Biological Safety Guidelines for the Sentinel Laboratory

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Laboratory Director
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Training Objectives

- **At the end of the training, participants will be able to:**
  - Discuss the importance of biosafety in the clinical laboratory.
  - Describe the risk of Laboratory Acquired Infections (LAIs).
  - Perform a risk assessment in the clinical microbiology laboratory.
  - Define the four biosafety levels.
  - Explain best practices for work practice controls
  - Describe biosafety concerns when using microbial identification systems for high-risk pathogen identification.

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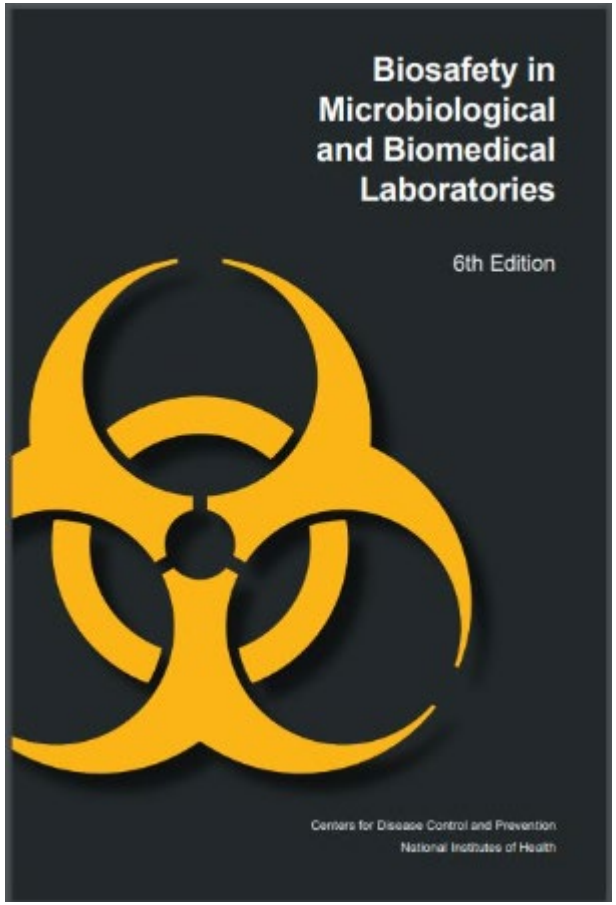
BMBL 6th Edition

- SECTION I: Introduction
- SECTION II: Biological Risk Assessment
- SECTION III: Principles of Biosafety
- SECTION IV: Laboratory Biosafety Criteria
- SECTION V: Vertebrate Animal Biosafety Level Criteria for Vivarium Research Facilities
- SECTION VI: Principles of Laboratory Biosecurity
- SECTION VII: Occupational Health Support for Biomedical Research
- SECTION VIII A-H: Agent Summary Statements



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ASM Resource

Interim Clinical Laboratory Guideline for Biological Safety

The American Society for Microbiology

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What is Biosafety?

- **The discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.**
- **Two Main Components:**

  - **Risk Assessment**: determine the hazards, likelihood exposure would cause an infection, and the consequences of infection from exposure

  - **Containment**: The combination of microbiological practices, safety equipment and facility safeguards to protect laboratory workers, the environment , and the public from exposure to infectious microorganisms that are present in the laboratory.

Laboratory Acquired Infections

- Approximately 500,000 US laboratorians work with or handle infectious materials and/or cultures every day.
- Occurs from working in a laboratory or doing laboratory-related activities.
- Can be caused by bacteria, viruses, fungi, and parasites.
- Can be symptomatic or asymptomatic
- Not reportable, so the actual number is unknown
- ABSA LAI Database: https://my.absa.org/LAI

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Date(s) of LAI / exposure: **January, 2021**	Location where LAI / exposure occurred: **Phoenix, Arizona, USA**
Occupation(s) of affected personnel: **clinical laboratorian**	Age(s) of affected personnel: **unknown**
Agent(s) involved: **Burkholderia psuedomallei** find in Risk Group Database > (NOTE: you may have to edit search to be more specific)	

ABSA LAI Database

Biological Safety Level (BSL) for work being performed?: **BSL-2**	Setting in which LAI / exposure occured: **clinical laboratory**
Device or equipment involved: **open benchtop plate culture, MALDI-TOF mass spectrometer**	Procedure being performed: **examination of culture plates, MALDI-TOF mass spectrometry**

How LAI / exposure occurred: **A clinical isolate was being identified. A variety of tests were performed, but due to some inconsistent results, Burkholderia was not suspected. After another lab confirmed the identity, exposed staff were identified.**

PPE worn at the time of LAI / exposure: **Not described,**

Engineering controls used at the time of the LAI / exposure: **Unknown**

Follow-up procedures taken: **After confirmation of the culture identity, staff that were at risk for exposure were identified. Thirty possible exposures were identified, and narrowed down to two low-risk and one high-risk.**

Actions that may have been taken to prevent exposure: **unknown**

Post-exposure prophylaxis provided: **PEP (course of antibiotics) was offered to the three at-risk employees.**

Agency(ies) LAI / exposure reported to: **The institution where the incident occurred, Federal government agency (e.g., CDC, OSHA),**

References
Speiser LJ, Graf EH, Seville M, et al. Burkholderia pseudomallei Laboratory Exposure, Arizona, USA. Emerging Infectious Diseases. 2023;29(5):1061-1063. doi:10.3201/eid2905.221865.

ABSA Risk Group Database

Bacteria

Genus	Species
Burkholderia	**mallei**

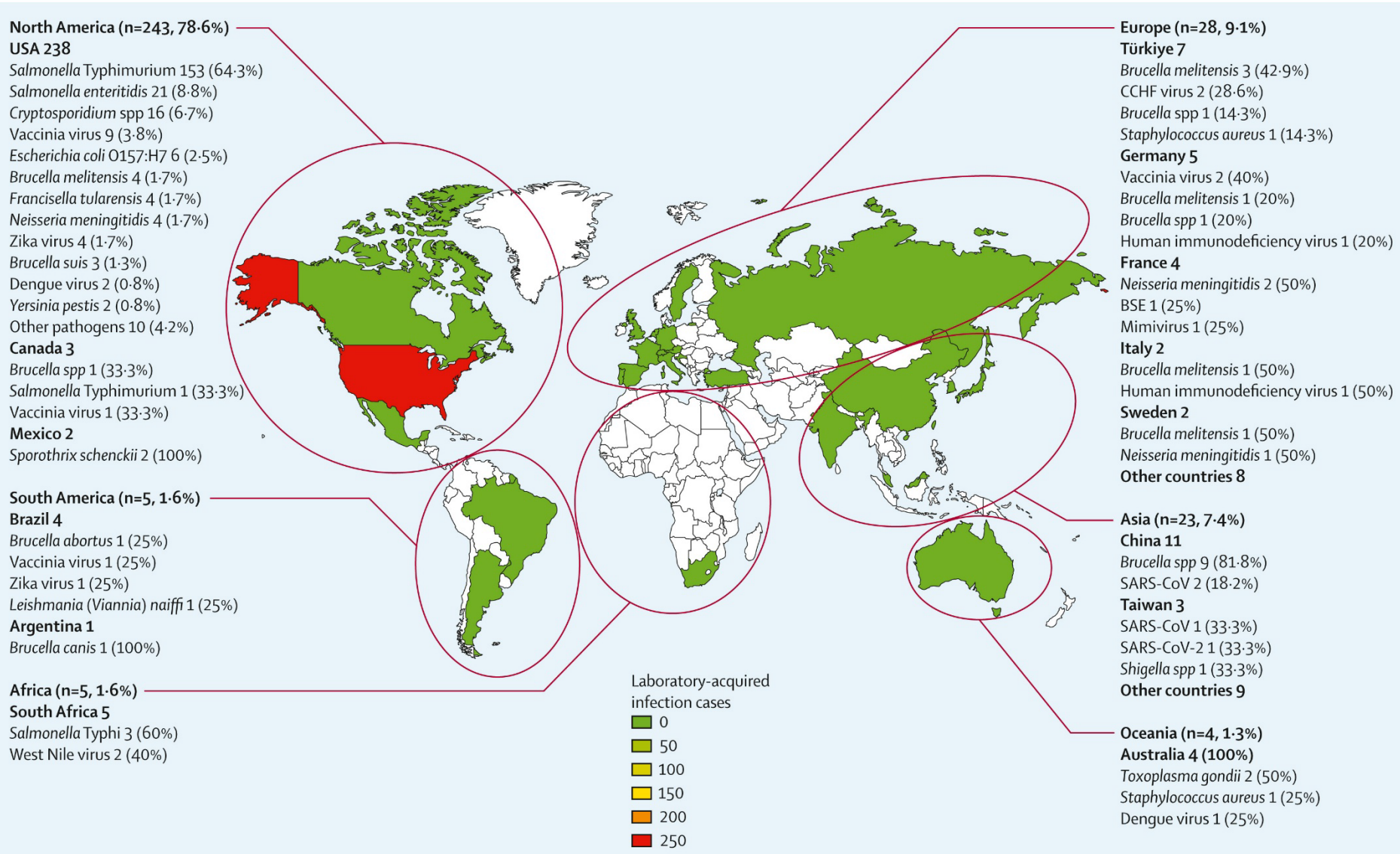
NIH (2024): 3
notes: Pseudomonas mallei
BMBL (2019)*: 3
Belgium (2008): 3
Canada ePATHogen: 3
notes: Biosafety level 3 practices and containment for activities utilizing infectious body fluids, tissues and cultures; Agriculture Canada may impose additional requirements or restrictions on the use of this agent.
Canada PSDS: https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment/burkholderia-pseudomonas-mallei-material-safety-data-sheets-msds.html
EU (2000): 3
notes: Pseudomonas mallei
Germany (2024): 3
notes: Z
Singapore: 3
notes:
Singapor Schedule: First Schedule Part II
UK (2023): 3
Human Pathogen: y **Animal Pathogen:** y **Plant Pathogen:** n
Select Agent CDC: y **Select Agent USDA:** y

What's the risk?

Laboratory-acquired infections and pathogen escapes worldwide between 2000 and 2021: a scoping review

- Recent review article of 94 reports detailing 309 LAIs
  - Bacteria, viruses, parasites, fungal, prion
  - The majority of the reports from the USA (n=39, 41.5%)

	N cases	N fatalities†
Bacteria		
Salmonella Typhimurium	154 (49·8%)	1 (12·5%)
Salmonella enteritidis	21 (6·8%)	
Brucella spp*	12 (3·9%)	
Brucella melitensis	11 (3·6%)	
Neisseria meningitidis	7 (2·3%)	3 (37·5%)
Escherichia coli O157:H7	6 (1·9%)	


North America (n=243, 78·6%)
USA 238
Salmonella Typhimurium 153 (64·3%)
Salmonella enteritidis 21 (8·8%)
Cryptosporidium spp 16 (6·7%)
Vaccinia virus 9 (3·8%)
Escherichia coli O157:H7 6 (2·5%)
Brucella melitensis 4 (1·7%)
Francisella tularensis 4 (1·7%)
Neisseria meningitidis 4 (1·7%)
Zika virus 4 (1·7%)
Brucella suis 3 (1·3%)
Dengue virus 2 (0·8%)
Yersinia pestis 2 (0·8%)
Other pathogens 10 (4·2%)
Canada 3
Brucella spp 1 (33·3%)
Salmonella Typhimurium 1 (33·3%)
Vaccinia virus 1 (33·3%)
Mexico 2
Sporothrix schenckii 2 (100%)
South America (n=5, 1·6%)
Brazil 4
Brucella abortus 1 (25%)
Vaccinia virus 1 (25%)
Zika virus 1 (25%)
Leishmania (Viannia) naiffi 1 (25%)
Argentina 1
Brucella canis 1 (100%)
Africa (n=5, 1·6%)
South Africa 5
Salmonella Typhi 3 (60%)
West Nile virus 2 (40%)
Europe (n=28, 9·1%)
Türkiye 7
Brucella melitensis 3 (42·9%)
CCHF virus 2 (28·6%)
Brucella spp 1 (14·3%)
Staphylococcus aureus 1 (14·3%)
Germany 5
Vaccinia virus 2 (40%)
Brucella melitensis 1 (20%)
Brucella spp 1 (20%)
Human immunodeficiency virus 1 (20%)
France 4
Neisseria meningitidis 2 (50%)
BSE 1 (25%)
Mimivirus 1 (25%)
Italy 2
Brucella melitensis 1 (50%)
Human immunodeficiency virus 1 (50%)
Sweden 2
Brucella melitensis 1 (50%)
Neisseria meningitidis 1 (50%)
Other countries 8
Asia (n=23, 7·4%)
China 11
Brucella spp 9 (81·8%)
SARS-CoV 2 (18·2%)
Taiwan 3
SARS-CoV 1 (33·3%)
SARS-CoV-2 1 (33·3%)
Shigella spp 1 (33·3%)
Other countries 9
Oceania (n=4, 1·3%)
Australia 4 (100%)
Toxoplasma gondii 2 (50%)
Staphylococcus aureus 1 (25%)
Dengue virus 1 (25%)
Laboratory-acquired infection cases
0
50
100
150
200
250

Most common findings:

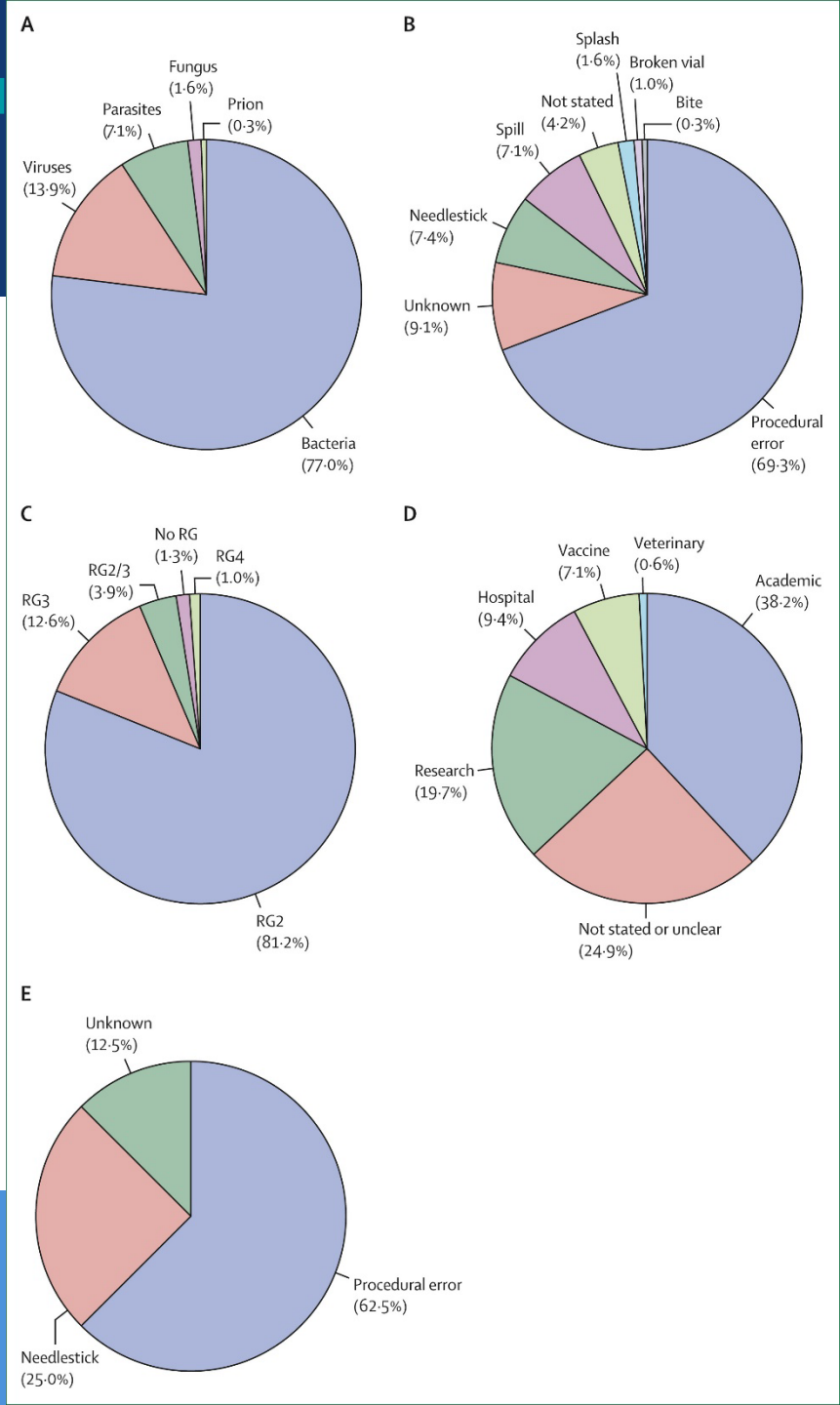
A. Pathogen type: Bacteria

B. Incident Cause: Procedural error

C. Pathogen-risk group: RG2

D. Type of lab: Academic

E. Incident cause resulting in a fatal LAI case: Procedural error



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Laboratory Challenges

- High workload and high stress environment
- Unfamiliar with agent (not endemic)
- Lack of time for training
- Limited staff
- Assumption that BSC and PPE are 100% effective
- PPE usage not always enforced
- Work conducted on open bench before risk was known
- Insufficient biosafety cabinet space
- Lack of time and/or resources
- Others?

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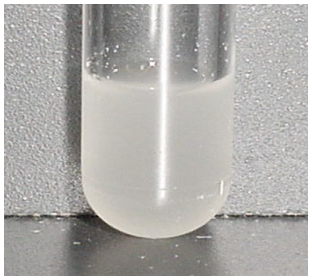
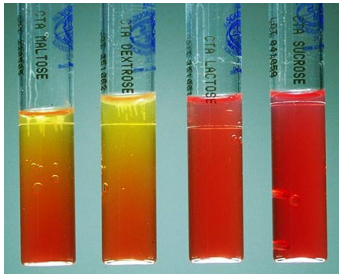
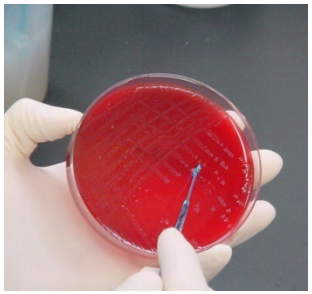
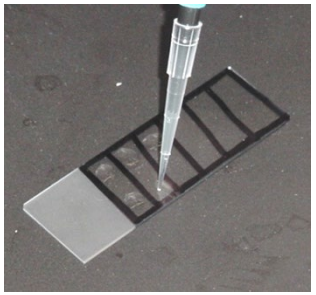
Examples of High Risk Activities

- Sniffing plates?
- Generating aerosols-anything that imparts energy to a suspension
- Subculturing, picking colonies
- Centrifuging /vortexing
- Making slides
- Inoculating biochemicals
- Not using or improper use of BSC









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Laboratory Risk Assessments

A process that identifies potential hazards in a lab and determines how to reduce or eliminate those risks.

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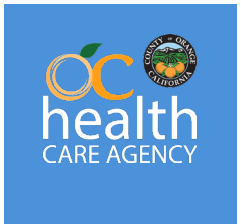
When to perform a risk assessment?

- When bringing a new assay or test process on board
- When a new instrument is placed
- When new laboratory staff begin working
- When a new threat or hazard is identified (i.e. novel influenza virus)
- The Risk Assessment is a continual process that must be periodically reviewed and evaluated
  - Unusual event, incidents or accidents



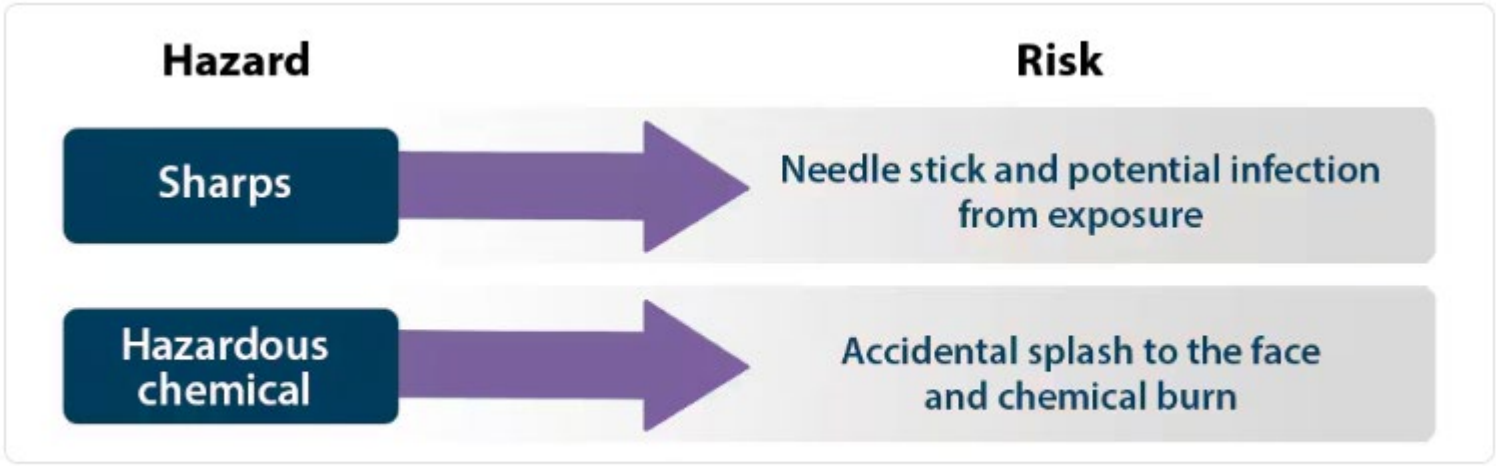
Who should perform the RA?

- **(CLIA) regulations state that the laboratory director must:**
  - Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards.
- **However – laboratory safety is a team effort!**
- **A quality RA depends on the knowledge and expertise of the laboratory staff, infection prevention, and safety professionals**

Laboratory Risk Assessment

Step 1 - Identify the hazards and risks

1. Identification of hazards
   a) Risk Group Classification (next slide)
   b) Routes of infection, infective form and dose
   c) Procedural factors: use of sharps, aerosol generation
   d) Mechanical Hazards: centrifuge, pipettes, BSCs
   e) Personnel Assessment – competency, experience, vaccination history

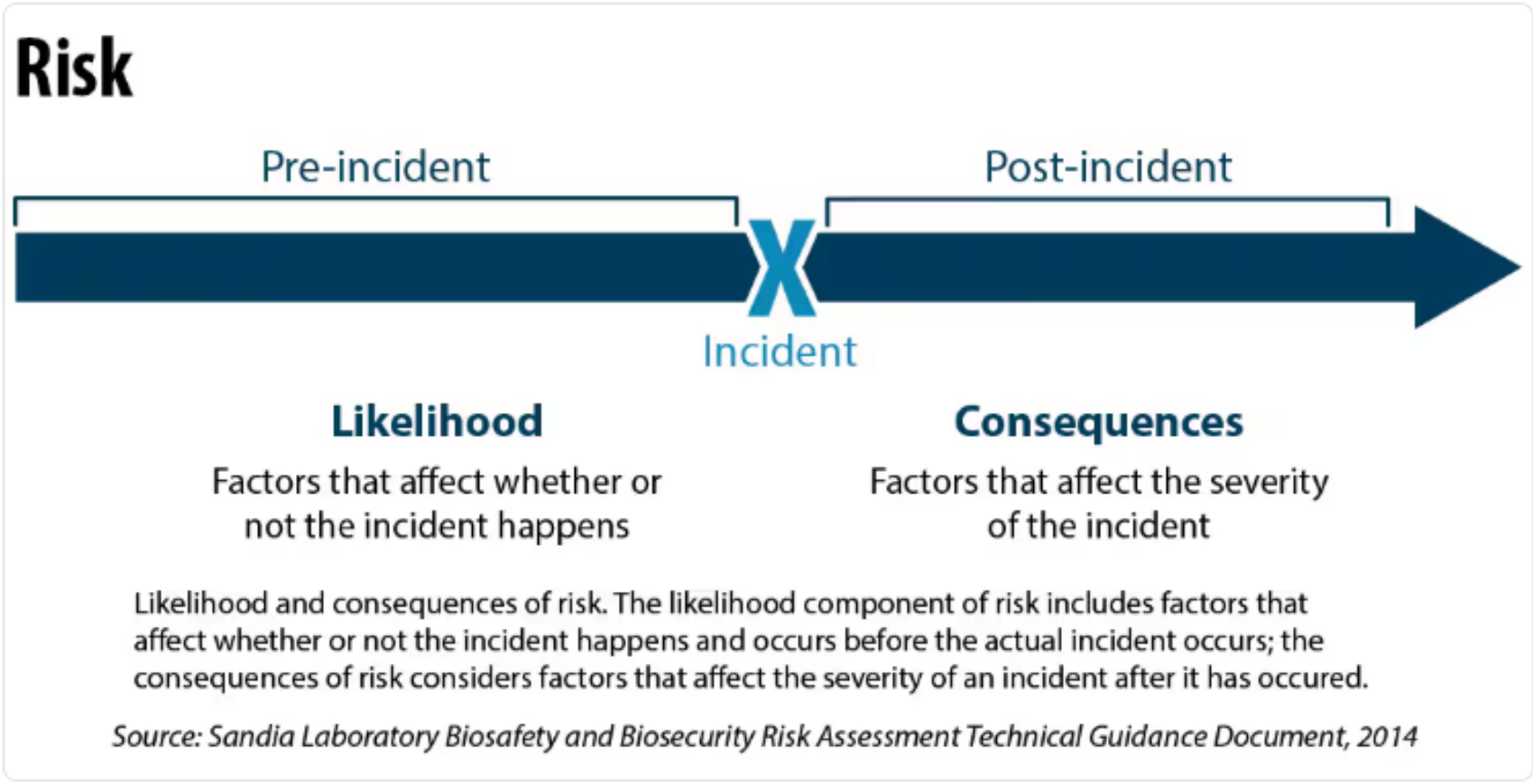


Hazard and Risk Examples in Laboratory Settings.

Risk Group Classification (WHO)

Risk Group	Definition	Examples
1	biological agents not associated with disease in healthy humans	*E. coli* K-12, *S. cerevisiae* (yeast), *Lactobacillus, B. subtilis*
2	agents that cause disease in humans, but pose only minimal or moderate risks of transmission or disease in laboratory workers	*Salmonella typhimurium, Pseudomonas aeruginosa, Pathogenic E.coli*, Respiratory syncytial virus (RSV)
3	easily transmitted within the laboratory and are capable of causing serious disease in humans, but for which effective therapies are available, following exposure or for treatment of infections	*Yersinia pestis*, HIV, SARS virus, *Francisella tularensis*, Hantavirus, West Nile virus
4	cause severe disease in humans and are easily transmissible, but unlike some RG-3 organisms, effective prophylactics and	Ebola virus, Marburg virus, Lassa virus

Step 2 – Evaluate the Risks



Likelihood and consequences of risk. The likelihood component of risk includes factors that affect whether or not the incident happens and occurs before the actual incident occurs; the consequences of risk considers factors that affect the severity of an incident after it has occured.

Source: Sandia Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document, 2014

Pre-Incident and Post-Incident Risk Factors Diagram.

Source: Sandia National Laboratory Biosafety and Biosecurity Risk Assessment Technical Guidance Document, 2014

Step 2 – Evaluate the Risks

- **Characterize the risks: Likelihood and consequences**
- **Likelihood of risk**
  - Biological agent factors
  - Laboratory/testing environment factors
  - Human factors
- **Consequences of risk**
  - Biological agent factors
  - Administrative controls
  - Host factors
- **Prioritize the risks and determine if risks are acceptable**

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Risk Matrix - Example

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

- Low Risk hazard – may require no mitigation steps
- High Risk hazard – will require mitigation steps
- Extreme Risk hazard – will require significant control measures or alternate procedure

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Steps 3-4: Implement a risk mitigation plan

https://www.osha.gov/safety-management/hazard-prevention

- Risk mitigation strategies
  - Elimination of the hazard – may not be possible
  - Substitution of the hazard - Using plastic instead of glass
  - Engineering controls - Using sealed centrifuge rotors
  - Administrative controls - Ensuring staff are appropriately trained and strictly adhering to the SOPs
  - Incorporating PPE – last resort
- Implement control measures
  - Control plan should be documented and clearly communicated with laboratory staff
  - Ensure that staff follow SOPs, including safety procedures
  - Ensure that proper PPE is available and used correctly

Step 5: Evaluate effectiveness of controls

- Review the risk assessment
  - Review the overall process
  - Determine the effectiveness of the implemented controls
  - If necessary, modify risk mitigation strategies
- Continuous process that must be routinely reviewed
- Especially following incidents, accidents or illness
- With any changes to the procedure
  - New equipment, new reagent

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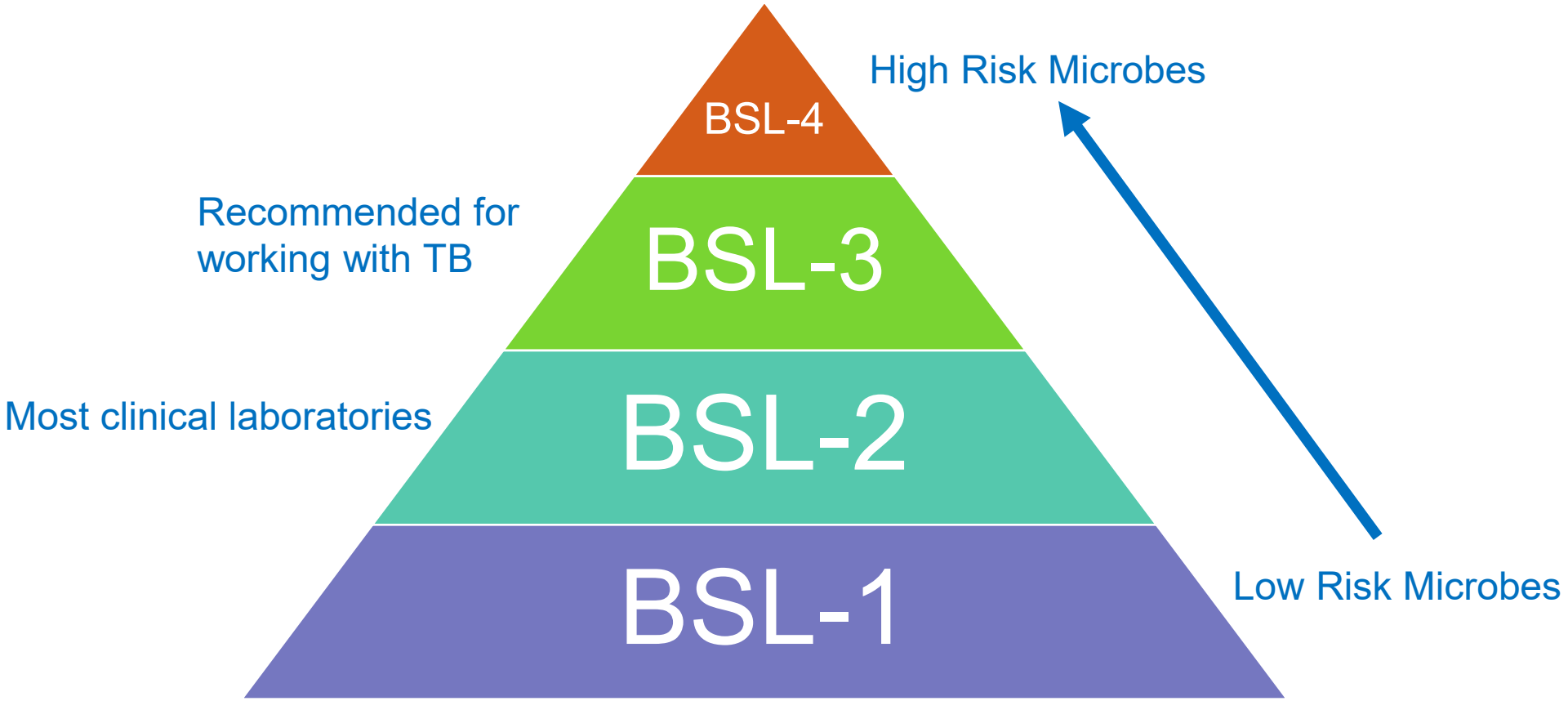
Laboratory Biosafety Levels



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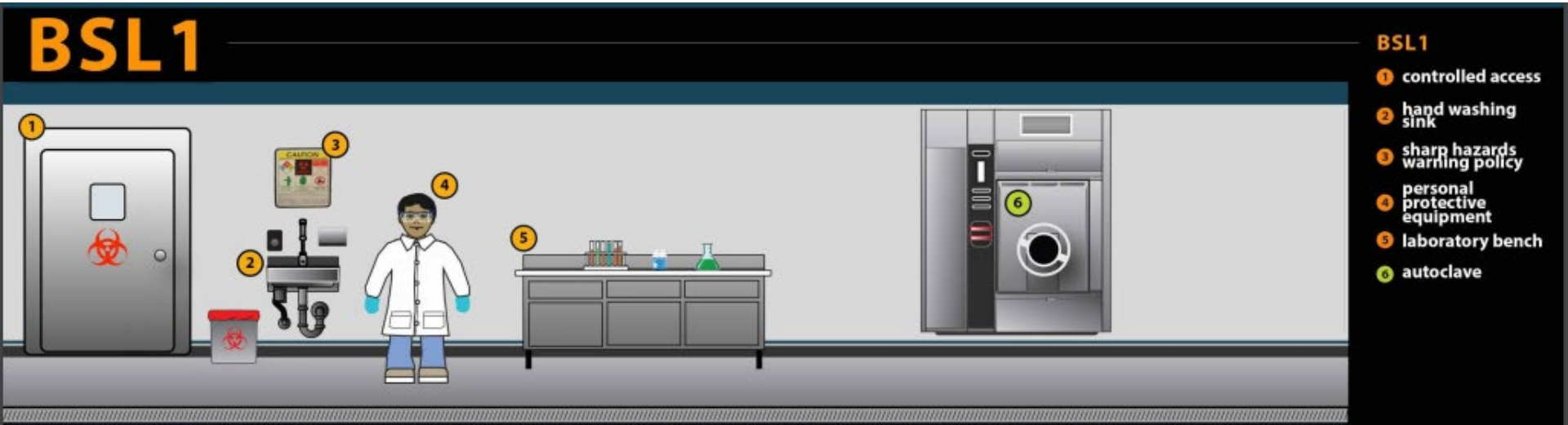
Standard Microbiological Work Practices – All levels

- Limited access (doors to control access)
- No mouth or eye contact
- Wash hands (sinks available for handwashing)
- Sharps handling
- Limit or contain aerosols
- Training in procedures and biosafety
- No eating, drinking, handling contact lenses, applying cosmetics or storing food
- Decontaminate work surfaces after spill or completion of work
  - all laboratory work surfaces, chairs, and floors must be made of or lined with non-porous, non-absorbent materials that are resistant to chemical and physical agents
- Decontaminate potentially infectious materials before disposal
- Universal biohazard symbol at lab entry
- Pest management program
- No animals or plants in the lab

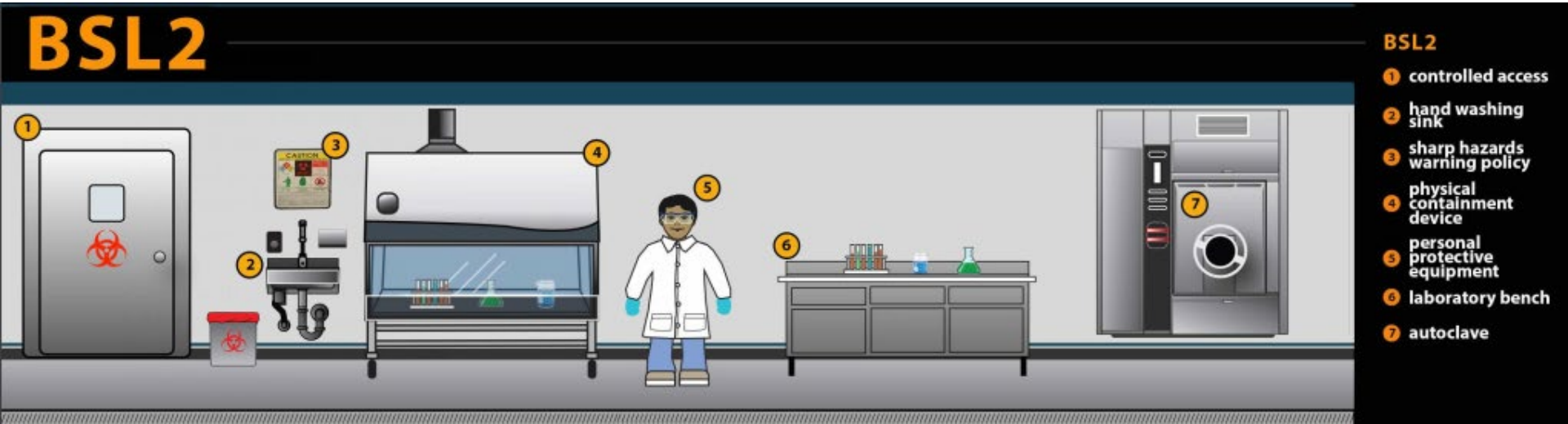
Biosafety Level - 1

- Work with microorganisms that are not known to consistently cause disease in healthy adult humans and that pose minimal risks to laboratory personnel and the outside environment
- Manipulations of microorganisms in BSL-1 laboratories can be safely performed on the open bench top – think university biology lab
- https://www.cdc.gov/cpr/infographics/00_docs/biosafety.pdf



Biosafety Level - 2

- Manipulations of microorganisms that pose a moderate risk to laboratory staff and to the outside environment
- Many manipulations of microorganisms in BSL-2 laboratories can be safely performed on the open bench top.
  - examination of routine bacteriological cultures derived from clinical specimens
- All procedures that are likely to create aerosols or splashes of infectious material must be conducted using appropriate engineering controls.



Biosafety Level – 2

BSL-1, PLUS:

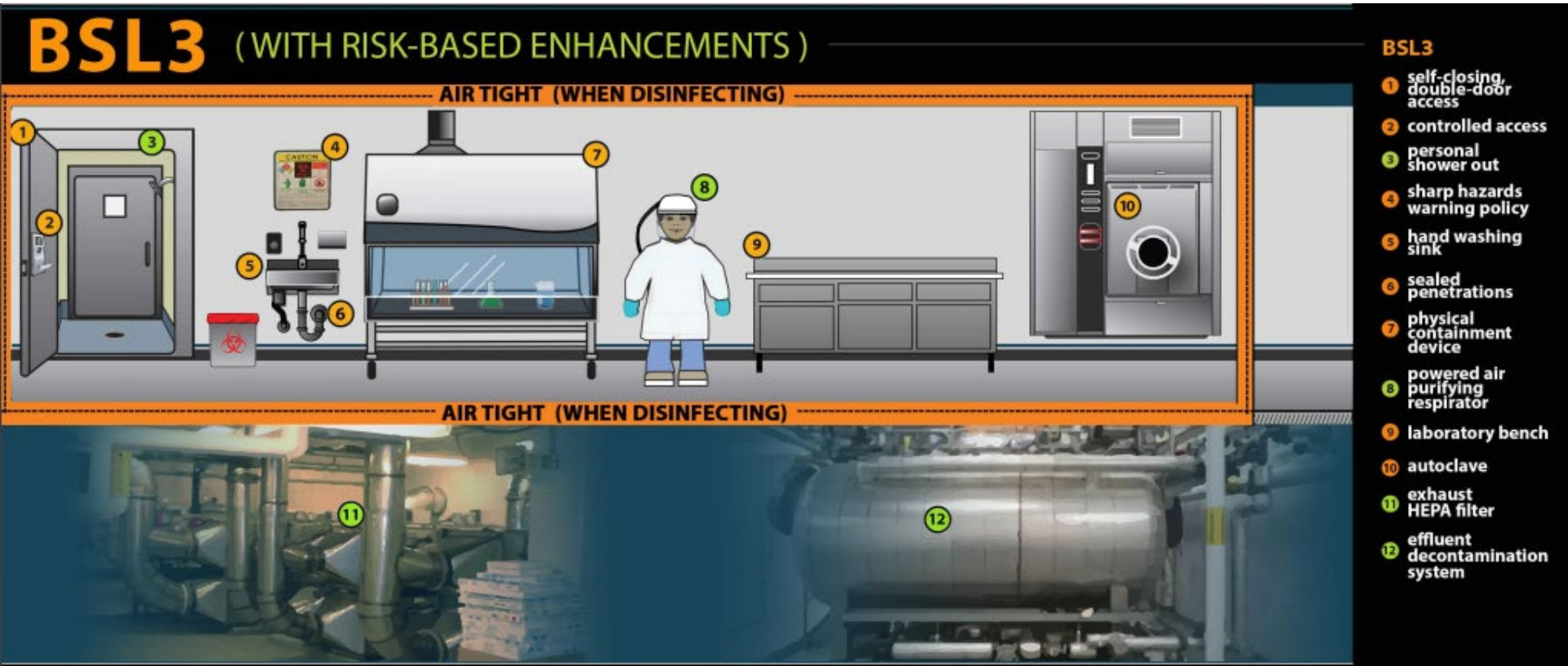
- A manual outlining biosafety policies and practices:
  - spill cleanup
  - emergency response
  - post-exposure follow-up measures
- Biohazard signs must be posted at all laboratory entrance points
- Biohazard labels must be affixed to all biomedical waste containers, incubators, refrigerators, freezers, centrifuges, and other devices or containers used for the storage, propagation, manipulation, and/or disposal of infectious materials.
- Biological safety cabinets (BSCs), splash shields, and other physical containment devices must be available for the manipulation of infectious agents when procedures likely to generate aerosols and splashes are conducted.
- Filtered exhaust air from BSCs can either be recirculated into the laboratory space or can be vented into dedicated plenums.

Biosafety Level – 2

- Competency and proficiency assessments of employees engaged in work with infectious materials, including clinical specimens, must be periodically performed.
- Eyewashes must be available throughout the laboratory.
- Laboratories must provide appropriate medical surveillance (e.g., tuberculin skin testing) and offer vaccinations against agents for which vaccines are available (e.g., hepatitis B virus, *Neisseria meningitidis*, etc.).
- Vacuum lines connected to aspirators must be protected with in-line high-efficiency particulate air/arrestance (HEPA) filters and liquid disinfectant traps to minimize the risk of house-vacuum or dedicated pump contamination.

Biosafety Level - 3

- For manipulations of indigenous and exotic infectious agents that pose a serious risk to laboratory personnel and to the outside environment.



Biosafety Level - 3

- The agents worked with at BSL-3 are well-established pathogens that **cause serious and often debilitating or fatal diseases**.
- Many of the agents can be transmitted to personnel through **inhalation**, so facility and PPE enhancements are required to mitigate the risks of LAI.
- For some agents, effective therapies and vaccinations are available, but for the vast majority, no specific treatments or prophylactics are available.
- Agents requiring BSL-3 containment include numerous bacteria, fungi, and viruses, including many select agents;

Biosafety Level - 3

BSL-2 PLUS:

- Lockable, self-closing doors between BSL-3, anteroom and outside areas
- Sealing of floors, walls, and ceilings to create a single, seamless surface. Windows must be sealed.
- Laboratory floors, walls, and ceilings must be constructed of smooth, non-absorbent materials that are easily cleaned and decontaminated.
- Unidirectional, single-pass airflow that travels from areas of low risk to areas where high-risk work is performed.
- Negative air pressure is maintained within BSL-3 laboratories and associated anterooms or staging areas by way of dedicated ventilation units that draw air from workspaces through a HEPA filter prior to discharge into the atmosphere.
  - Must be monitored by, at minimum, visual air pressure indicators.

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Biosafety Level - 3

BSL-2 PLUS:

- All procedures must be within a Class II or Class III BSCs: no work with infectious agents is permitted on the open bench.
- Personnel must be thoroughly trained in BSL-3 work practices and must undergo periodic competency and performance assessments.
- Personnel must wear solid-front gowns, smocks, or jumpsuits.
- All wastes should be decontaminated prior to removal from the containment space.
- All facility safety features, including air-handling systems, autoclaves, and BSCs, must be certified/verified prior to opening of a BSL-3 laboratory and re-certification must occur at least annually thereafter.

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Table 1. Summary of Laboratory Biosafety Levels (BSLs)

BSL	Agents	Special Practices[a]	Primary Barrier and Personal Protective Equipment[a]	Facilities (Secondary Barriers)[a]
1	Well-characterized agents not known to consistently cause disease in immunocompetent adult humans and present minimal potential hazard to laboratory personnel and the environment.	Standard microbiological practices	No primary barriers required; protective laboratory clothing; protective face, eyewear, as needed	Laboratory doors; sink for handwashing; laboratory bench; windows fitted with screens; lighting adequate for all activities
2	Agents associated with human disease and pose moderate hazards to personnel and the environment	Limited access; occupational medical services including medical evaluation, surveillance, and treatment, as appropriate; all procedures that may generate an aerosol or splash conducted in a BSC; decontamination process needed for laboratory equipment	BSCs or other primary containment device used for manipulations of agents that may cause splashes or aerosols; protective laboratory clothing; other PPE, including respiratory protection, as needed	Self-closing doors; sink located near exit; windows sealed or fitted with screens; autoclave available
3	Indigenous or exotic agents; may cause serious or potentially lethal disease through the inhalation route of exposure	Access limited to those with need to enter; viable material removed from laboratory in primary and secondary containers; opened only in BSL-3 or ABSL-3 laboratories; all procedures with infectious materials performed in a BSC	BSCs for all procedures with viable agents; solid front gowns, scrubs, or coveralls; two pairs of gloves, when appropriate; protective eyewear, respiratory protection, as needed	Physical separation from access corridors; access through two consecutive self-closing doors; hands-free sink near exit; windows are sealed; ducted air ventilation system with negative airflow into laboratory; autoclave available, preferably in laboratory

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Biosafety Level - 4

- These maximum biocontainment, laboratories are reserved for work involving pathogens that are readily transmissible to laboratory personnel, pose significant public health threats if released into the outside environment, and cause serious and often life-threatening diseases in those they infect.
- To date, all known agents requiring BSL-4 containment are viruses.

Work Practice Controls

Engineering Controls

- Defined by CDC as devices that protect laboratory staff by reducing hazardous conditions or by placing a barrier between the worker and the hazard.
- They include:
  - Air pressure-resistant doors;
  - Autoclaves;
  - Aerosol-containment (sealed) lids on centrifuge buckets and/or rotors
  - BSCs
  - Chemical fume hoods and benchtop fume extractors
  - High-efficiency air(or particulate arrestance) filters
  - Laboratory access control systems
  - Laboratory anterooms
  - Puncture-resistant sharps containers
  - Sharps safety devices (e.g., integrated needle sheathing devices)
  - Splash shields

Biosafety Cabinets

- **A ventilated cabinet for personnel, product, and environmental protection.**
  - Open front with inward airflow personnel protection,
  - Downward HEPA filtered laminar airflow for product protection,
  - HEPA filtered exhausted air for environmental protection
- **Certified as least annually**
- **Location:**
  - Isolated from other work areas and high traffic areas
  - Away from lab HVAC exhaust and supply vents
  - Away from laboratory entry doors
  - 12-14” away from ceiling and walls

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BSC Best Practices

- Keep equipment and supplies to a minimum. Don't overload the BSC or block front or rear grills.
- Try to minimize movement in and out of the BSC.
- Do not use Bunsen burners or flammable substances in the BSC.
- Check pressure gauge before working on the BSC.
- Perform work clean → dirty
- Clean up spills promptly.
- Work in center of work area (or at least 4 inches from the front grille).

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CLEAN → WORKING → DIRTY

When you are done working in the BSC:

- **Disinfect materials before removal from BSC**
- **Seal and remove and properly dispose of biohazardous waste**
- **Disinfect work surface, rear wall, sides, inside front window**
  - Can use “Swiffer-type” cleaning tools
- **Leave cabinet running for at least 10 minutes**
  - If turned off overnight, close sash

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Administrative Controls

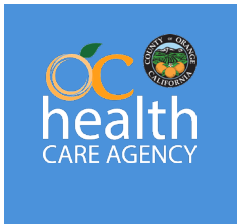
- Defined as changes in procedural practices that help mitigate workplace hazards to laboratory staff.
  - Developing and implementing thorough standard operating procedures.
  - Developing a hazardous substance inventory.
  - Implementing a hazard communication system that uses biohazard signs, labels, and tags to identify biologically contaminated and potentially infectious materials or areas.
  - Limiting access to high-hazard areas to only well-trained, dedicated personnel.

Exposure monitoring and vaccination

- May be required for work involving some pathogens such as *Mycobacterium tuberculosis*
  - TST or QFT every 6 months, annually or bi-annually, depending on exposure risk
- Post-exposure monitoring of laboratory personnel who have been exposed to a BT agent
- Vaccine-preventable infectious diseases such as hepatitis B, meningococcal disease, influenza

ID Systems for High-Risk Pathogens

- Automated ID systems may impact risk depending on:
  - Level of automation
  - Specimen type required
  - MisID or failure to ID completely due to library used
- Automated phenotype-based identification systems
  - VITEK-2, Phoenix Automated Microbiology System, MicroScan
- MALDI-TOF MS
- Molecular methods including nucleic acid amplification tests (NAATs)
- Total Laboratory Automation
  - BD Kiestra
  - Copan WASP/WASPLab



Biosafety Steps to Prevent Exposures

- **Vent blood culture bottles in the BSC**
- **Use microincenerator (no Bunsen burner)**
- **Use BSC when working with unknowns**
  - Slow growing
  - Gram negative/variable organisms
- **Practice ASM protocols for ruling-out and referring potential BT agents**
- **Not using automated ID systems when BT agent is suspected**
- **Using benchtop shields or face protection when working on open bench**
- **Contact your local PH reference laboratory for support**
- **Adopt and verify recommended inactivation protocols**

Automated phenotype-based ID systems

- Require pure bacterial or fungal isolate
- Risk: manual subculture and high concentration
  - Aerosol-generating procedures
- Manipulation of any suspected BT agent should be in the BSC until it is ruled-out
- Unreliable to ID BT agents
  - fastidious, slow-growing, or biochemically inert and do not generate an adequate or reproducible biochemical profile.
  - often absent from the organism database of commercially available test systems and therefore cannot be identified
  - can result in low-confidence identification scores or misidentification as other, more common organisms in the systems' database.

Limitations of MALDI-TOF MS

- Requires pure bacterial or fungal isolate, single well-isolated colony OK
- Ionization of the isolate within the instrument can produce aerosols
- Any potentially infectious organism should be made completely non-viable
  - Several methods depending on organism and instrument, so check with manufacturer and in literature
  - B. anthracis endospores
- **Recognition of isolates that should not be analyzed by MALDI**
- All pre-treatment steps (for suspected BT agents should be carried out in the BSC using a sealed-centrifuge rotor
- Unreliable to ID BT agents
  - Current FDA-cleared databases lack reference spectra for BT agents

Molecular Identification Methods

- Extraction and purification of nucleic acids
  - Manual – use sealed rotor
  - Automated – reduce risk of direct exposure, but have demonstrated variable performance for BT agents (*B. anthracis* endospores)
- Currently no commercially available, FDA-cleared NAATs for bacterial isolates
- Biofire (next slide) – specimen is whole blood
- Validation and ongoing PT is a significant challenge for most laboratories
- Specimen should be referred to a local LRN laboratory for definitive identification.

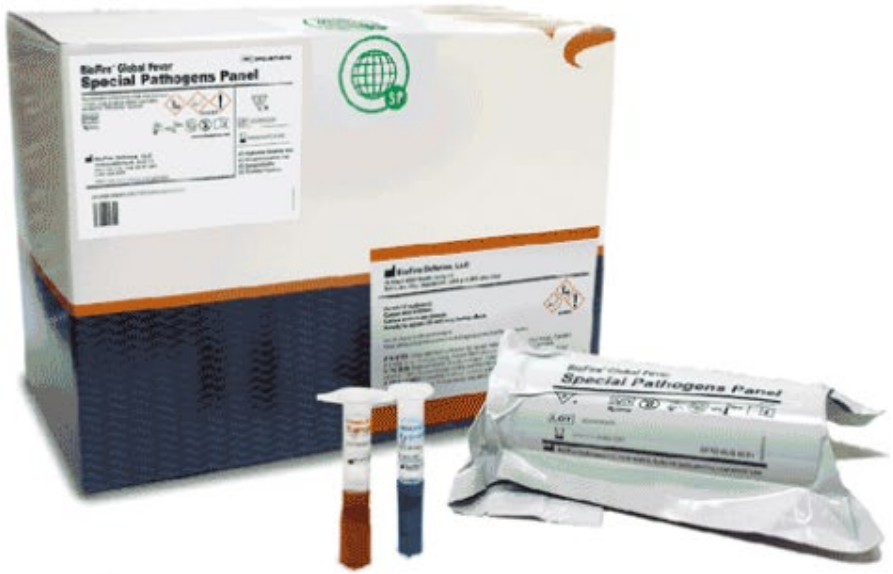
OC health CARE AGENCY

BioFire® Global Fever Panel GF

1 Test, 6 Targets, in 50 Minutes

BioFire® Global Fever Special Pathogens Panel SP

1 Test, 16 Targets, in 50 Minutes



GF	SP	
		Bacterial
	■	*Bacillus anthracis*
	■	*Francisella tularensis*
■	■	*Leptospira* spp.
	■	*Yersinia pestis*
		Viral
■	■	Chikungunya virus
	■	Crimean-Congo hemorrhagic fever virus
■	■	Dengue virus (serotypes 1, 2, 3 and 4)
	■	*Ebolavirus* spp. (Bundibugyo, Reston, Sudan, Taï Forest, Zaire)
	■	Lassa virus
	■	*Marburgvirus*
	■	West Nile virus
	■	Yellow fever virus
		Protozoan
	■	*Leishmania* spp.
■	■	*Plasmodium* spp.
■	■	*Plasmodium falciparum*
■	■	*Plasmodium vivax/ovale*

BioFire Global Fever Panels

Total Laboratory Automation

- Enhances safety through reduced exposure opportunities to primary specimens and cultured isolates
- Suspect BT specimens should not be processed on these systems
- “Telemicrobiology”
- Limited data comparing the safety of automated systems to routine laboratory practices

Questions?

Resources

Interim Clinical Laboratory Guideline for Biological Safety:
https://www.asm.org/ASM/media/Policy-and-Advocacy/Biosafety-white-paper-2019.pdf

Canada Pathogen Safety Data Sheets: https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html

Biosafety in Microbiological and Biomedical Laboratories, 6th Edition:
https://www.cdc.gov/labs/bmbl/index.html

The Association for Biosafety and Biosecurity: https://absa.org/

ABSA Risk Group Database (also available as an app):
https://my.absa.org/tiki-index.php?page=Riskgroups

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