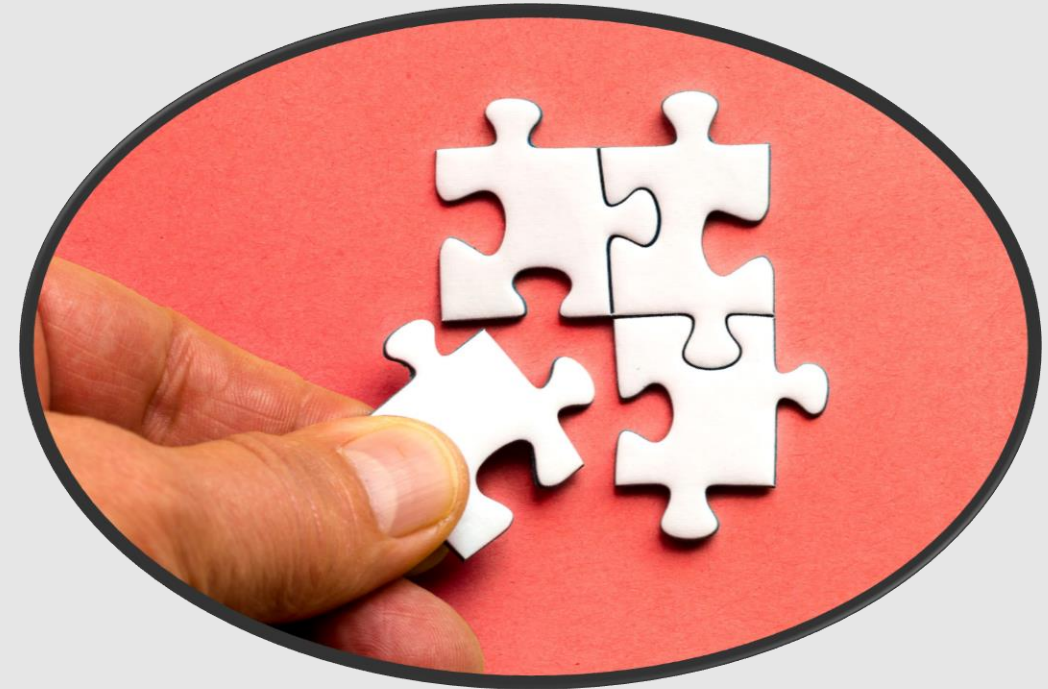


- Leadership led and supported from the top down and all throughout the company
- Money and time spent on biosafety are essential
- Accidents and near misses are teachable moments for learning, not for punishment and blame
- Responsibility and Accountability - Everyone has responsibility for their safety and the safety of everyone they work with
- Biosafety is continually assessed and continually evolving
- As a result, people feel safe and valued in the laboratory

Assembling the Biosafety Plan



- A Biosafety plan is a tool every laboratory must have and utilize to be prepared for whatever comes their way.
- Laboratories often lack a specific plan for the laboratory and rely on a hospital or health system plan.
 - Doesn't have the laboratory specifics needed
- Like a puzzle, laboratories typically have in place many of the pieces of a biosafety plan, but they haven't assembled the pieces together to complete the puzzle, so they can easily view the entire biosafety plan.



Contents of a Biosafety Plan



- Vaccinations
- Biosafety Training
- Competency Assessment
- Risk Assessments
- Mitigation Measures
- Incident Reporting
- Contact Information of Partners and When to Contact
- Exposure Assessment and Monitoring Tool
- Root Cause Analysis Tool
- Outreach and Strong Effective Communications with Partners
- After Action Reports



Make sure all employees know where the Biosafety Plan is kept!

Vaccinations

- What testing are you performing?
- What specimens/samples are you working with?
- What are the likely biohazardous agents contained in them?
- What vaccines are available to help protect and prepare staff to work with the likely biohazardous agents?



Biosafety Training



Initial Training:
New, Hires Students

Annual / Refresher Training:
All Staff

- **Training includes:**

- Review of lab biosafety/biosecurity expectation
- Use of biosafety cabinets, fume hoods, centrifuges, dead-air boxes, autoclave
 - Protection of employees vs. protection of what they are working with
- Use of PPE
 - Donning and doffing including gloves
- Bloodborne pathogens
- LAIs and routes of infections
- Use and storage of reagents
- Risk assessment
- Exposure assessment
- Incident reporting and response
- Spill drills
- Biosafety competencies

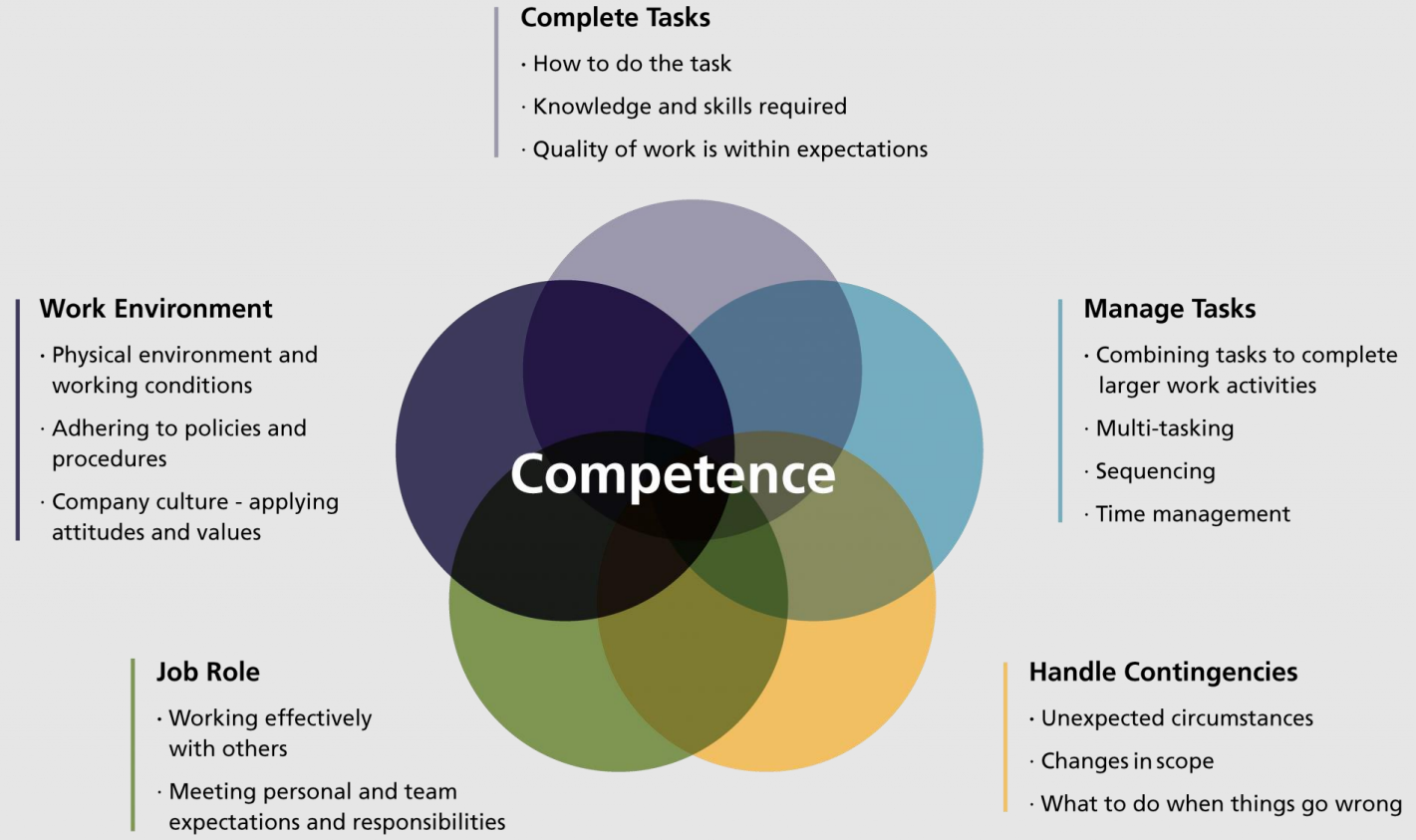


**Teach all to look at the lab through
the lenses of biosafety glasses**

Competency Assessment



- How will you assess the biosafety competency of every person working in the laboratory to ensure each individual understands, is comfortable with, and adopts the biosafety culture you have established?
- Biosafety huddles
 - Discussion of potential biosafety threats
 - Team teaching moments to review and resolve biosafety issues and near misses
- Biosafety competency questions asked during training and on annual competencies required for accreditation



Make sure biosafety is included in all competency assessments!



Risk Assessment

- What forms/tools does your laboratory use?
- Things to consider:
 - What are you working with?
 - How hazardous is the specimen?
 - Where will you be working?
 - Will others be working nearby?
 - What are the testing steps and how will you manipulate the specimen?
 - What is your immune status?
 - What is your mental status?
- Who performs the risk assessment?
- Risk assessment requires continual re-assessment



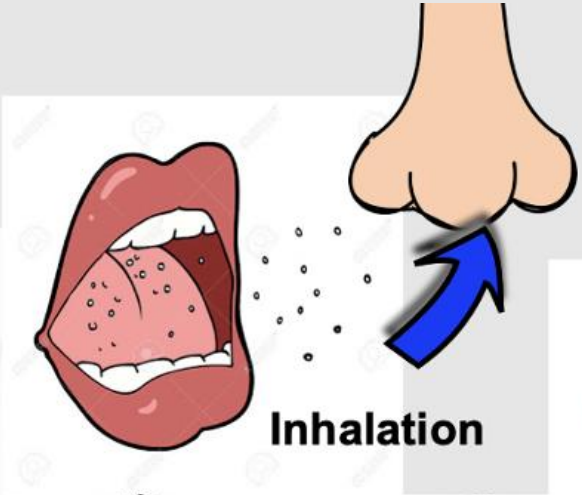
Routes of Laboratory Infection



Mucosal membrane splash



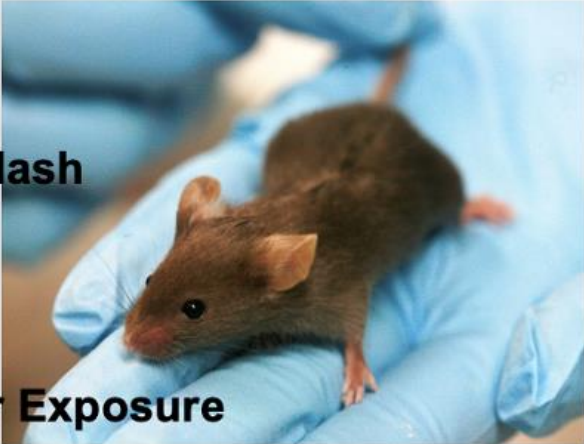
Ingestion



Inhalation



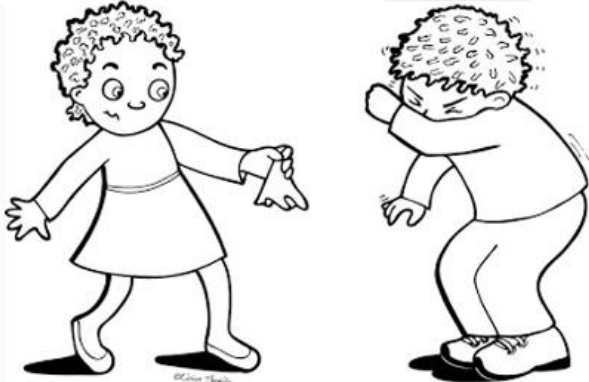
Unknown



Lab Animal/Vector Exposure



Needlestick



Sick Co-Worker



Assess the Level of Risk



Begin by identifying all the hazards in whatever work you are doing

- **Likelihood of hazard occurrence**

Hazard Likelihood	Description of Likelihood
1. Rare	Will only occur in exceptional circumstances
2. Unlikely	Not likely to occur within the foreseeable future
3. Possible	May occur within the foreseeable future, sporadic exposure is possible
4. Likely	Likely to occur within the foreseeable future, routine exposure is likely
5. Highly Likely	Almost certain to occur within the foreseeable future, consistent exposure is highly likely

- **Consequence of hazard occurrence.**

Hazard Consequence	Description of Consequence
1. Insignificant	No treatment required
2. Minor	Minor injury requiring First Aid treatment (e.g. minor cuts, bruises, bumps)
3. Moderate	Injury requiring medical treatment or lost time
4. Major	Serious injury (injuries) requiring specialist medical treatment or hospitalization
5. Critical	Loss of life, permanent disability or multiple serious injuries

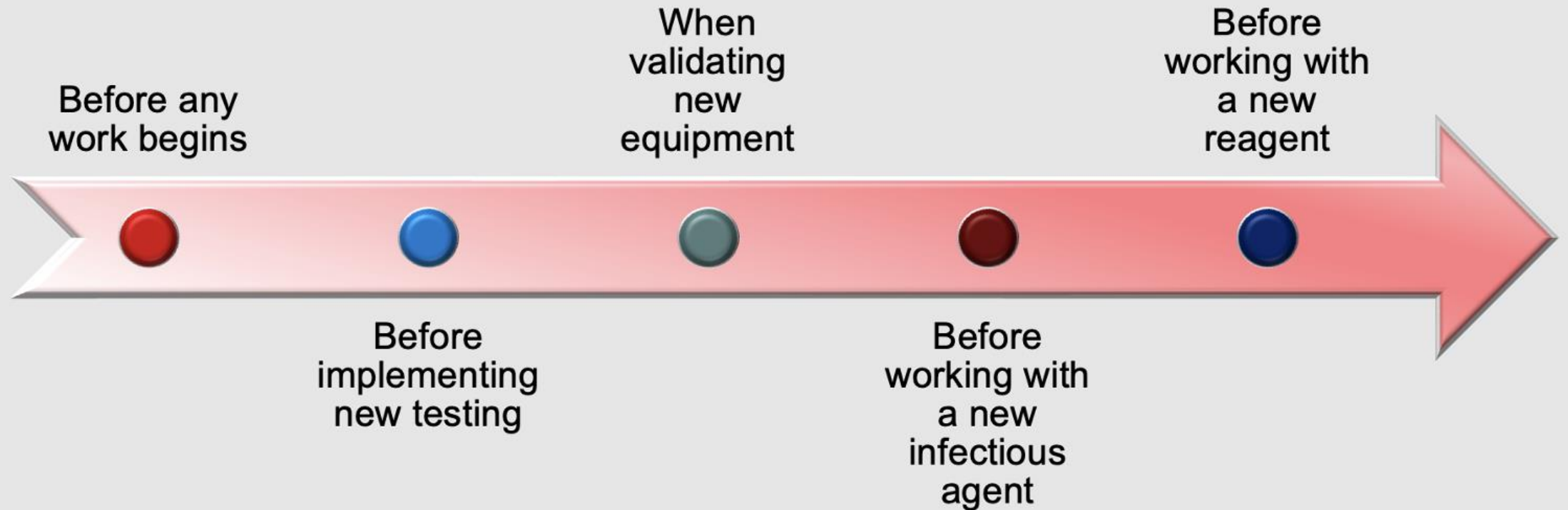
Likelihood Vs. Consequence



Risk Assessment Matrix		Hazard Consequence				
		Insignificant	Minor	Moderate	Major	Critical
Hazard Likelihood	Highly likely	Medium	Medium	High	Extreme	Extreme
	Likely	Low	Medium	High	High	Extreme
	Possible	Low	Medium	High	High	High
	Unlikely	Low	Low	Medium	Medium	High
	Rare	Low	Low	Low	Medium	Medium

Assessed Risk Level		Description of Risk Level	Actions
<input type="checkbox"/>	Low	If an incident were to occur, there would be little likelihood that an injury would result.	Undertake the activity with the existing controls in place.
<input type="checkbox"/>	Medium	If an incident were to occur, there would be some chance that an injury requiring First Aid would result.	Additional controls are advised.
<input type="checkbox"/>	High	If an incident were to occur, it would be likely that an injury requiring medical treatment would result.	Control will need to be in place before the activity is undertaken.
<input type="checkbox"/>	Extreme	If an incident were to occur, it would be likely that a permanent, debilitating injury or death would result.	Consider alternatives to doing the activity. Significant control measures will need to be implemented to ensure safety.

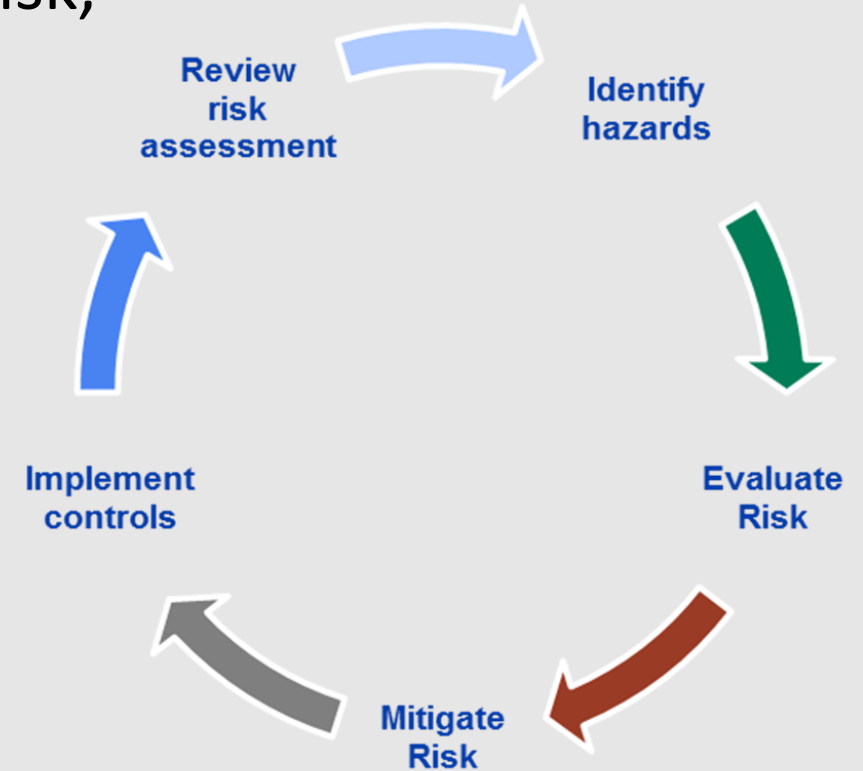
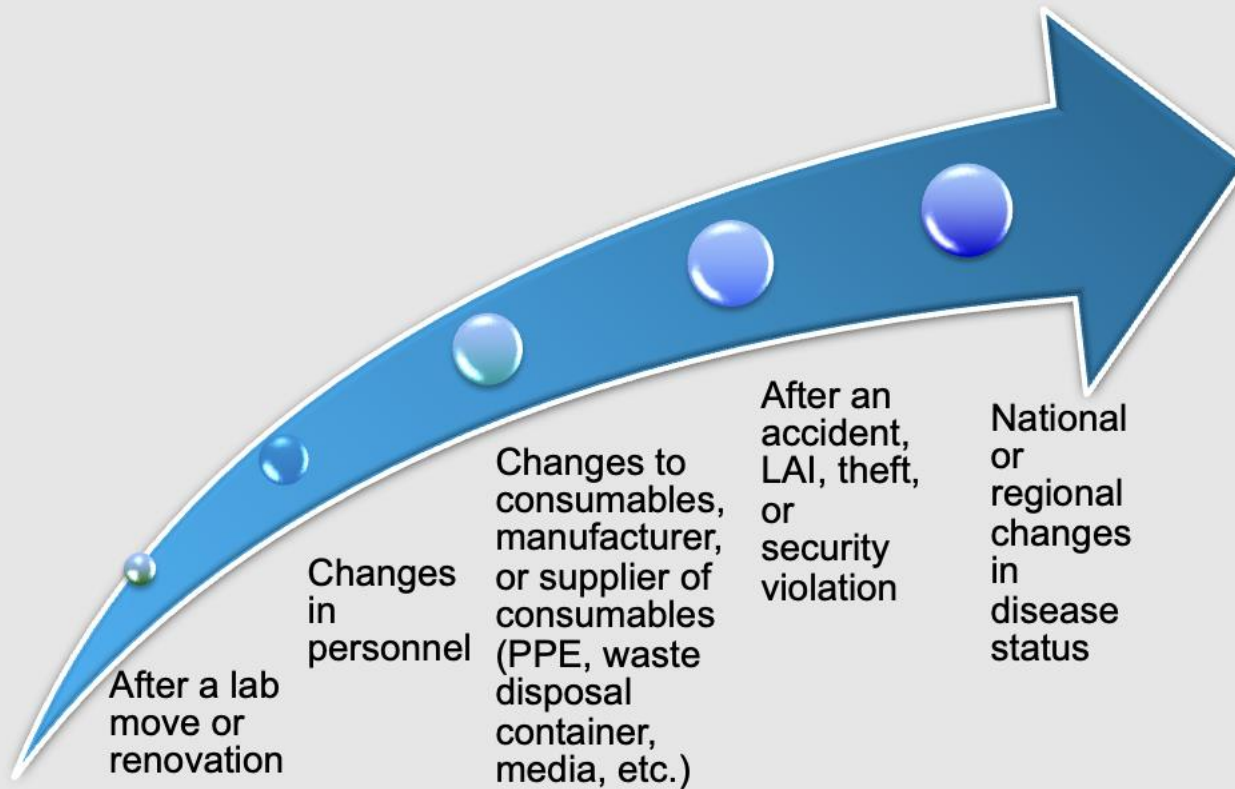
When to Perform an Initial Risk Assessment?



Repeating and Revising Risk Assessment



- Whenever someone identifies a new potential risk, **repeat** your risk assessment



- Modify or add additional mitigation measures as needed

Risk Assessment Task Based Tool



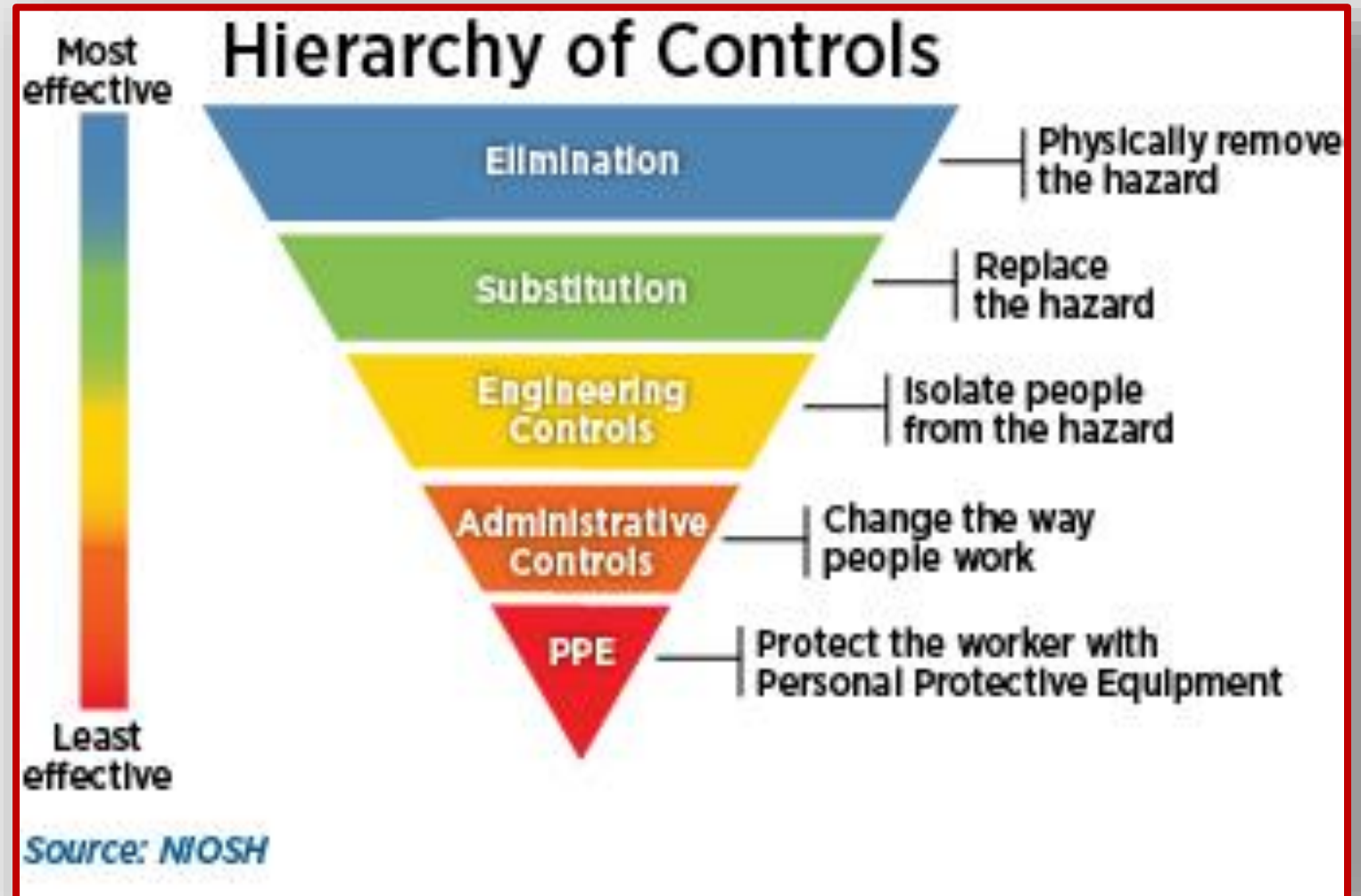
Task/Procedure	Hazard	Initial Risk Level	Mitigation Measure	Residual Risk Level
Describe the task or procedure steps	Describe the hazards	Select the risk level	Describe the appropriate mitigation measures	Select the residual risk level

Note: Additional columns for who is responsible for implementing the mitigation steps as well as the date this will be done aren't included in this view.



Risk Mitigation

- What is your level of risk tolerance?
- What mitigation steps will you put in place to reduce the risk?



Mitigation Measures

- 🦠 **Engineering Controls:** Physical changes to work stations, equipment, materials, production facilities, or any other relevant aspect of the work environment that reduce or prevent exposure to hazards
- 🦠 **Administrative Controls:** Policies, standards and guidelines used to control risks
- 🦠 **Practices and Procedures:** Processes and activities that have been shown in practice to be effective in reducing risks
- 🦠 **Personal Protective Equipment:** Devices worn by the worker to protect against hazards in the laboratory





Incident Reporting



Never assign blame!

- What do you report?
 - Actual incidents
 - Near misses
- Who do you report to?
- How long do you have to file your report?
- What forms do you use?
- Where are the forms kept?
- Where do you go if medical follow-up is necessary?
- How do you get there?
- What do you need to bring with you?

Contact Information of Partners and When to Contact



It Takes a Team of Partners



Determine Who is Responsible for What!

Exposure Assessment and Monitoring Tool



CLINICAL LABORATORY BIOLOGICAL EXPOSURE EVALUATION TOOL

Potential Exposure Event Summary

Date of Potential Exposure: _____ Exposure Location(s): _____

Multiple people exposed? No Yes. Complete this form for each person to determine individual exposure risk.

Name/Identifier of Person Potentially Exposed: _____

Individual's Predispositions: Pregnant Immunocompromised Other: _____

Interactions with Organism

Individual worked with organism: Within BSC Outside BSC Did not work directly with organism

Individual did not work with organism, but was: Within five feet More than five feet away Unsure

Individual wore: Gloves Lab coat/gown Safety glasses

Individual performed the following activities or types of manipulation with organism:

- | | | |
|--|--|---|
| <input type="checkbox"/> Removed caps or swabs from culture containers, opened lyophilized cultures or cryotubes | <input type="checkbox"/> Flamed a loop | <input type="checkbox"/> Exposed |
| <input type="checkbox"/> Manipulated needles, syringes or sharps | <input type="checkbox"/> Wet preps | <input type="checkbox"/> Smear |
| | <input type="checkbox"/> Rapid antigen testing | <input type="checkbox"/> Centrifugation |
| | <input type="checkbox"/> Blood culture bottle | <input type="checkbox"/> Culture |

What work was done by whom, where and what PPE was worn? Who else was present and how close were they?

Exposure Event Follow-up

Treatment and Monitoring

Post Exposure Prophylaxis (PEP): Will begin PEP Declined PEP N/A

Serological Monitoring: Will begin serological monitoring Declined N/A

Fever Watch: Yes No N/A

Other Notes:

Corrective Actions and Mitigations

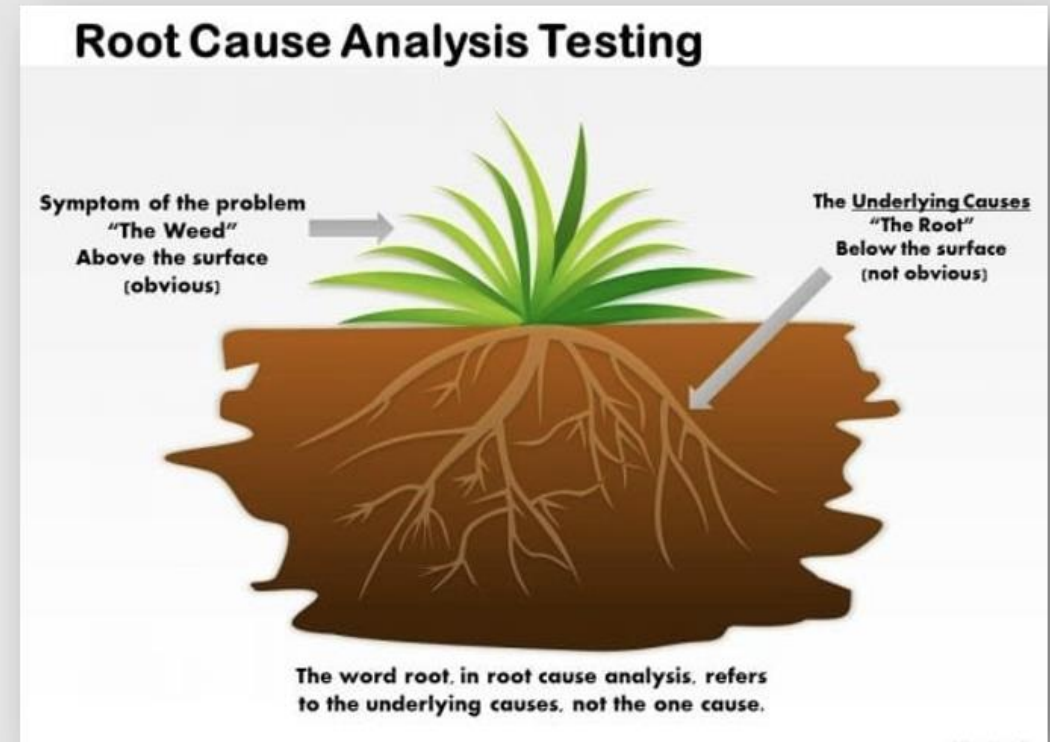
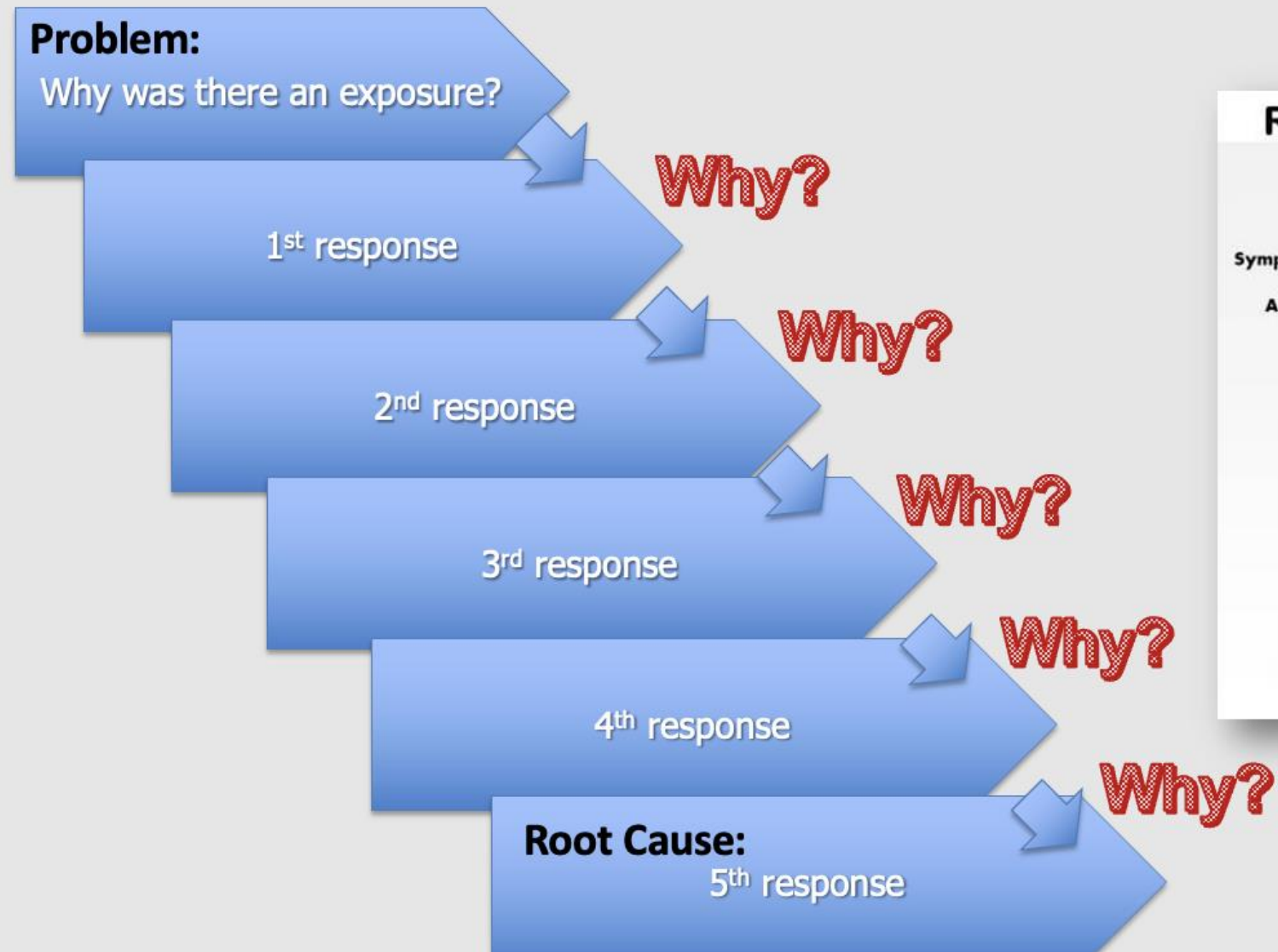
Use the risk assessment determinations above to evaluate the overall risk of exposure according to the likelihood of occurrence and severity of consequences.

What treatment is needed and who will be monitoring the treatment?



Root Cause Analysis

Ask 5 “whys” to get to the underlying root cause



Outreach and Building Relationships with Partners



- Establishing and maintaining relationships with partners is a core function of public health laboratories
 - Invest time and energy in building relationships
 - Communicate honestly and clearly to build trust and earn respect
 - Develop mutually beneficial relationships so each party finds value in the relationship
 - Maintain accurate records of contact information



An emergency is not the time to exchange business cards!

Strong Effective Communications



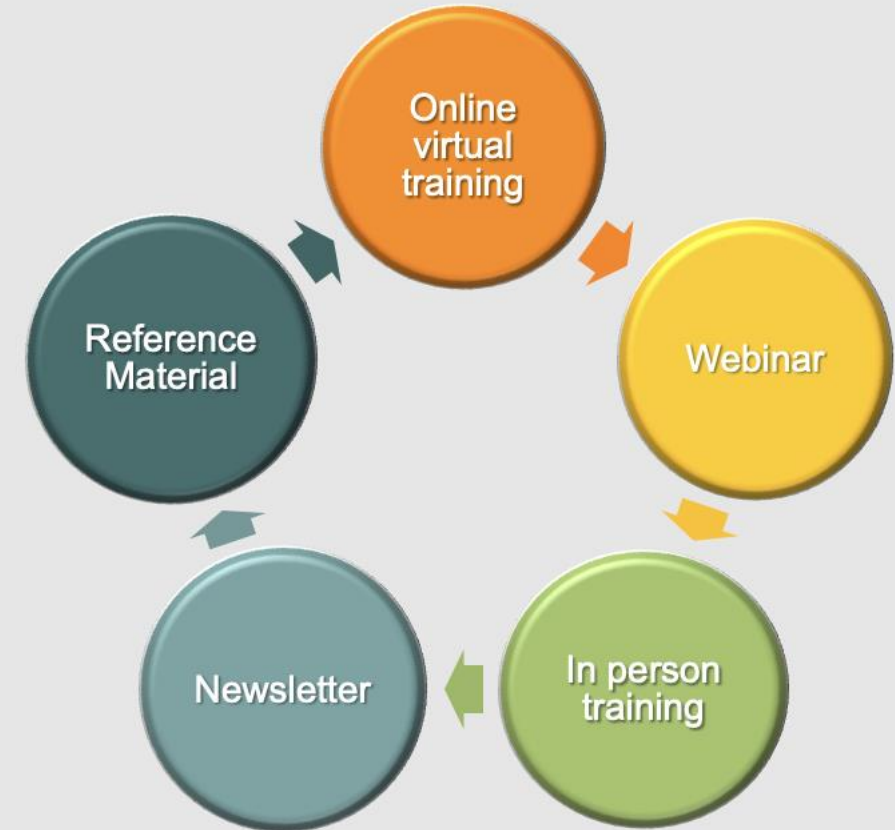
- Dynamic relationships are strengthened by regular communication
- Don't withhold information, but share it in a timely manner
- Be transparent and honest
- It is good to admit to what you don't know as well as sharing what you know
- Have different communication options available to use





Provide Outreach Training for Clinical Laboratory Partners

- It is not enough to teach clinical partners how to perform a risk assessment and put mitigation measures into place
- Must provide training and assess competence at a minimum on:
 - Donning and doffing PPE
 - Proper use of respiratory and eye protection
 - Biosafety cabinet
 - Fume hood
 - Centrifuge
 - Proper disinfection
 - Proper use of sharps
 - Waste disposal
 - Spill clean-up
 - Packaging and shipping
 - Building a strong biosafety culture





After Action Report

After a response to an emerging pathogen:

- Gather internally to perform an after action report
- Gather with key partners to perform an after action report

What worked well?

What didn't work well?

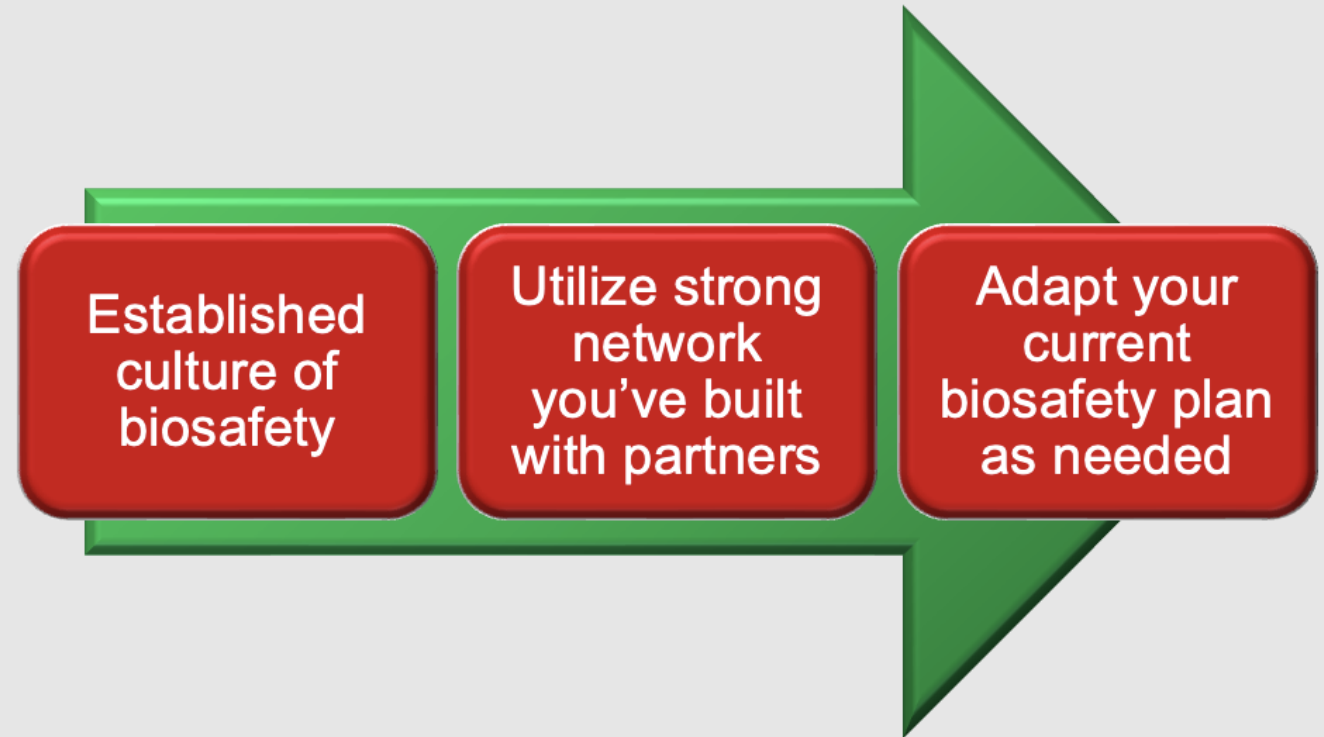


Confronting a New Emerging Pathogen



Grab your Biosafety Plan and Perform a Risk Assessment!

- What do you know about the emerging threat?
- What other agents do you work with that have similar characteristics?
- Adopt similar biosafety measures until you learn more about the emerging pathogen
- As you learn more, continue to revise your risk assessment and modify your mitigation measures and your biosafety plan
- Share information with partners





It is Not Magic!

Yes, we are prepared!

- We have a great biosafety plan that can be easily modified
- We continually train our employees and clinical partners
- We review literature and learn from past threats
- We can adapt to defend against any emerging or re-emerging public health threat!



References and Resources



- Perkins D, Danskin K, Rowe AE, Livinski AA. The Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences: A Comprehensive Literature Review. *Appl Biosaf*. 2019 Mar 1;24(1):34-45. doi: 10.1177/1535676018778538. Epub 2019 Mar 1. PMID: 36034634; PMCID: PMC9093240.
- Association of Public Health Laboratories “Laboratory Exposure Assessment and Symptom Monitoring Guide”, November 2023 [Laboratory Exposure Assessment Guide \(aphl.org\)](https://aphl.org/~/media/Association-of-Public-Health-Laboratories/2023-11-16-Laboratory-Exposure-Assessment-and-Symptom-Monitoring-Guide-11-16-2023.pdf)

Questions?

