Biological Risk Assessment and Biosafety Considerations in the Laboratory

The science you expect.
The people you know.

What is biosafety?

Containment principles, technologies, and practices that are implemented to prevent unintentional exposure to biological agents or their inadvertent release.

- WHO Laboratory Biosafety Manual, 4th edition

Biosafety’s goal: reduce risk of laboratory-associated infections (LAIs)

- **LAIs** are defined as **all** infections associated with laboratory or laboratory-related activities regardless whether they are symptomatic (you show symptoms) or asymptomatic (you don’t show symptoms)
- 80% from inhalation of infectious aerosols (and droplets); directly or hand contamination
- Aerosols can be generated by any action where energy is applied to a sample!
- Other potential routes of exposure include: puncture with sharp object, contact of broken skin with infected materials, contact with mucous membranes

Foundation of biosafety: risk assessment

Overall goal: reduce the risks associated with a given activity or procedure to a level that the institution and individuals determine is acceptable

The only way to completely eliminate all risks is to not do the work at all!

Risk assessment is a process used to:

- Identify the hazards associated with the material being worked with
- Identify the activities that can result in a person being exposed
- Identify the potential likelihood and outcome of potential exposures

The risk assessment data are used to:

- Determine where work should be performed
- Determine what safety equipment and work practices should be used
- Assess the capabilities of the staff to control the hazards
- Identify additional precautions (including training) to further mitigate risks
- Inform long-term planning (renovations, new construction)

Steps for conducting a risk assessment

Key considerations in the risk assessment

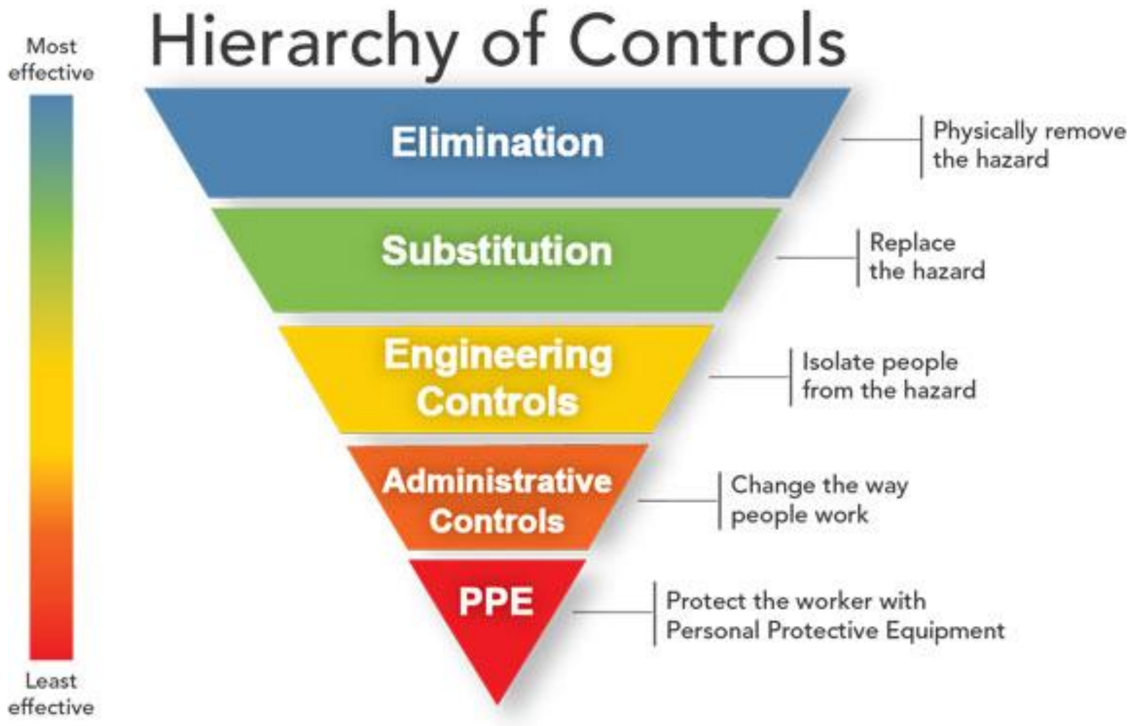
Step	Key considerations
1. Gather information (hazard identification)	• What biological agents will be handled and what are their pathogenic characteristics? • What type of laboratory work and/or procedures will be conducted? • What type(s) of equipment will be used? • What type of laboratory facility is available? • What human factors exist (for example, what is the level of competency of personnel)? • What other factors exist that might affect laboratory operations (for example, legal, cultural, socioeconomic, public perception)?
2. Evaluate the risks	• How could an exposure and/or release occur? • What is the likelihood of an exposure and/or release? • What information gathered influences the <u>likelihood</u> the most? • What are the consequences of an exposure and/or release? • Which information gathered influences the <u>consequences</u> the most? What is the overall initial risk of the activities? • What is the acceptable risk? • Which risks are unacceptable? • Can the unacceptable risks be controlled, or should the work not proceed at all?
3. Develop a risk control strategy	• What resources are available for risk control measures? • What risk control strategies are most applicable for the resources available? • Are resources sufficient to obtain and maintain those risk control measures? • Are proposed control strategies effective, sustainable and achievable in the local context?

Key considerations in the risk assessment

Step	Key considerations
4. Select and implement risk control measures	• Are there any national/international regulations requiring prescribed risk control measures? • What risk control measures are locally available and sustainable? • Are available risk control measures adequately efficient, or should multiple risk control measures be used in combination to enhance efficacy? • Do selected risk control measures align with the risk control strategy? • What is the level of residual risk after risk control measures have been applied and is it now acceptable? • Are additional resources required and available for the implementation of risk control measures? • Are the selected risk control measures compliant with national/international regulations? • Has approval to conduct the work been granted? • Have the risk control strategies been communicated to relevant personnel? • Have necessary items been included in the budget and purchased? • Are operational and maintenance procedures in place? • Have personnel been appropriately trained?
5. Review risks and risk control measures	• Have there been any changes in activities, biological agents, personnel, equipment or facilities? • Is there any new knowledge available of biological agents and/or the processes being used? • Are there any lessons learnt from incident reports and investigations that may indicate improvements to be made? • Has a periodic review cycle been established?

Hierarchy of controls

- Once risks are characterized, mitigation strategies can be determined
- Certain risk mitigation strategies are more effective than others
- During the risk assessment process, it is important to identify which strategies:
  - Are feasible
  - Are cost effective
  - Make effective use of available resources



From: https://www.cdc.gov/niosh/topics/hierarchy/default.html

Hierarchy of controls: elimination and substitution

Elimination

- Hardest level of control for research and diagnostic hazards
  - Bioinformatics and other *in silico* technologies can eliminate some need for *in vitro* and *in vivo* laboratory work
- Rarely, an institution decides not to do the work at all due there being no way to reduce the risks to an acceptable level

Substitution

- Replace hazards with something safer
- For example:
  - Using SYBR green dye instead of ethidium bromide to stain agarose gels for DNA
  - Using molecular methods instead of culture-based methods for detecting and identifying microorganisms
  - Using plasmids instead of whole viruses as positive controls for molecular assays

Hierarchy of controls: engineering controls

- Use of equipment to isolate people (and the environment) from the hazard
  - Laboratory mechanical systems (e.g. filtered laboratory exhaust air)
  - Effluent decontamination systems (primarily high and maximum containment laboratories)
  - Primary containment devices (e.g. biosafety cabinets, chemical fume hoods, containment centrifuges)






Hierarchy of controls: administrative controls

- Change the way people work!
- Often the most cost-effective types of controls to implement
- Requires strong lines of communication between all stakeholders (laboratory staff, support staff, management) to ensure all administrative controls are properly and consistently implemented

Universal precautions

- Always assume a sample is infectious!
- For example, even if a blood sample tests negative for one pathogen of interest, it could still be positive for:
  - Hepatitis C virus
  - Hepatitis B virus
  - Human immunodeficiency virus
  - Malaria
  - *Brucella* species
  - Babesiosis
  - Crimean-Congo hemorrhagic fever virus
  - Rift Valley fever virus
  - *Rickettsia* species

Good safety practices

- Hands must be washed after handling any potentially infectious or other hazardous materials and before leaving laboratory areas
- No mouth pipetting allowed
- No eating, drinking, smoking, applying cosmetics, or handling contact lenses in the laboratory
- No storing human food or drinks in laboratory working areas
- Minimize generation of aerosols during work

Sharps management

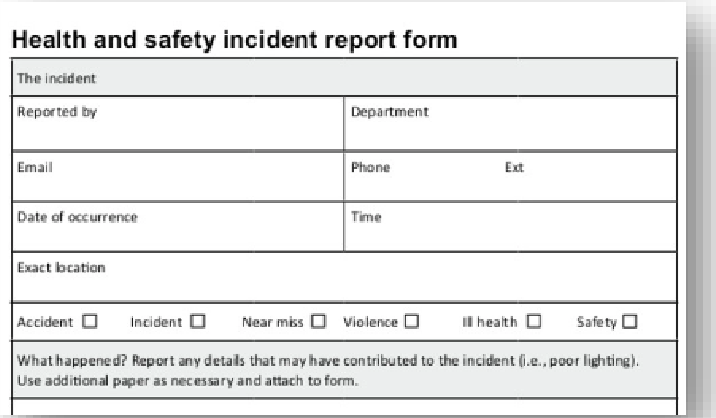
- What are sharps?
  - Anything that can potentially scratch or puncture the skin
  - Examples include needles, capillary tubes, glass slides and coverslips, broken glass, scalpels, scissors
- Dispose of used and broken sharps in a puncture-resistant container
- Do not overfill the container
- Seal and dispose of container and its contents when it is 2/3 full
- Never directly handle broken glass



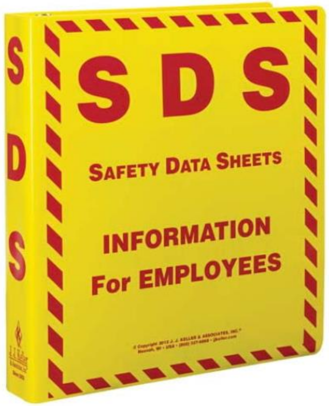



Documents and documentation

- Written procedure developed and followed for the clean-up of all spills
- Safety or operations manual that identifies known and potential hazards, and specifies practices and procedures to eliminate or minimize such hazards
- Safety data sheets for all chemicals in use collected and easily available for reference
- Occurrences, incidents, and accidents reported and documented (including investigations and corrective actions taken)


Health and safety incident report form

The incident	
Reported by	Department
Email	Phone Ext
Date of occurrence	Time
Exact location	
Accident ☐ Incident ☐ Near miss ☐ Violence ☐ Ill health ☐ Safety ☐	
What happened? Report any details that may have contributed to the incident (i.e., poor lighting). Use additional paper as necessary and attach to form.	



Work area management

- Access to laboratory spaces restricted to authorized personnel only (no family, friends, pets)
- Doors kept closed
- Appropriate hazard signage posted on rooms where hazardous materials are stored and used
- Defined workflows to prevent spread of both hazardous material and molecular (genomic) contamination
- Work surfaces decontaminated after any spill of hazardous material and at the end of the work day

Arranging a workspace to improve workflow safety

- Clearly define areas for donning and doffing PPE
- Clearly define areas for separating and collecting different waste types (biohazardous waste, chemical waste, non-hazardous waste)
- Keep work surfaces clean, decontaminated, and free of unnecessary equipment and supplies
- Create separate spaces for “clean” activities such as tube labeling, microscopy, and data analysis/reporting and “dirty” activities such as sample processing and testing.
- Set up work surfaces to allow you to work from “clean” to “dirty”

Decontamination- definitions

- Decontamination: rendering an area, device, item, or material safe to handle
- Disinfection: decontamination that eliminates nearly all recognized pathogenic microorganisms, but not necessarily all microbial forms
  - Spores are not necessarily eliminated
- Sterilization: decontamination that kills all microorganisms (including spores)

All biohazardous waste <u>must</u> be appropriately decontaminated prior to disposal!

"Appropriate" decontamination is based on applicable regulations, institutional policies, and risk assessment.

Common decontamination strategies

	Chemical	Autoclaving	Incineration
What is it?	The disinfection of hazardous substances by liquid chemicals	Sterilization of equipment and other objects by steam and pressure	The destruction of something, especially waste material, by burning
Used for	• Liquid biological waste • Surfaces and spaces • Absorbent materials	• Sharps • Infectious material • Biological waste (solid or liquid)	• Biological waste • Pathological waste • Pharmaceutical waste
Considerations	• Microorganism type, concentration, and susceptibility • Amount of organic matter present • Active concentration • Contact time	• Water availability • Temperature • Pressure • Time	• Temperature • Time • Fuel availability • Completeness of the destruction

Sodium hypochlorite (bleach) facts

- One of the most commonly-used chemical disinfectants
- Caustic—can cause severe skin burns, eye damage
- Corrosive—will damage stainless steel surfaces
- Rapidly degrades in light, heat
- Loses effectiveness in the presence of large amounts of organic matter (blood, feces, etc.)
- Working concentration: 1:100 for general housekeeping, 1:10 for disinfection purposes
- Contact time (length of time a substances is held in direct contact with the treating agent in order for the agent to be effective): ≥10 minutes on nonporous surfaces, ≥20 minutes liquid waste

Solid biohazardous waste

Should be collected in leak-proof containers labeled with the universal biohazard symbol

- Biohazard bag, surgical instrument tray with lid taped shut
- Double-bagging biohazardous waste is preferred if it will be autoclaved or transported long distances
- When hard-sided cans are used, use a biohazard bag to line them

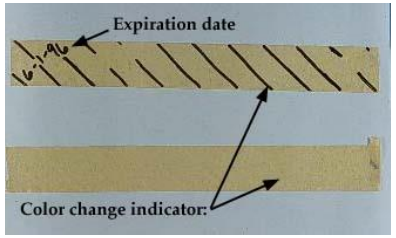
Glassware, plastics, surgical instruments, laboratory coats and other reusable items must be decontaminated prior to washing

Waste intended for disposal should never be compacted

Free-standing waste collection containers should have lids

Autoclave facts

- Effectiveness dependent on steam penetration and the time the material is kept at the appropriate temperature and pressure
- Highly porous or highly dense materials may require special cycles
- High risk of steam- and burn-related injuries—wear appropriate PPE!
  - Eye protection, long-sleeve lab coat, close toed shoes, heat resistant gloves
- Performance needs to be verified routinely
  - Autoclave tape should be used with every run to indicate whether the appropriate temperature was achieved
  - Biological indicators should be used routinely to verify that appropriate temperature and pressure are maintained for the appropriate amount of time

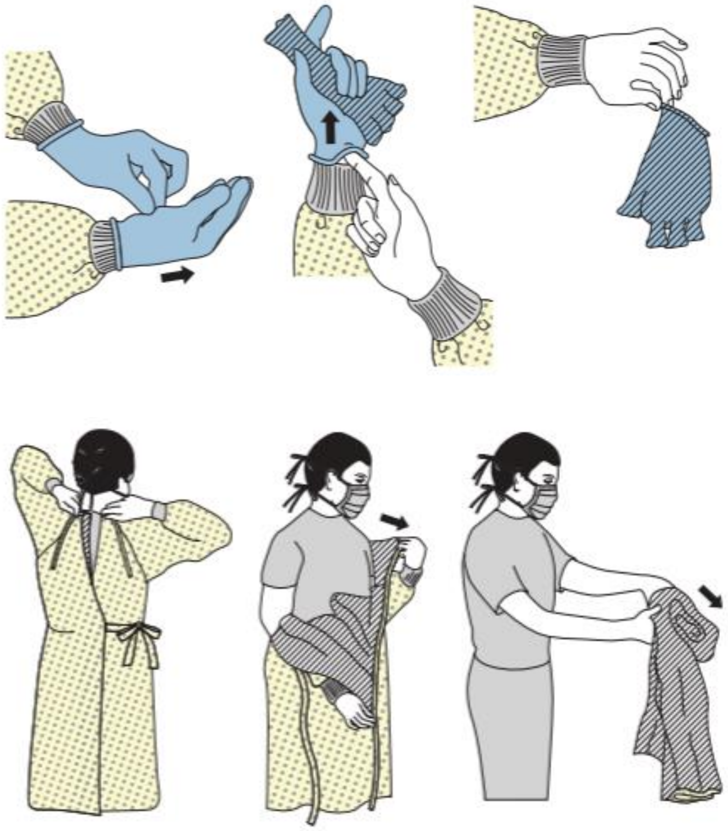


Hierarchy of controls: personal protective equipment (PPE)

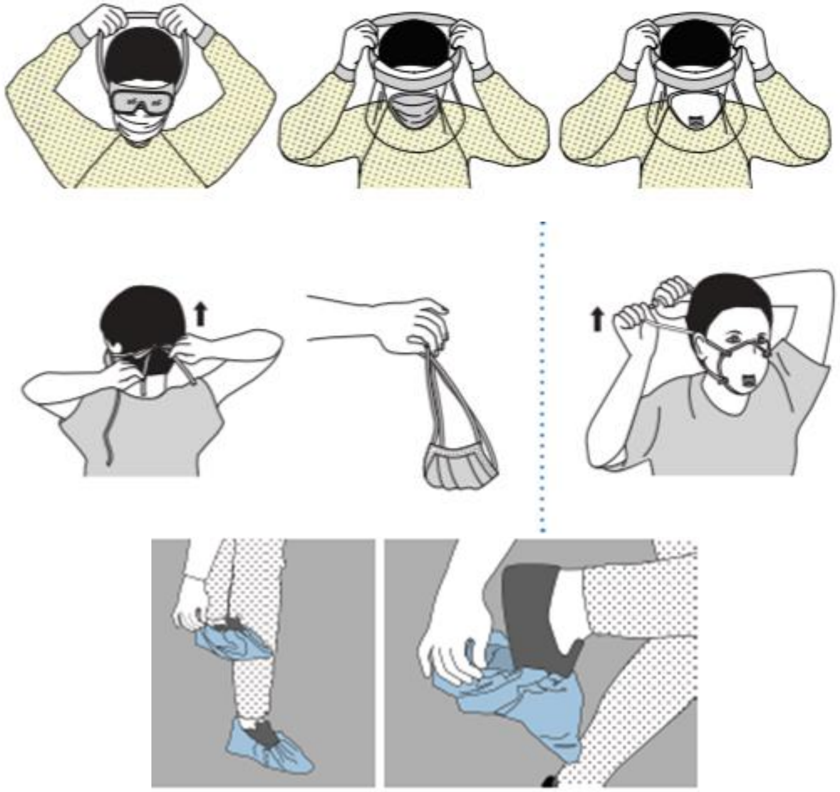
- Selection of PPE should be based on the initial risk assessment!
- Goals:
  - Minimize risk of exposure if there is a splash or spill of hazardous material or if aerosols are generated
  - Prevent transfer of hazardous materials to skin or normal clothing, and spread from there to other individuals or the environment
  - Prevent transfer of molecular or microbial contamination from the worker to the experiment
- Form barrier between the materials being manipulated and the person doing the manipulation
- Proper donning and doffing of all PPE pieces is <u>extremely</u> important for ensuring user safety

Biggest doffing challenge: avoid touching contaminated PPE to bare skin

Touch inner surfaces



Touch rear-facing surfaces



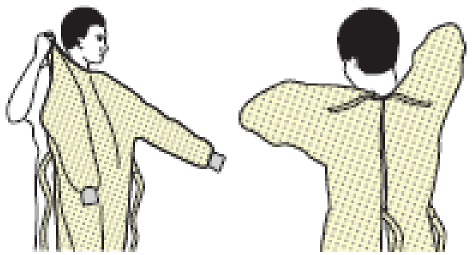
How to don a laboratory coat or gown

Re-usable laboratory coat

- Select appropriate size
- Opening is in the front
- Secure with buttons in front
- Can be re-used but should be disinfected and laundered weekly

Disposable laboratory coat

- Select appropriate size
- Opening may be in the front or the back, depending on risk assessment
- For back closing: secure at neck and waist
- Dispose of when soiled or after each use, depending on risk assessment



Face shield, safety goggles and safety glasses

Face shield

- To be used when splashes or sprays are anticipated
- Should fully cover forehead, eyes, nose, mouth and extend below chin
- Will protect surgical or respirator masks from splashes or sprays

Safety goggles and glasses

- To be used when splashes or sprays are anticipated
- Goggles should be:
  - A snug fit
  - Anti-fogging
- Personal glasses are not a substitute for safety glasses

Masks and respirators

A surgical mask and respirator mask are not the same thing.

- Surgical or other masks are not necessarily respirators
  - Not tight fitting
  - Limited respiratory protection
  - Primarily meant to protect others, not person wearing the mask
  - Have not been NIOSH or EC tested or provided a rating
- Surgical Mask: protects sample
- Respirator Mask (e.g. N95, EN FFP2, cartridge-based negative pressure system): protects user and sample
- Powered Air Purifying Respirator (PAPR): protects user and sample
- When possible, personnel should undergo a fit test to verify that the respirator mask fits properly

Fit check- respirator mask

- Negative pressure test
  - Cup hands over mask
  - Inhale normally
  - Respirator should collapse slightly
  - Air should not flow in around edge of mask
- Positive pressure test
  - Cup hands over mask
  - Exhale normally
  - Respirator should expand slightly
  - Air should not leak out around edge of mask

How to don a surgical or respirator mask

- Surgical Mask

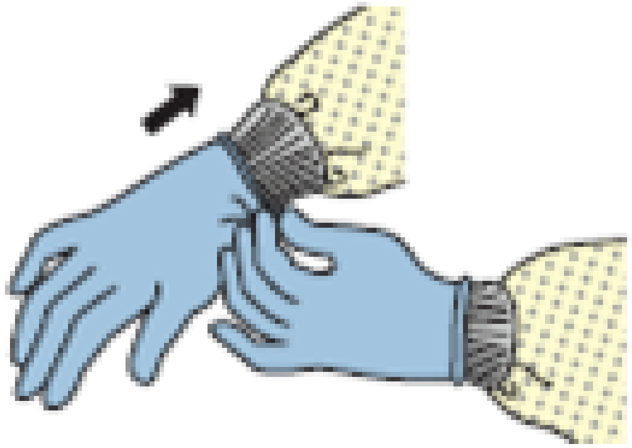
- Respirator Mask

Gloves

Glove types	**Single-use gloves** • Retain touch sensitivity and dexterity • Poor resistance to physical hazards, some chemical hazards- not recommended for manual labor • NEVER RE-USE	**Re-usable gloves** • Limited touch sensitivity and dexterity- not recommended for laboratory work • Improved resistance to physical and chemical hazards • Must decontaminate and inspect for damage prior to re-use
Single-use glove materials	**Latex gloves** • Good for biohazard protection • Difficult to detect puncture holes • Can cause or trigger latex allergies	**Nitrile gloves** • Good for biohazard protection • Clear indication of tears or breaks • Minimal to no allergy risk

Donning gloves

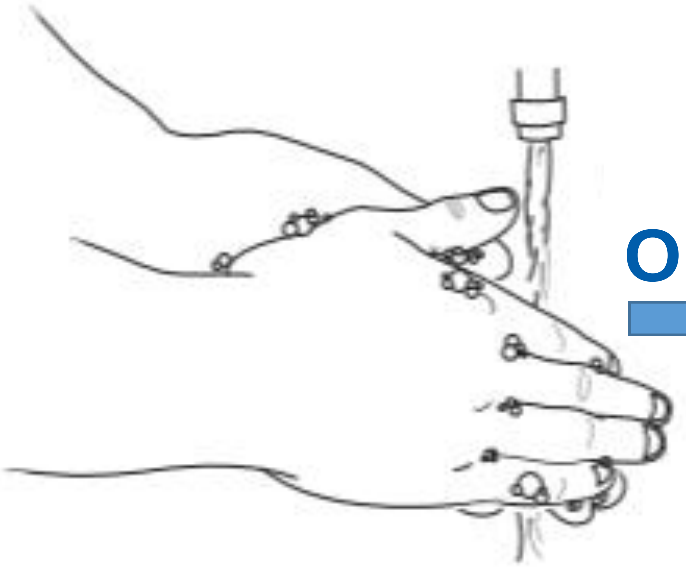
1. Insert hands into gloves
2. Pull cuff over gown (if using a cuffed lab coat or gown)
3. Secure cuff to gown or coat with masking tape or duct tape if necessary
4. Don second pair of gloves if recommended by risk assessment



Gloves should be the last PPE item donned and the first PPE item doffed.

After removing PPE

ALWAYS



OR

Incident and emergency response

Do you and your colleagues know what to do:

- For a biohazardous spill inside a biosafety cabinet?
- For a biohazardous spill outside a biosafety cabinet?
- For a potential exposure event (needlestick, splash)?
- For a chemical spill?
- For a fire?

Your risk assessments can help you identify the most likely incident types

- Plan for them!
- Prepare for them!
- Practice your plans!
- Refine your plans!

Biological spill kits

- Biological Spill Kits
  - Easy to assemble one for each laboratory
  - Immediate access to lab staff
  - Everything available in one container
  - Determine before work begins with agent which chemical disinfectant(s) are effective and which absorbent materials are compatible with the chemicals(s) that may become biologically contaminated.
    - Also, can materials contaminated by the chemicals can be autoclaved?

Spill response procedures

Notification	Spill Containment	Response Planning	Clean-up	Reporting
1.Warn others not to enter contaminated area 2.Have someone: -Post spill sign -Notify the Director and the Safety Office 3.Move away from spill site 4.Remove any contaminated clothing 5.Exit the laboratory	1.Avoid inhalation 2.Allow aerosols to settle 3.Contain spill 4.Create barrier and cover spill with paper towels	1.Plan the spill cleanup strategy 2.Locate appropriate spill kit 3.Prepare materials	1.Wear appropriate PPE 2.Gently pour proper disinfectant solution on towels until soaked 3.Start at edge and move toward center 4.Do not allow solution to spread beyond the paper towels 5.Allow 15 minutes of contact time, or up to 20 for larger volumes. 6.Clean surrounding work surfaces, equipment and floor where material may have splashed	Report incident to proper supervisor and fill out appropriate documentation (e.g. incident report)

Safety equipment

- Do you know what you have?
- Do you know how works?
- Do you know when to use it?


Summary

- The risk assessment process forms the foundation for how we approach biosafety
- The hierarchy of controls are used to mitigate the risks identified as part of the risk assessment
- Administrative controls, in particular, can be a cost-effective way to mitigate a wide variety of risks
- Plans should be developed, practiced, and refined for a wide range of possible incidents and emergencies so that personnel can respond automatically, if and when, an incident occurs

Thank you for your attention!

Any additional questions?

Image References

- Slide 8, Hierarchy of controls: https://www.cdc.gov/niosh/topics/hierarchy/default.html
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