Biosafety Practices in Clinical and Public Health Laboratories

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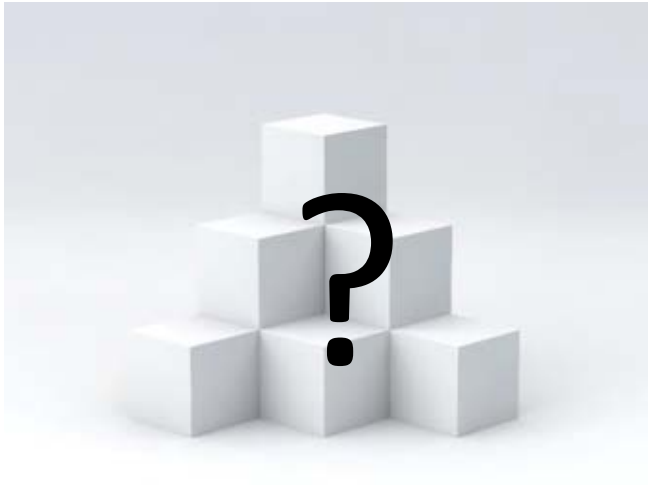
Objectives

- Review some of the biosafety risks in the clinical lab
- Discuss the biosafety program in the clinical lab
- Review examples of exposures and lab acquired infections



Evolving Biosafety In Clinical Laboratories

1880's

1920's

1950's

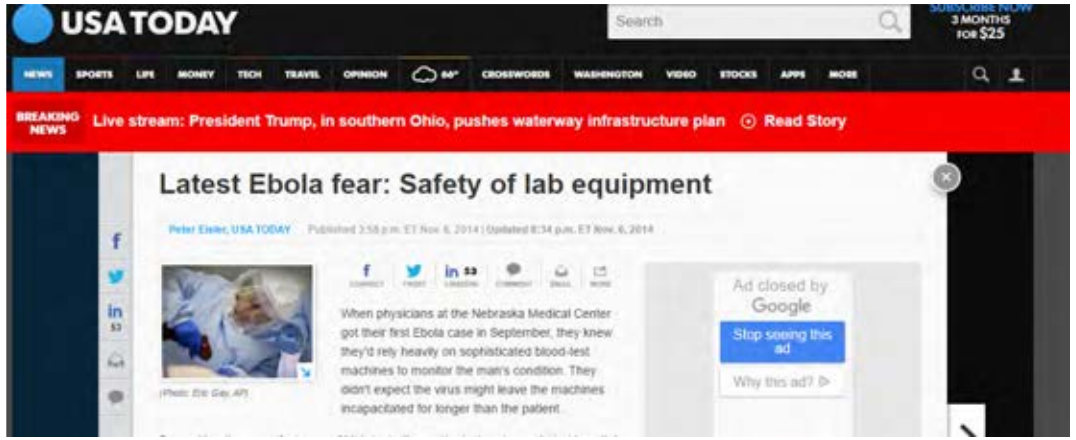
1980's

2000's

Today's clinical laboratory is mission driven, designed for high volume, emphasizes efficiency, and has little time to train staff.

Ebola and Safety:
Remember that In Labs across the country in 2014….

- Some clinical labs refused to test any samples from suspect ebola patients
- A major commercial lab refused to accept specimens
- Some instrument manufacturers refuse to service instruments used to test patients suspected of having ebola



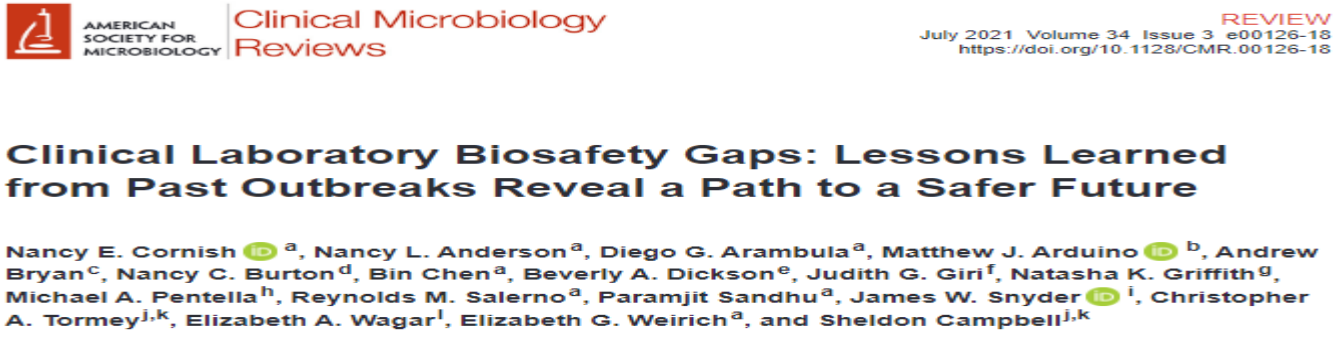
Delays in Laboratory Testing for Fear of Ebola

- ***At least two persons who tested negative for Ebola died from other causes***. **Based on reports from health departments and healthcare providers, in several instances efforts to establish *alternative diagnoses were reported to have been hampered or delayed because of infection control concerns.* For example, laboratory tests to guide diagnosis or management (e.g., complete blood counts, liver function tests, serum chemistries, and malaria tests) were reportedly *deferred in some cases until there were assurances of a negative Ebola virus test result*.**

Karwowski et al. Clinical Inquiries Regarding Ebola Virus Disease Received by CDC — United States, July 9–November 15, 2014. MMWR Morbidity and Mortality Weekly Report. December 5, 2014. 63(49);1175-1179

Specific Laboratory Concerns Observed Related to Ebola

- Insufficient certified staff and supplies available to pack and ship specimens to nearest Laboratory Response Network
- Risk assessments not being performed
- Biosafety cabinet practices
- Confusion about PPE (specimen transport vs. lab testing)
- Confusion about how to handle liquid waste from instruments
- Confusion about how to decontaminate equipment
- Gaps in communication among clinical care staff, infection prevention/control and laboratory
- Open tube systems



Sources of Laboratory Acquired Infections

Pike et al. 1976. in 3,921 laboratories

- Types of Lab
  - 59% research labs
  - 17% diagnostic labs

- Activities
  - Work with infectious agents 21%
  - Accidents 18%
    - Needle-sticks 25%
    - Splashes or spills 27%
    - Sharp objects 16%
  - Work with animals 17%
  - Aerosol exposures 13%
  - Work with clinical specimens 7%
  - Autopsies 2%
  - Unknown 20%

APHL Biosafety Practices and Needs in Clinical Laboratories Survey

- Launched in **June 2018**
- Purpose: to determine needs in clinical laboratories
- Estimated target audience of 5,000 laboratories: 489 laboratories responded
- 376 stated they were defined as a sentinel clinical laboratory
- 147 stated they identified an Ebola Assessment Hospital
- 21 stated they identified as an Ebola Treatment Center

Clinical Laboratory Survey Responses

Question	Yes	No
Does your institution have full time staff who are responsible for biosafety?	34.7%	54.4%
Are you aware of the following Competency Guidelines?	55.2%	44.7%
From May 2015 to May 2018, did your institution complete risk assessments?	56.4%	32.9%

Has your staff received training on the following topics: 100% - 95%

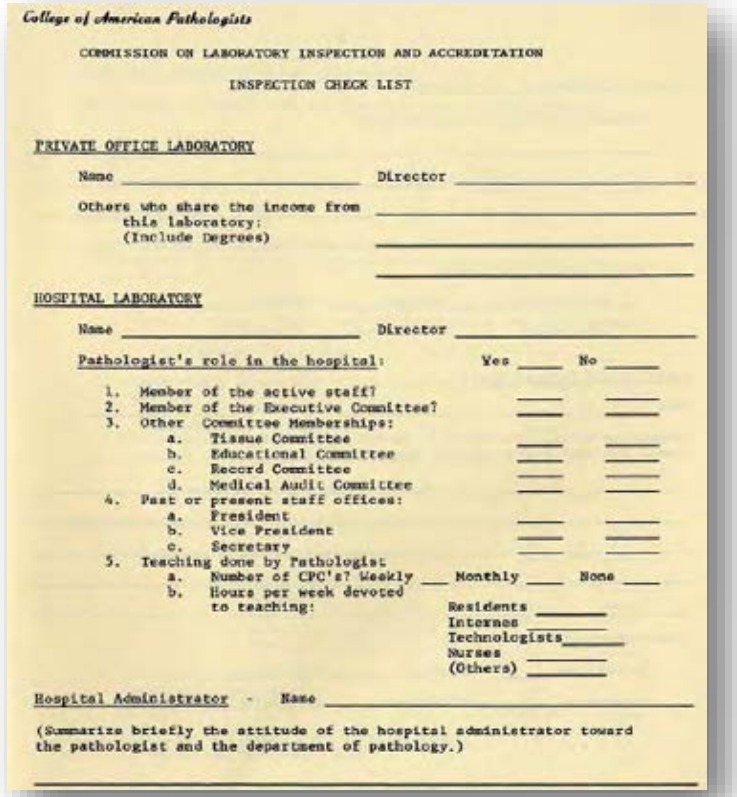
TOPIC	YES	N =	No	N =
Sharps Hazard	**99.6%**	**487**	**0.4%**	**2**
Bloodborne Pathogens	**99.4%**	**486**	**0.6%**	**3**
Personal Protective Equipment (PPE)	**99.2%**	**485**	**0.8%**	**4**
Spill Prevention, Control, and Countermeasure	**97.5%**	**477**	**2.5%**	**12**
Chemical Hazards	**95.9%**	**469**	**4.1%**	**20**

Has your staff received training on the following topics: 89%-30%

TOPIC	YES	N =	No	N =
Certification in packaging/shipping of IATA Division 6.2 infectious substances (Category A)	89.4%	437	10.6%	52
Decontamination	87.5%	428	12.5%	61
Biological Risk Assessment	69.3%	339	30.7%	150
Select Agent Regulations	67.1%	328	32.9%	161
Biosecurity Plan	64.6%	316	35.4%	173
BSL-3 safety practices	44.4%	217	55.6%	272
Safe Handling and Use of Cryogenic Liquids	30.5%	149	69.5%	340

College of American Pathologists: Historically: Safety – Concern

First CAP checklist in 1965



College of American Pathologists

COMMISSION ON LABORATORY INSPECTION AND ACCREDITATION

INSPECTION CHECK LIST

PRIVATE OFFICE LABORATORY

Name _____ Director _____

Others who share the income from this laboratory: (Include Degrees) _____

HOSPITAL LABORATORY

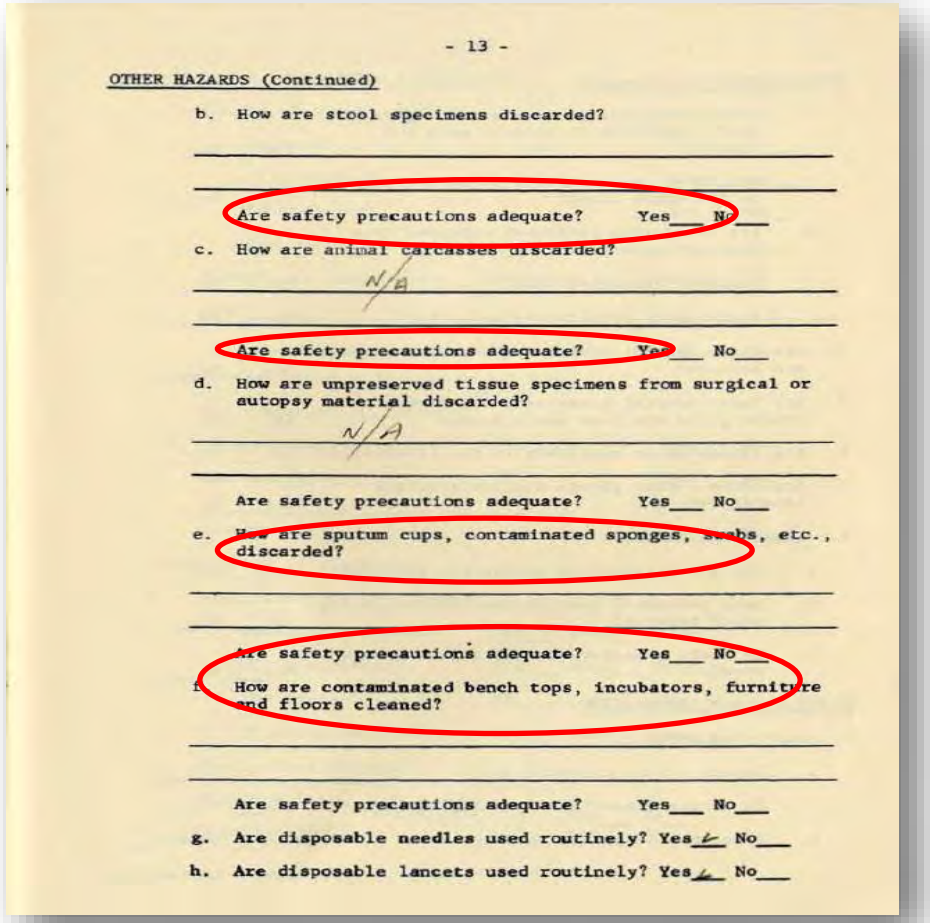
Name _____ Director _____

Pathologist's role in the hospital: Yes ____ No ____

1. Member of the active staff?
2. Member of the Executive Committee?
3. Other Committee Memberships:
   a. Tissue Committee
   b. Educational Committee
   c. Record Committee
   d. Medical Audit Committee
4. Past or present staff offices:
   a. President
   b. Vice President
   c. Secretary
5. Teaching done by Pathologist
   a. Number of CPC's? Weekly ___ Monthly ___ None ___
   b. Hours per week devoted to teaching:
      Residents _____
      Internes _____
      Technologists _____
      Nurses _____
      (Others) _____

Hospital Administrator - Name _____

(Summarize briefly the attitude of the hospital administrator toward the pathologist and the department of pathology.)



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OTHER HAZARDS (Continued)

b. How are stool specimens discarded?

Are safety precautions adequate? Yes___ No___

c. How are animal carcasses discarded?

N/A

Are safety precautions adequate? Yes___ No___

d. How are unpreserved tissue specimens from surgical or autopsy material discarded?

N/A

Are safety precautions adequate? Yes___ No___

e. How are sputum cups, contaminated sponges, swabs, etc., discarded?

Are safety precautions adequate? Yes___ No___

f. How are contaminated bench tops, incubators, furniture and floors cleaned?

Are safety precautions adequate? Yes___ No___

g. Are disposable needles used routinely? Yes✓ No___

h. Are disposable lancets used routinely? Yes✓ No___

Slides courtesy of Denise Driscoll, College of American Pathologists

CAP and CLIA address safety

CAP Addresses Safety

LABORATORY GENERAL Checklist:

Safety policies, procedures and records
Bloodborne Pathogens
Other Infectious Hazards
Fire Prevention and Protection
Electrical Safety
Chemical Safety
Compressed Gases
Radiation Safety
Environmental Safety
Other Hazards
Waste Disposal

MICROBIOLOGY CHECKLIST:

Biosafety
Laboratory Safety

CLIA Addresses Safety:

§493.1101, §493.1254 (a)(1)(2), §493.1407 (e)(2, 10, 11 & 12), §493.1445 (e) (11, 12, & 13)
Safety procedures must be established
Facilities – space, ventilation, and utilities meet the testing needs.
Director – ensure that the testing environment is safe

Clinical Laboratory Improvement Amendments

OSHA Laboratory Safety Guidance 2011

- **General Duty Clause**, employers "shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or likely to cause death or serious physical harm to his employees."
- **Bloodborne Pathogens standard (29 CFR 1910.1030**), including the Needlestick Safety and Prevention Act of 2001, requires employers to protect workers from infection with human bloodborne pathogens in the workplace.
- **Personal Protective Equipment (PPE) standard (29 CFR 1910.132)** requires that employers provide and pay for PPE and ensure that it is used
- **Respiratory Protection standard (29 CFR 1910.134)** requires that a respirator be provided to each worker when such equipment is necessary to protect the health of such individual.
- **Hand Protection standard (29 CFR 1910.138)** requires employers to select and ensure that workers use appropriate hand protection when their hands are exposed to hazards

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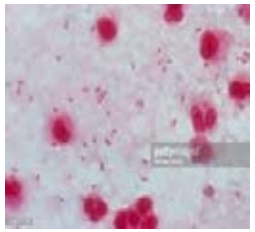
Clinical Laboratory Settings Posing LAI Risk

Setting	Activities
Pre-Analytical	Sample collection and transport
Analytical	Sample handling, manipulation, amplified material
Post-Analytical	Sample storage, retrieval, archival
Equipment and Instrumentation Use	Selection, disinfection
Waste Management	Decontamination, storage, transport

Recent Lab Acquired Infections in US



1988

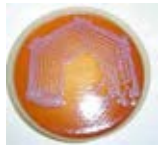
California, clinical lab scientist dies after lab exposure to Neisseria meningitidis MMWR 1991

2000

Maryland researcher acquired Burkholderia mallei in the lab diagnosed with glanders

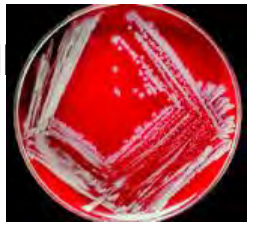
2002

Iowa, PHL microbiologist acquired West Nile virus through a scalpel wound when handling a dead crow



2003

California, 17 clinical lab scientists exposed to Burkholderia pseudomallei, all received antibiotics, no illnesses



2006

Indiana and Minnesota, clinical lab scientists acquired Brucellosis after lab exposures, unrelated strains

2016

Pennsylvania, Lab acquired zika virus through needle stick

Surveillance of laboratory exposures to human pathogens and toxins: Canada 2018

D Choucrallah[1], L Sarmiento[1], S Ettles[1], F Tanguay[1], M Heisz[1], E Falardeau[1]*

- N = 89 exposures reported through Laboratory Incident Notification Canada (LINC) surveillance system (est.2016)
- 235 people exposed with 5 suspected and 1 confirmed LAI

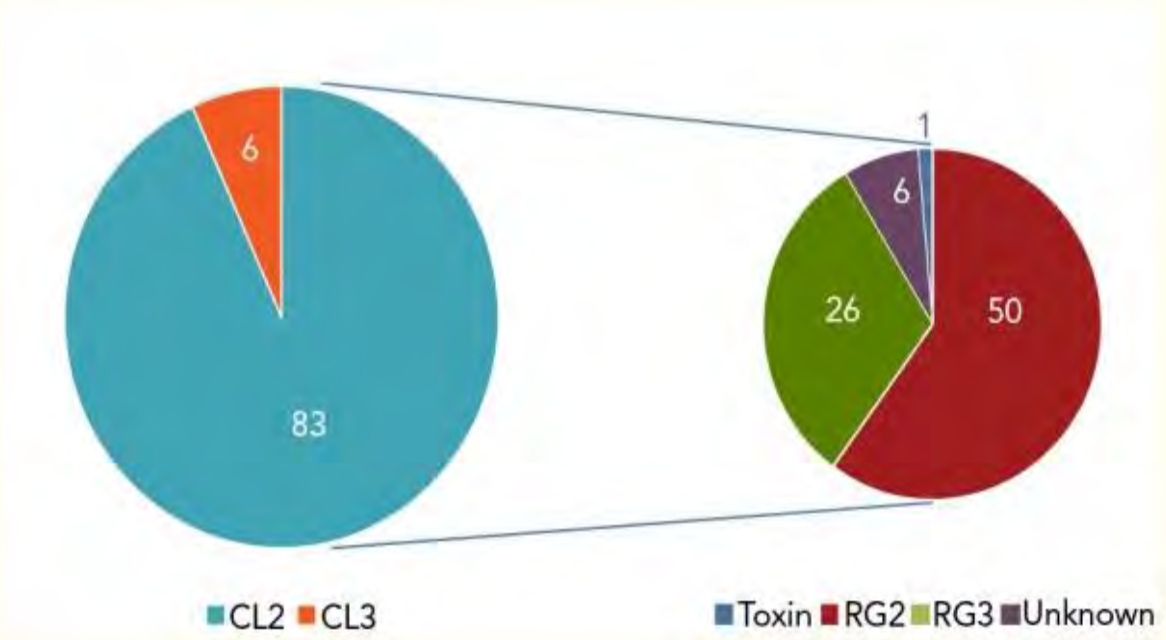


Figure 3

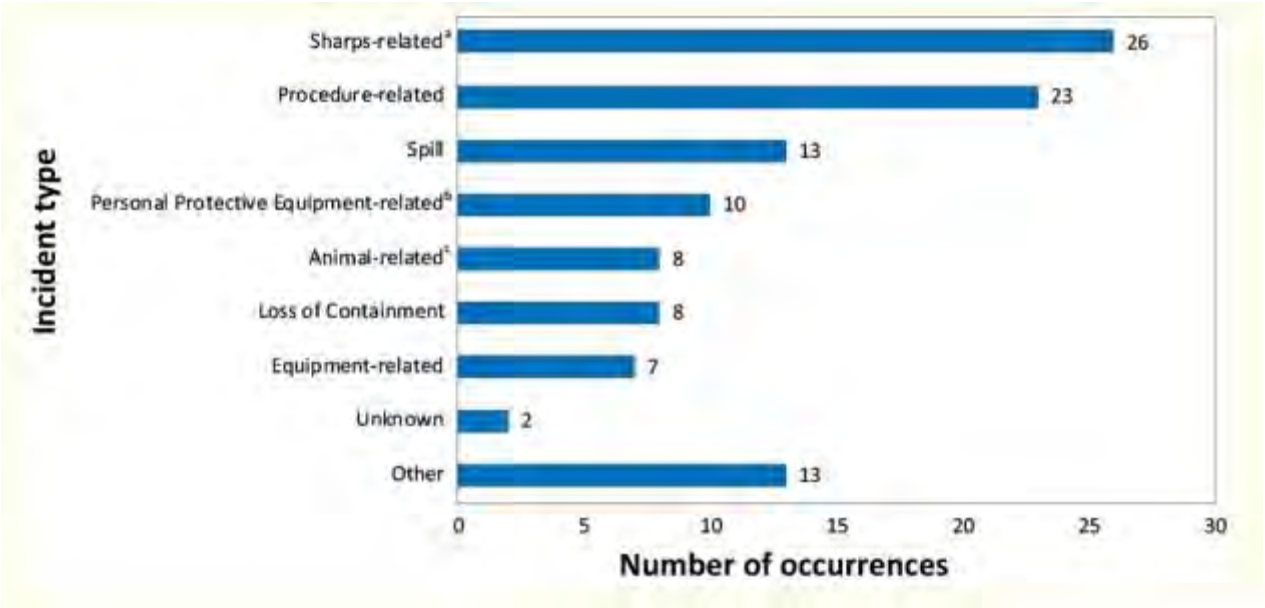
Exposure incidents by containment level, and distribution of exposure incidents by risk groups in containment level 2 facilities, Canada, 2018

Abbreviations: CL, containment level; RG, risk group

Source: Laboratory Incident Notification Canada (LINC)

Numbers of laboratory incidents and exposed individuals by biological agent, Canada, 2018

Biological agent	Incidents (N=89)	Exposed individuals (N=235)		
		Exposure only (n=229)	Suspected LAI (n=5)	Confirmed LAI (n=1)
RG2	50	63	4	1
Neisseria meningitidis	5	8	–	–
Staphylococcus aureus	3	3	–	–
Escherichia coli	2	4	–	–
Lymphocytic choriomeningitis mammarenavirus	2	2	1	–
Salmonella enterica	2	1	–	1
Other RG2 incidents	36	45	3	–
RG3	32	159	1	–
Brucella melitensis	7	105	1	–
Coccidioides immitis	6	15	–	–
Francisella tularensis	3	13	–	–
Mycobacterium tuberculosis	3	9	–	–
Other RG3 incidents	13	17	–	–
Toxins	1	1	–	–
Unknown	6	6	–	–


Incident type
Sharps-related[a]
Procedure-related
Spill
Personal Protective Equipment-related[b]
Animal-related[c]
Loss of Containment
Equipment-related
Unknown
Other
26
23
13
10
8
8
7
2
13
0
5
10
15
20
25
30
Number of occurrences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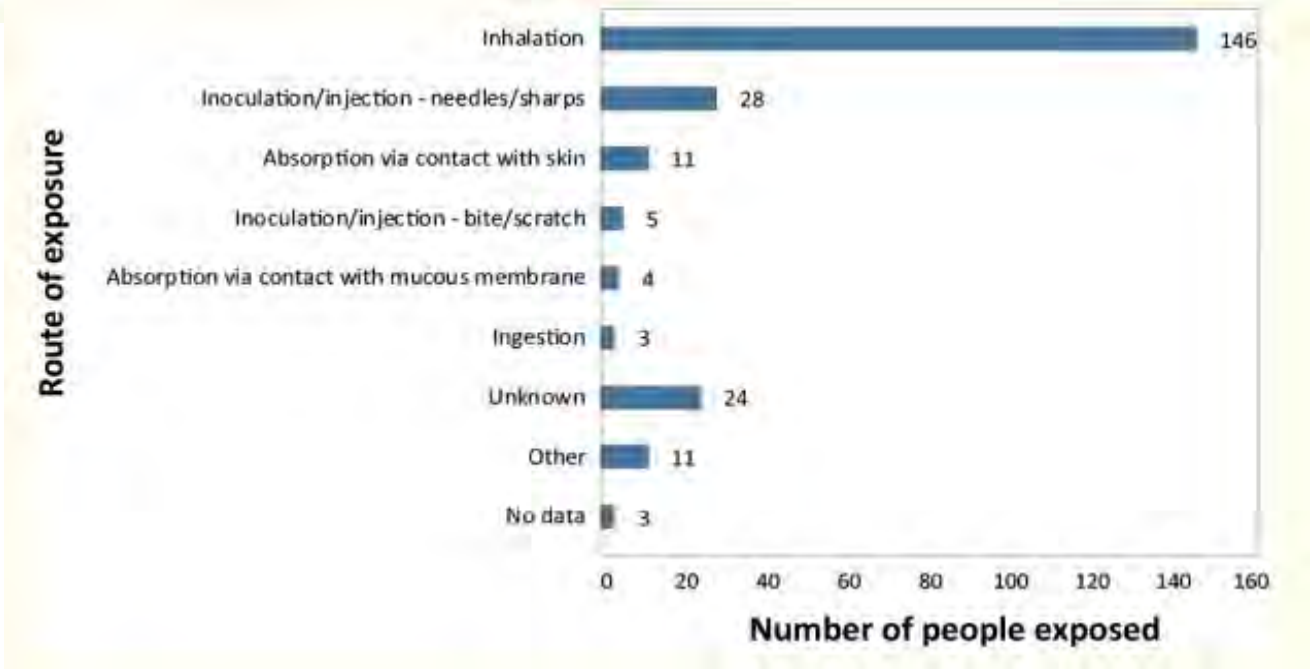
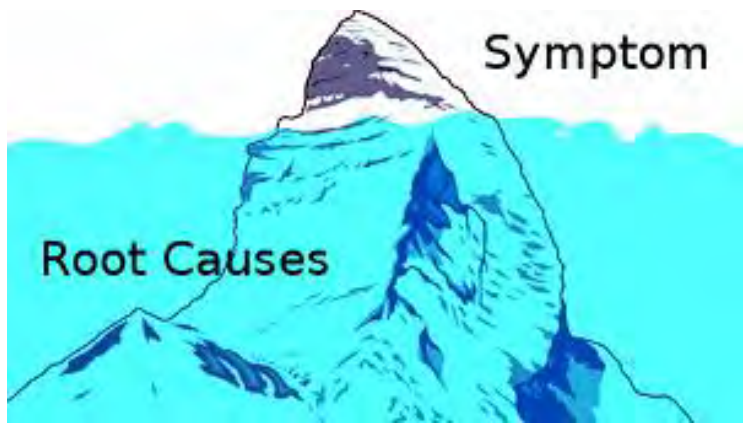

Route of exposure
Inhalation
Inoculation/injection - needles/sharps
Absorption via contact with skin
Inoculation/injection - bite/scratch
Absorption via contact with mucous membrane
Ingestion
Unknown
Other
No data
146
28
11
5
4
3
24
11
3
0
20
40
60
80
100
120
140
160
Number of people exposed

Root causes and area of improvement reported for exposure incident involving human pathogens or toxins, Canada, 2018 (N=233)

Root cause/area of improvement	Example of areas of concern	Citations	
		2018	
		n	%
Human interactions	Workload constraints/pressures/demands	53	23
Standard operating procedure	Procedures were not known/not followed correctly	52	22
Equipment	Equipment was not properly designed/maintained	32	14
Training	Training was not implemented or developed	27	12
Communication	There was no method or system for communication	24	10
Management and oversight	Supervision needed improvement	24	10
Other	Not applicable	21	9



Neisseria meningitidis

Requires BSL 2 and some BSL3 practices, BSC, aerosol/droplet precautions.

<u>12 out of 32</u> LAIs were fatal in lab techs preparing a suspension or doing a catalase test on the open bench.

Estimated 3,000 isolates of Nm per year. Est. attack rate= 13/100,000 lab techs vs 0.3/100,000 adults aged 30-59.

TABLE 1. Years of occurrence, ages, sex, identified serogroups of *N. meningitidis*, and outcomes in 16 cases of probably laboratory-acquired meningococcal disease from 1985 to 2000

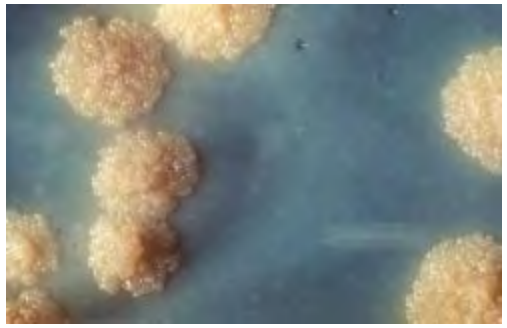
Case	Yr	Age of patient	Sex[c]	Serogroup	Outcome
1	1985			B	
2[a]	1985		F	C	Fatal
3[a]	1987		F	B	Fatal
4	1989		F	B	Fatal
5	1991	46	F	B	Fatal
6	1991		F	C	Fatal
7[a]	1992		M	B	Survived
8[a]	1995		M	B	Survived
9[a]	1997	40	M	B	Survived
10	1997		F	B	Survived
11	1998	45	F	B	Survived
12[a]	1999		F	C	Survived
13[a]	1999		F	C	Survived
14[a]	2000	35	M	C	Fatal
15[a]	2000	52	F	C	Fatal
16[a]	2000		F	C	Fatal
17[b]	2002	50	F	C	Survived
18[b]	2002	21	M	A	Survived
19[b]	2002	65	F	C	Survived

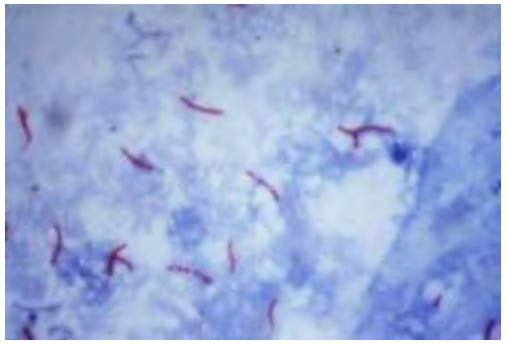
[a] U.S. cases, included in analysis.
[b] Identified following conclusion of study.
[c] F, female; M, male.

Sejvar, J.J. et. al. 2005. JCM. 43: 4811-4814.

Mycobacterium tuberculosis

- Infectious dose 1-10 organisms – *No safe level of exposure*
- Risk to laboratorians who process specimens in microbiology and histology labs
- Airborne droplet nuclei can be spread through normal air currents for long periods of time and spread throughout a room or building





Risk to laboratorians

- Tuberculosis among persons who work with *M. tuberculosis* in the laboratory is 3-5X greater than among those who do not
- Frequency of infection for persons who manipulate *M. tuberculosis* is 100 X greater than for the general population.
  - (Reid DP. Incidence of tuberculosis among workers in medical laboratories. Br Med J 1957;2:10-14.)

D. L. Sewell. 1995. Clinical Microbiology Reviews. 8: 389-405.

TABLE 1. Most frequently reported laboratory-acquired infections in the United States and Great Britain

Infection	Total no. (%) of cases reported for:			
	U.S.[a]	U.S. and world[b]	Great Britain[c,d]	NADC[e]
Brucellosis	274 (9.4)	423 (10.8)	2 (2.1)	18 (52.9)
Q fever	184 (6.3)	278 (7.1)	0	
Typhoid fever	292 (10.0)	256 (6.5)	3 (3.2)	
Hepatitis	126 (4.3)	234 (6.0)	19 (20.0)	
Tularemia	129 (4.4)	225 (5.7)	0	
Tuberculosis	174 (6.0)	176 (4.5)	24 (25.3)	4 (11.8)
Dermatomycosis	84 (2.9)	161 (4.1)	0	2 (5.9)
Venezuelan equine encephalitis	118 (4.1)	141 (3.6)	0	
Typhus	82 (2.8)	124 (3.2)	0	
Psittacosis	70 (2.4)	116 (3.0)	0	4 (11.8)
Coccidioidomycosis	108 (3.7)	93 (2.4)	0	
Streptococcal infections	67 (2.3)	78 (2.0)	3 (3.2)	
Histoplasmosis	81 (2.8)	71 (1.8)	0	
Leptospirosis	43 (1.5)	87 (2.2)	0	3 (8.8)
Salmonellosis	54 (1.9)	48 (1.2)	11 (11.6)	1 (2.9)
Shigellosis	54 (1.9)	58 (1.5)	26 (27.4)	
All reported infections	2,912	3,921	95	34

[a] 1969 data adapted from reference 151.
[b] 1976 data adapted from reference 110.
[c] 1980 to 1989 data adapted from references 51 through 55.
[d] Includes possibly attributable and attributable cases.
[e] NADC, National Animal Disease Center; 1975 to 1985 data adapted from reference 93.

Reports of conversions

- Kubica described 15 separate incidents in which 80 of 291 (27%) exposed lab staff developed positive TST:
  - 8 involved poor directional airflow
  - 5 associated with BSC failures
  - 1 linked to an autoclave failure
  - 1 due to equipment failure.

Kubica GP. Your Tuberculosis Laboratory: Are You really Safe from Infection ? Clinical Microbiology Newsletter 1990; 12: 85-87.

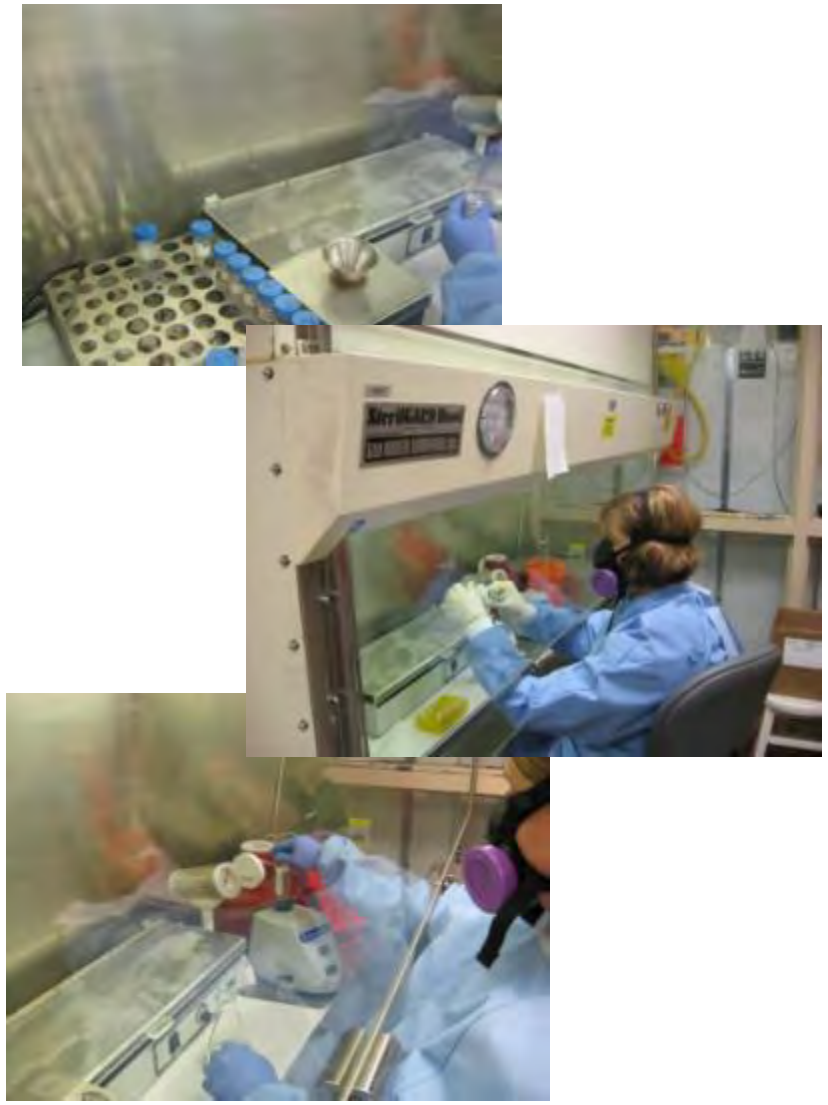
Recent Findings

- Overall HCW TST conversion 2.3 per 10,000 FTEs in non hospital settings
- TST reactivity claims highest for physician offices 3.7 / 10,000 FTEs
- Medical labs 2.6 / 10,000 FTEs were second

Shah et.al. Am J Infect Control 2006 34:338-342.

Generation of Droplets & Droplet Nuclei during TB procedures

- Pouring liquid cultures and supernatant fluids
- Using fixed-volume automatic pipetter. Mixing liquid cultures with a pipette
- Preparing specimen and culture smears
- Dropping tubes or flasks containing cultures



TB Lab Containment Equipment – Respiratory Protection

- No BSC is 100%
- Respirators provide greater protection
  - Filters are more efficient
  - Can be fit-tested
  - Can be fit-checked by the user to ensure a tight seal to the face
- Respiratory protection program requires: SOP, training, storage, inspection, medical review, program evaluation

Occupationally acquired infections in health care workers

- 15 airborne infections: tuberculosis, varicella, measles, influenza and RSV
- Outbreak-associated attack rates range from 15-40%
- Most occupational transmission is associated with violation of one or more of three basic principles of infection control:
  - Handwashing
  - Vaccination of health care workers
  - Prompt placement of infectious patients into isolation

Brucella spp.

- Highly infectious; frequent cause of LAI
- Containment BSL-3 facility and practices
- BSC use is prudent for clinical samples or proficiency test cultures
- PEP after lab exposure (MMWR 57: 39-42. 2008. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5702a3.htm)

Demographics of Lab-Acquired Brucellosis

Occupation or facility	No. exposed (*n* = 167)	No. with LAB (*n* = 71)
Occupation		
Microbiologist	158	62
Researcher	3	3
Clinician	3	3
Administrator	2	2
Unknown	1	1
Facility		
Clinical	142	46
Reference	2	2
Research	15	15
Vaccine production	2	2
Unknown	6	6

Traxler, R.M. etal. A Literature Review of Laboratory-Acquired Brucellosis. JCM 2013

NYC 11 brucellosis cases: 2015-17

- 10 Brucella exposure incidents, 7 laboratories
- 219 exposures, 112 high risk, 71 PEP, no LAI
- Each incident analyzed to determine
  - Clinical presentation
  - Diagnostic workup
  - Clinical management
  - Clinician query for known brucellosis risk factors
  - Determination if clinician suspected brucellosis and informed the clinical lab with culture submission

Ackelsberg et al. Brucella exposure risk events in 10 clinical laboratories, New York City, USA, 2015 to 2017. JCM Feb 2020

Examples: 2018 Cases of Brucella by State

- California: 36 (Incidence of 0.10 per 100k)
- Texas: 12
- New York: 5
- Minnesota: 2
- Louisiana: 4
- Ohio: 2
- North Carolina: 6

NYC 11 brucellosis cases

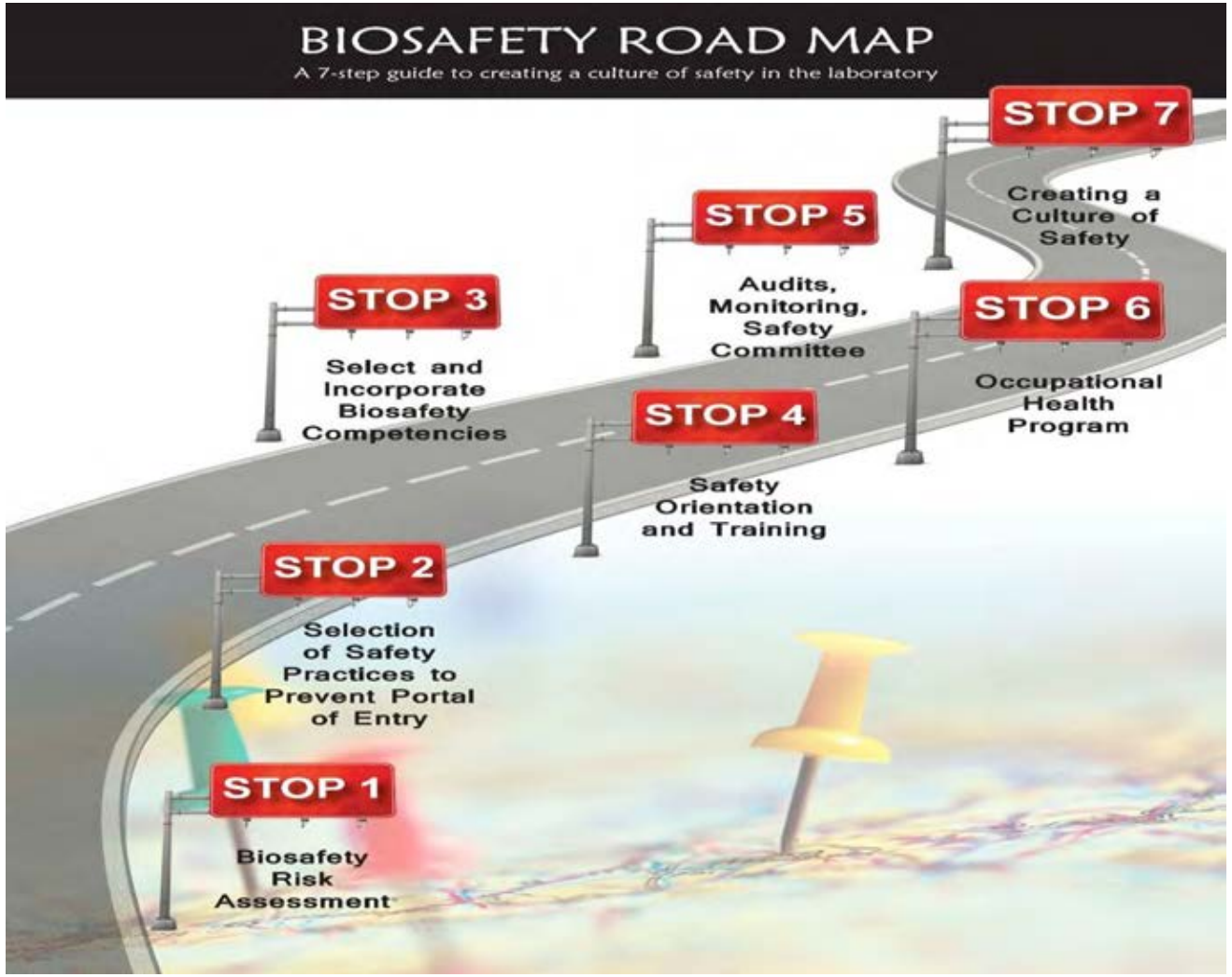
- Laboratory risk assessment
  - Unrecognized *Brucella* on open benches for median of 2 (2-7days). Work included:
    - Opening and manipulating plates
    - Catalase test and oxidase test
    - MALDI spotting
    - Subcultures
    - Vortexing specimen
    - Kirby-Bauer test

Exposure management

- *Brucella* exposure risk assessment and PEP based on minimal, low or high risk
    1. Who was in the lab during the suspected time(s) of exposure
    2. Where they were in relation to the exposure
    3. What they did with the isolates
- Minimal – may consider symptom watch
- Low – symptom watch and sero monitor
- High – PEP and symptom watch

https://www.cdc.gov/brucellosis/laboratories/risk-level.html

Biosafety Roadmap for Clinical Labs



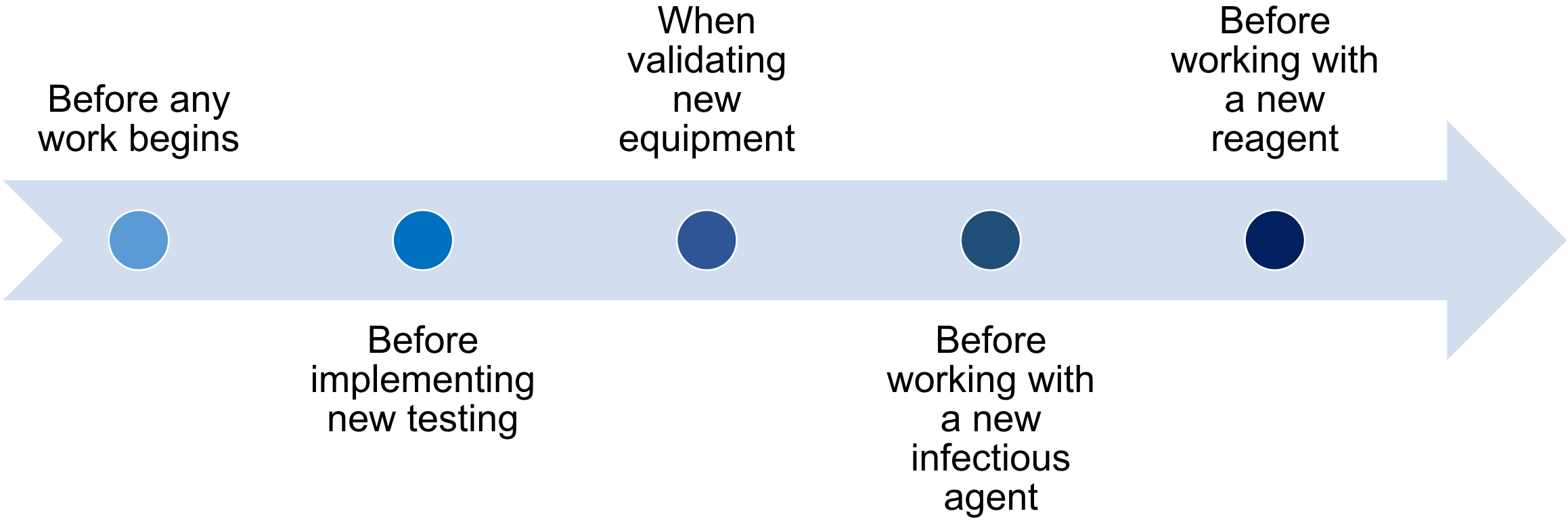
Stop 1

Tasks to complete the risk assessment

Risk assessments include consideration of biological agents and toxins (if known), facility design, laboratory equipment, procedures performed, and personnel involved .

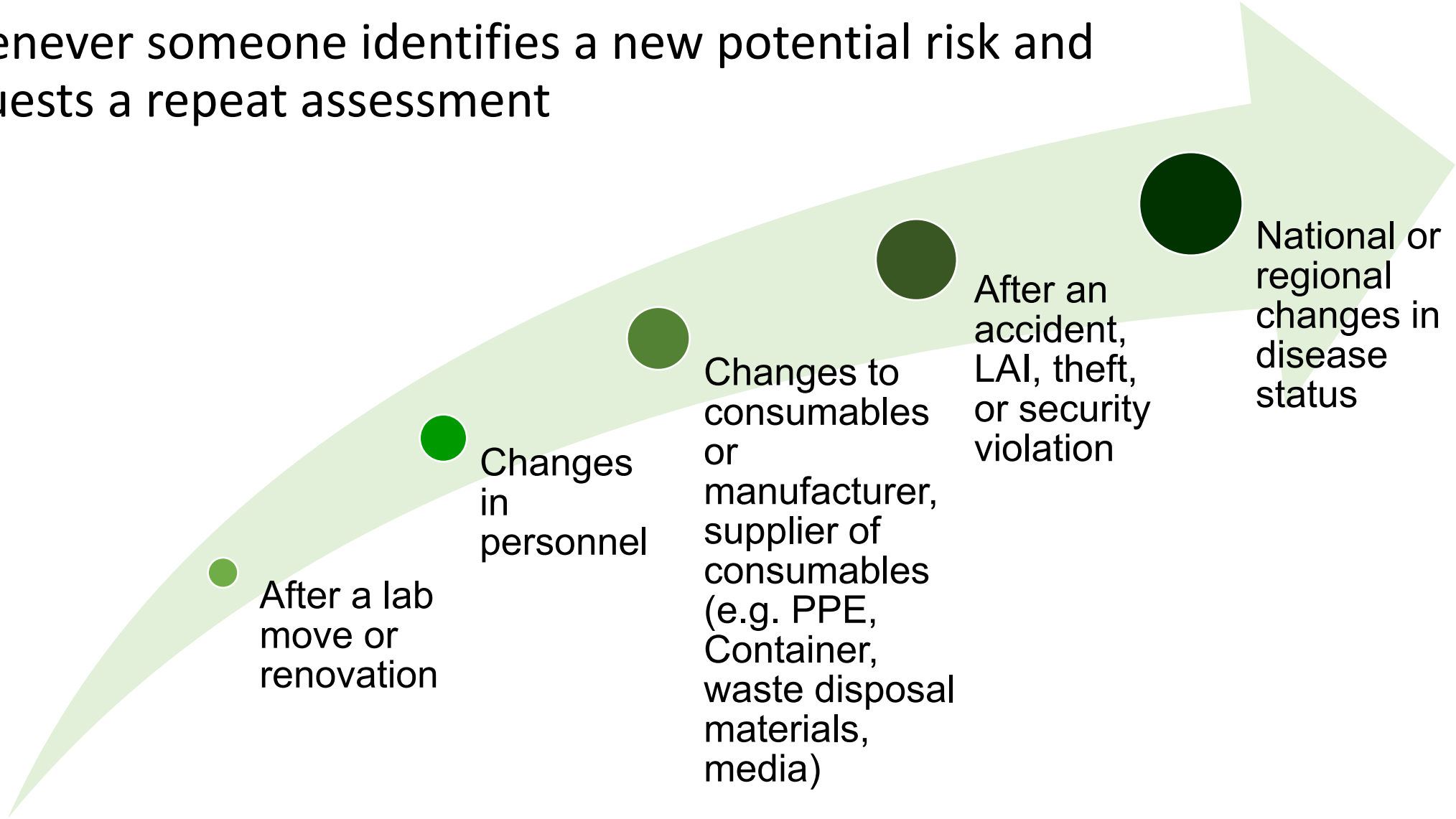
- Identification of any known biohazards used.
- If agent is known, the virulence factors that contribute to pathogenicity (i.e., infectious dose, susceptible host range, environmental stability, antibiotic resistance, ability to produce toxins, vaccine availability)
- If agent is known, the mode of transmission including:
  - Aerosol (inhalation);
  - Injection (sharps);
  - Ingestion (eating or drinking)
  - Absorption (direct contact on skin, non-intact skin)
  - Insect or animal vector (bite, sting or scratch)
  - Fomites (indirect contact via inanimate object)

When Do You Perform an Initial Risk Assessment?



When Do You Repeat a Risk Assessment?

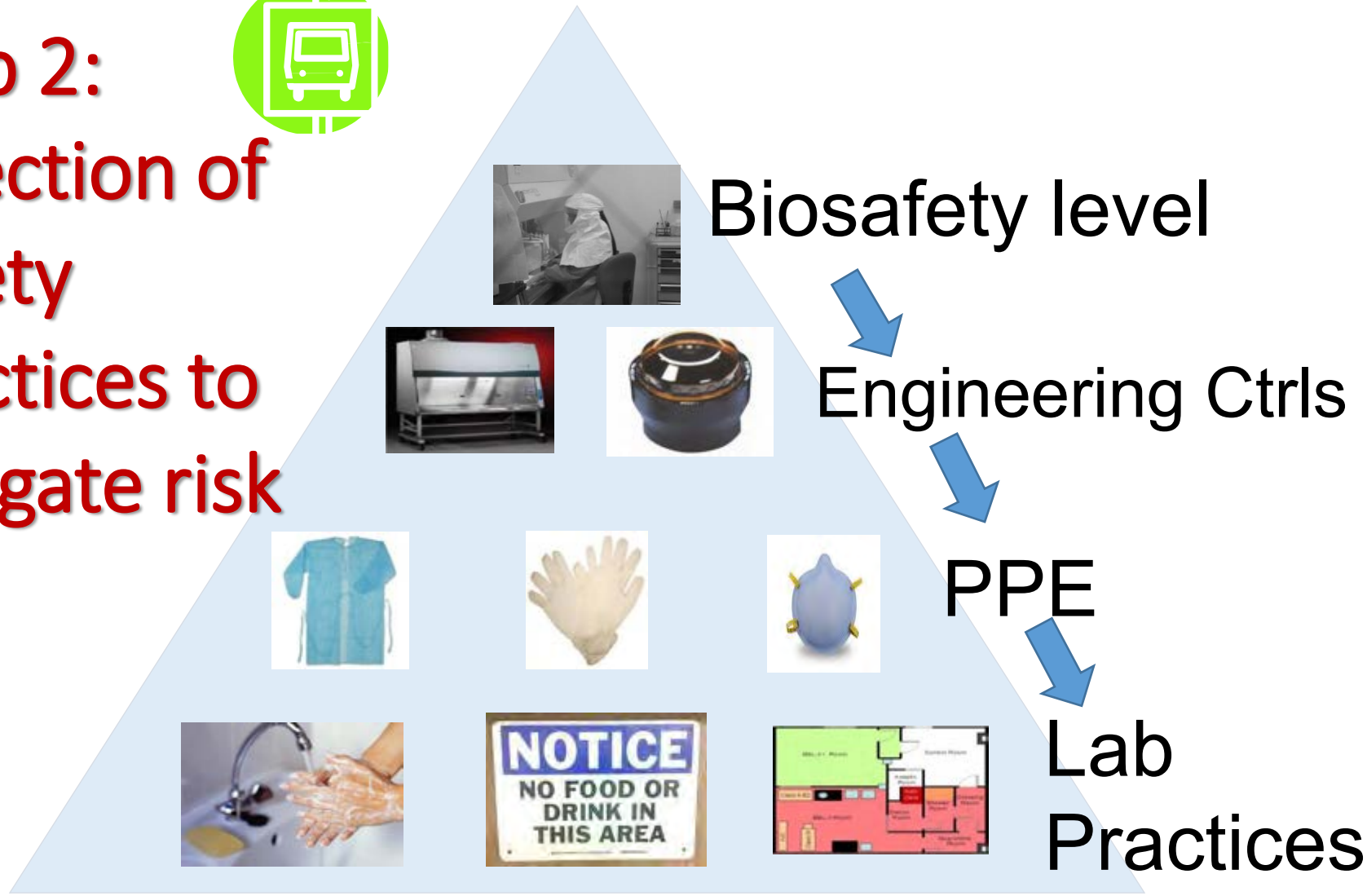
- Whenever someone identifies a new potential risk and requests a repeat assessment



Wisconsin Statewide Risk Assessment of Clinical Laboratories – Munson etal. JCM Nov 2017 http://jcm.asm.org/content/early/2017/11/02/JCM.01569-17.full.pdf

- “results…suggest the necessity for continued microbiology-based biosafety understanding, vigilance, and enforcement throughout the entire laboratory setting.”
  - Survey completed by 103/150(68.7%) labs
  - 88% of respondents complied with more than 75% of the mitigation measures listed in the survey
  - Not all labs who claimed to be BSL-1, 2 or 3 met the minimum qualifications
  - Many labs were able to correct identified minor deficiencies

Stop 2: Selection of Safety Practices to mitigate risk



Select, implement, and evaluate appropriate controls that minimize the risk for exposure

Stop 2

(Image from http://www.cdc.gov/niosh/topics/hierarchy/)

Engineering Controls

- Removes the hazard at the source before it comes in contact with the worker
  - Examples: biosafety cabinets, HEPA filtration, hoods, isolation units
- Initial cost can be higher than admin controls and PPE

Stop 3

Select and Incorporate Biosafety Competencies

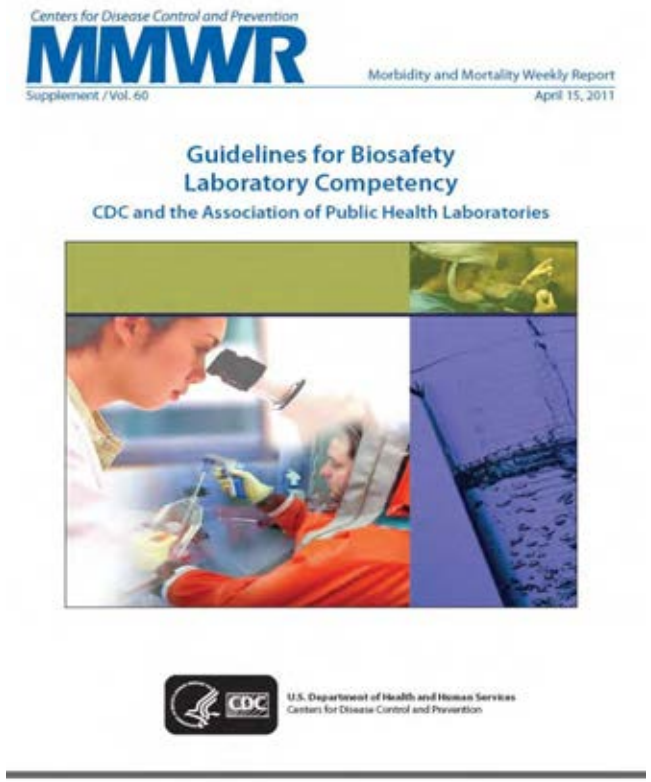
- Connect competencies to required skills
- Competencies are common practice in clinical labs
- Biosafety competencies should be incorporated into existing programs

Don’t Reinvent the Wheel!

Stop 3

2011 Biosafety Competencies

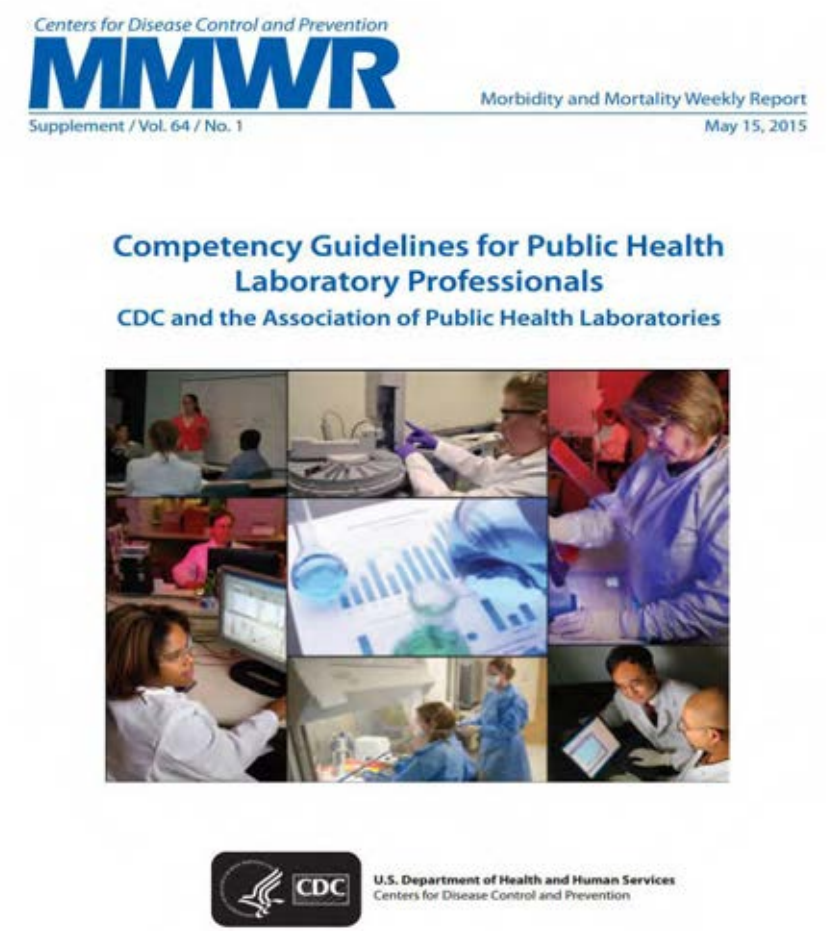
High level view of the required Biosafety Competencies



- Skill Domains
  - I: Potential hazards
  - II: Hazard controls
  - III: Administrative Controls
  - IV: Emergency preparedness and response
  - https://www.cdc.gov/mmwr/preview/mmwrhtml/su6002a1.htm

Stop 3

2015 Table 9. Public Health Laboratory competency guidelines: Safety Domain



- Subdomains (for this workshop)
  - *Potential Hazards*
  - *Hazard Control*
  - *Communication and Training*
- 4 levels of competency
  - Beginner
  - Competent
  - Proficient
  - Expert
- https://www.cdc.gov/mmwr/pdf/other/su6401.pdf

Stop 4:
Safety Orientation and Training

- Based on competencies determine the training that is needed.
- Determine what outside training is available and what site specific training will be developed.
- Consider the best format for the training.
- Write materials and exams for in house training.

Working Safely in a BSC

- https://www.cdc.gov/labtraining/training-courses/biological-safety-cabinets.html
- 1.0 PACE Contact Hours

Centrifuge Safety

- Inspect and grease o-rings routinely
- Inspect buckets, lids, and other components for damage
- Use aerosol-tight rotors or buckets
- Load and unload in a BSC
- Training: https://www.cdc.gov/labtraining/training-courses/fundamentals-centrifuge-safety.html

Stop 5:
Audits, Monitoring, Safety Committee

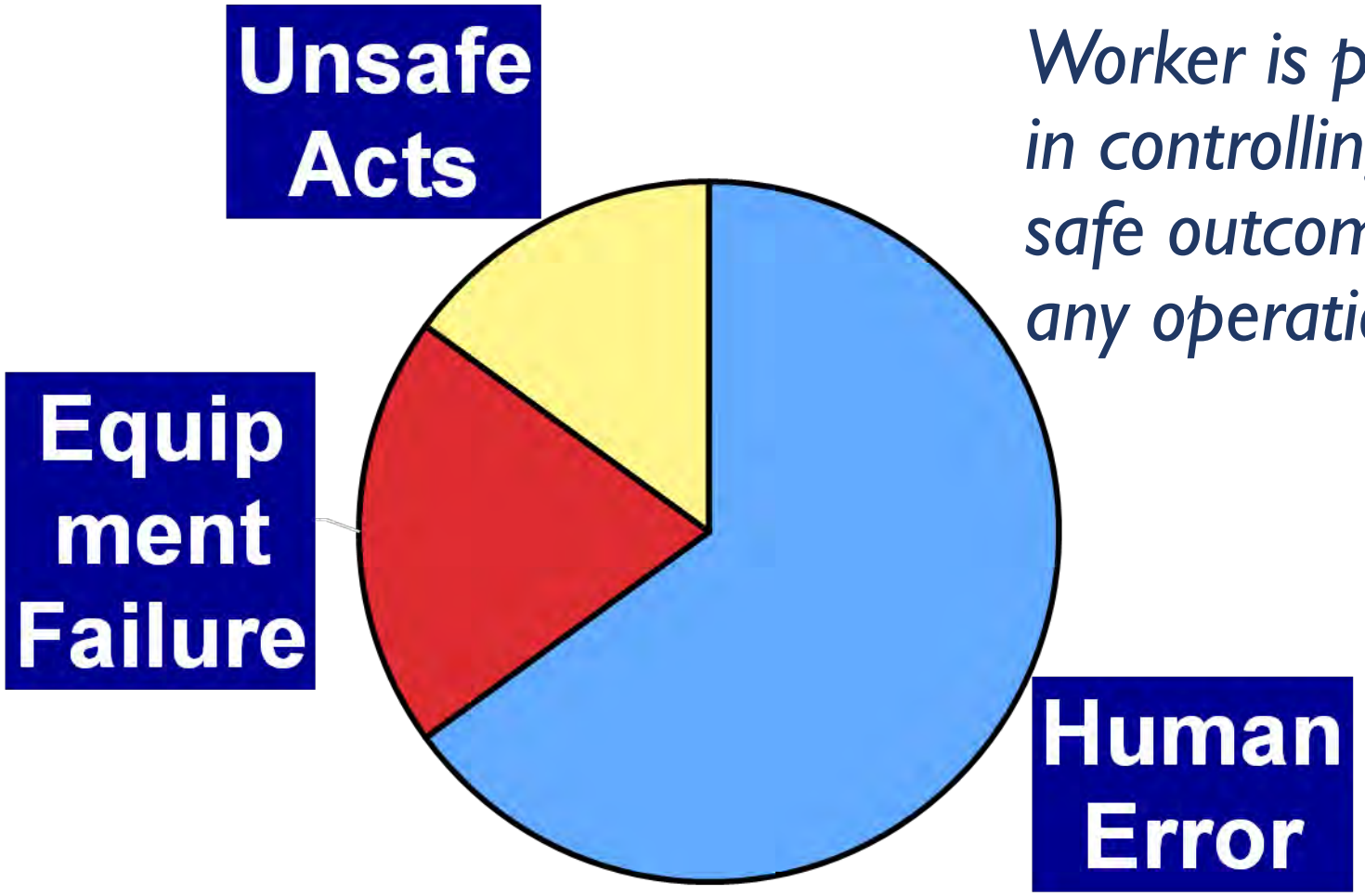
- **Audit** the program by self audits, internal audits, external audits
- **Monitor** staff and equipment performance regularly
- **Encourage Reporting and Follow up** on accidents, incidents, and near misses
- **Revise** the program accordingly
- **Prepare** for routine and emerging agents
- **Establish** a safety committee that meets regularly and reports to the lab director

Stop 6:
Occupational Health Program

- What vaccinations are offered or required
- Medical Surveillance
- Post Exposure Management Plan
- Respirator Program
- Partner with Occupational Health clinician

Stop 6

Behavior Patterns



Worker is pivotal in controlling the safe outcome of any operation!

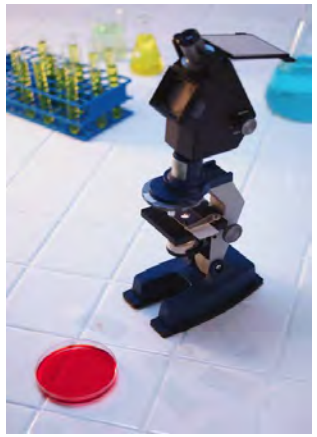
Phillips, G.B. In Lab Safety: Principles and Practices. 1st Edition

Risk Assessment Matrix for Behavior Factors

Risk factors	Degree of Laboratory Risk		
Impact of Behavior Factors	**Ex. of Low to Moderate Risk**	**Ex. of Moderate to High Risk**	**Ex. of High Risk**
Physical/emotional status	Feeling well and focused	Feeling well but fatigued and not well focused	Not feeling well – Very distracted
Perception of risk	Newer employee – is very conscious of hazards – follows SOPs methodically	Is conscious of hazards but has some lapses if in a hurry	Has become complacent and doesn't see work as hazardous
Attitude toward safety	Always follows SOPs	Safety is important but not willing to confront others who don't follow SOPs	Ignores SOPs and takes shortcuts
Safety Competency	Properly trained and complies with SOPs	Properly trained but doesn't always comply if safety slows down work	Properly trained but doesn't see the need for safety competency – doesn't comply

Stop 7:
Creation of Culture of Safety

- Maintain the Safety Committee
- Make safety an agenda item for every meeting
- Take every safety issue seriously
- Review the biosafety program at least annually



Post-Exposure Hidden Costs

- Retraining of staff
- Protocol review
- Risk of symptom relapse following completion of brucellosis treatment
  - Development of chronic brucellosis and health complications
- Costs associated with employee loss
  - Study showed ~50% of employees quit their job after acquiring occupational disease*

Beyan AC, Demiral Y, Cimrin A. Employment status changes of workers after referral to an occupational disease clinic. J Occup Health. 2018;60(6):494-501.

APHL Biosafety and Biosecurity Committee Charge

- Serve as Subject Matter Expert (SME), providing guidance and support for public health labs (PHLs)
- Coordinate national efforts to improve biosafety in PHLs and support outreach to clinical laboratories

May 05, 2016

Risk Assessment Best Practices

Dear Biosafety Officials:

The Association of Public Health Laboratories (APHL) has established a Biosafety and Biosecurity Committee (BBC) to assist public health laboratories with strengthening biosafety and biosecurity programs across the United States. A key activity of the BBC is to develop and promote biosafety and biosecurity tools (for example-risk assessments).

Risk assessments are an essential component of maintaining safety within a laboratory. The goal of a risk assessment is to identify and mitigate the risks of working in a laboratory environment. While all laboratories (including public health laboratories) should be performing risk assessments, the content and design of the template may be unique to the facility. Risk assessments must be performed regularly based on procedure or agent, and when there are changes in agents, procedures, equipment or staff. Risks identified by the assessment should be prioritized, and a mitigation plan should be established based on that prioritization. In other words, the highest risks should be mitigated relatively more than lower risks. The mitigation plan should be documented and clearly communicated to all relevant personnel. A risk assessment should follow the workflow from pre-analytical processes (sample receipt), through the laboratory (analytical), to post-analytical processes (waste disposal) and be reviewed by leadership (lab directors). It must be noted that risk assessments are dynamic documents that must be updated if any of the working assumptions for that protocol (equipment, personnel, material(s) changes.

Components of a Risk Assessment

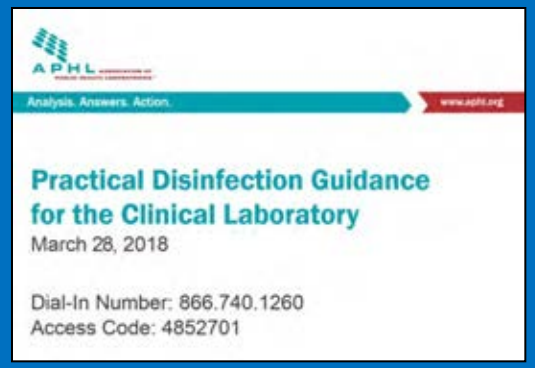
Key components of a risk assessment should address:

Workforce

- Identify personnel (individuals) who will be affected throughout the work flow
- Assess the competency and experience of laboratory personnel
- Identify which trainings to offer staff
- Consider staff enrollment in occupational health programs

Risk Characterization

- Identify hazards
- Consider risk group of the agent
- Classify the potential for exposure (modes of transmission, potential for spill or inhalation, organism concentrations, virulence, etc.)
- Identify activities which may increase risk of exposure
  - Classify which instruments will be used to process each sample and identify potential for exposure



Analysis. Answers. Action.

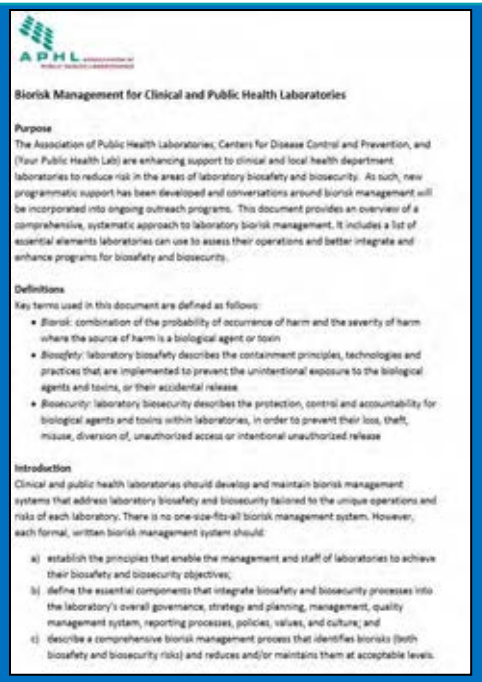
www.aphl.org

Practical Disinfection Guidance for the Clinical Laboratory

March 28, 2018

Dial-In Number: 866.740.1260
Access Code: 4852701

aphl.org/biosafety



Biorisk Management for Clinical and Public Health Laboratories

Purpose

The Association of Public Health Laboratories, Centers for Disease Control and Prevention, and (Your Public Health Lab) are enhancing support to clinical and local health department laboratories to reduce risk in the areas of laboratory biosafety and biosecurity. As such, new programmatic support has been developed and conversations around biorisk management will be incorporated into ongoing outreach programs. This document provides an overview of a comprehensive, systematic approach to laboratory biorisk management. It includes a list of essential elements laboratories can use to assess their operations and better integrate and enhance programs for biosafety and biosecurity.

Definitions

Key terms used in this document are defined as follows:

- *Biorisk*: combination of the probability of occurrence of harm and the severity of harm where the source of harm is a biological agent or toxin
- *Biosafety*: laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to the biological agents and toxins, or their accidental release
- *Biosecurity*: laboratory biosecurity describes the protection, control and accountability for biological agents and toxins within laboratories, in order to prevent their loss, theft, misuse, diversion of, unauthorized access or intentional unauthorized release

Introduction

Clinical and public health laboratories should develop and maintain biorisk management systems that address laboratory biosafety and biosecurity tailored to the unique operations and risks of each laboratory. There is no one-size-fits-all biorisk management system. However, each formal, written biorisk management system should:

a) establish the principles that enable the management and staff of laboratories to achieve their biosafety and biosecurity objectives;
b) define the essential components that integrate biosafety and biosecurity processes into the laboratory's overall governance, strategy and planning, management, quality management system, reporting processes, policies, values, and culture; and
c) describe a comprehensive biorisk management process that identifies biorisks (both biosafety and biosecurity risks) and reduces and/or maintains them at acceptable levels.

Knowledge Retention Toolkit

BIOSAFETY CHECKLIST — APRIL 2015

A Biosafety Checklist: Developing A Culture of Biosafety

Background

There is an inherent risk in a laboratory handling any infectious agents. Biosafety practices should be adhered to in all laboratories that receive potentially infectious material in order to ensure laboratory personnel, public and environmental safety. Recent incidents involving biosafety lapses highlight the need to enhance the culture of biosafety across the laboratory community in the United States. The Association of Public Health Laboratories (APHL) has developed *A Biosafety Checklist: Developing A Culture of Biosafety* to serve as a starting point for laboratories to assess the biosafety measures that they have in place.

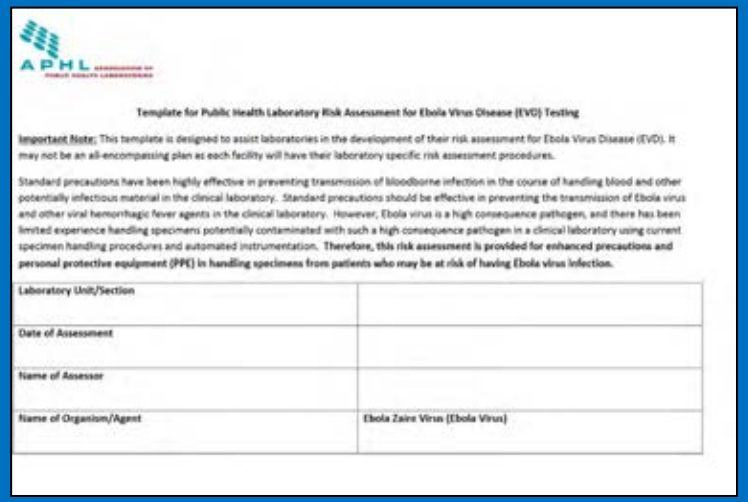
Intended Use

A Biosafety Checklist: Developing A Culture of Biosafety is intended for any laboratory performing testing on infectious agents or clinical specimens that could contain infectious agents in the United States. It is designed to provide laboratories with the broad recommendations for components that should be considered for inclusion in any laboratory's biosafety policy. The checklist consists of six sections:

1. Risk Assessment
2. Selection of Safety Practices
   - Biosafety Level
   - Engineering Controls
   - Personal Protective Equipment (PPE)
   - Laboratory Practices
3. Biosafety Competencies
4. Safety Orientation and Training
5. Audits, Monitoring and Safety Committee
6. Administrative Controls

This checklist is for your laboratory's internal use only. The questions in this checklist are included to guide biosafety discussion within your laboratory and do not address biosecurity practices. Some questions may not be applicable to every laboratory and some laboratories may want to add additional questions to perform their risk assessments. This tool can be modified to meet your laboratory's needs as necessary and information gained from this tool can be used to help laboratories identify areas for improvement in their biosafety practices.

ASSOCIATION OF PUBLIC HEALTH LABORATORIES — 1 — A Biosafety Checklist: Developing A Culture of Biosafety

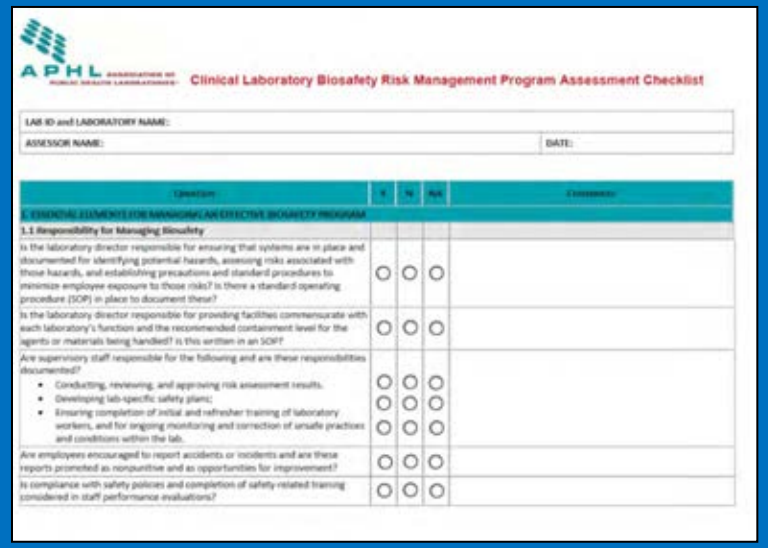


Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing

Important Note: This template is designed to assist laboratories in the development of their risk assessment for Ebola Virus Disease (EVD). It may not be an all-encompassing plan as each facility will have their laboratory specific risk assessment procedures.

Standard precautions have been highly effective in preventing transmission of bloodborne infection in the course of handling blood and other potentially infectious material in the clinical laboratory. Standard precautions should be effective in preventing the transmission of Ebola virus and other viral hemorrhagic fever agents in the clinical laboratory. However, Ebola virus is a high consequence pathogen, and there has been limited experience handling specimens potentially contaminated with such a high consequence pathogen in a clinical laboratory using current specimen handling procedures and automated instrumentation. **Therefore, this risk assessment is provided for enhanced precautions and personal protective equipment (PPE) in handling specimens from patients who may be at risk of having Ebola virus infection.**

Laboratory Unit/Section	
Date of Assessment	
Name of Assessor	
Name of Organism/Agent	Ebola Zaire Virus (Ebola Virus)



Clinical Laboratory Biosafety Risk Management Program Assessment Checklist

LAB ID and LABORATORY NAME:	
ASSESSOR NAME:	DATE:

Question	Y	N	N/A	Comments
I. ESSENTIAL ELEMENTS FOR MANAGING AN EFFECTIVE BIOSAFETY PROGRAM				
1.1 Responsibility for Managing Biosafety				
Is the laboratory director responsible for ensuring that systems are in place and documented for identifying potential hazards, assessing risks associated with those hazards, and establishing precautions and standard procedures to minimize employee exposure to those risks? Is there a standard operating procedure (SOP) in place to document these?	○	○	○	
Is the laboratory director responsible for providing facilities commensurate with each laboratory's function and the recommended containment level for the agents or materials being handled? Is this written in an SOP?	○	○	○	
Are supervisory staff responsible for the following and are these responsibilities documented? • Conducting, reviewing, and approving risk assessment results. • Developing lab-specific safety plans; • Ensuring completion of initial and refresher training of laboratory workers, and for ongoing monitoring and correction of unsafe practices and conditions within the lab.	○ ○ ○	○ ○ ○	○ ○ ○	
Are employees encouraged to report accidents or incidents and are these reports promoted as nonpunitive and as opportunities for improvement?	○	○	○	
Is compliance with safety policies and completion of safety-related training considered in staff performance evaluations?	○	○	○	

aphl.org/biosafety

Introductory Memorandum: Recruiting Biosafety Officers

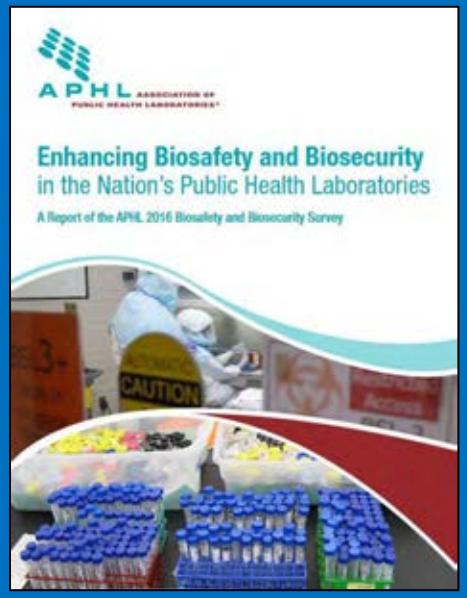
The Association of Public Health Laboratories (APHL) developed the enclosed **competency-based Biosafety Officer Position Description (PD) Template** to assist state and local public laboratories with their recruitment efforts. Utilizing funds from the Centers for Disease Control and Prevention (CDC) Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement and if applicable other sources, state and local public health laboratories will recruit Biosafety Officers with the ultimate goal of improving safety across the jurisdiction. While the term Biosafety is frequently used in the position description, APHL envisions that the Biosafety Officer will work in concert with other personnel to address safety across the public health laboratory and in sentinel clinical laboratories.

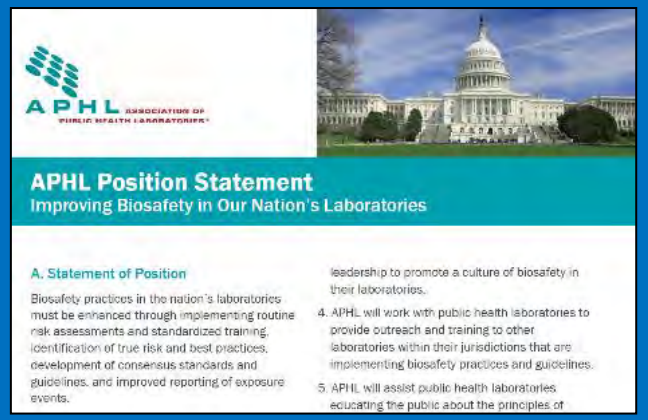
The majority of the competency statements used in the Biosafety Officer (PD) Template are from the Safety, Workforce Training, Security and Communications domains found in the *Competency Guidelines for Public Health Laboratory Professionals*.[1] To complete the expected duties and responsibilities of this unique position, additional competencies from the Microbiology, Emergency Management and Response, Quality Management Systems and General Laboratory Practice domains were also included. The competency tier levels selected from these eight domains are marked at the end of each competency statement (i.e., C = Competent, P = Proficient, E = Expert). Users may interchange tier levels to better fit the position responsibilities in their respective agencies. **APHL recommends reviewing the competency guidelines referenced above for additional tier levels and/or other competencies important to the specific position.**

Please note that in most instances, the competencies listed here are verbatim from the *Competency Guidelines for Public Health Laboratory Professionals*. **Users of the APHL Biosafety Officer PD Template may want to condense and/or combine competencies to meet their requirements and needs.**

The following may vary with the agency electing to use the Biosafety Officer PD Template: position title; recommended education and experience; agency organizational structure and reporting requirements; and weights (%) for each domain/topic area.

APHL thanks the Workforce Development Public Health Laboratory Competency Implementation Workgroup for developing the PD Template and appreciates the feedback provided by the Biosafety and Biosecurity Committee. In the coming months, APHL will work closely with CDC and other partners to create a Community of Practice for Biosafety Officers. For questions pertaining to APHL's biosafety activities, please contact biosafety@aphl.org.





APHL Position Statement
Improving Biosafety in Our Nation's Laboratories

A. Statement of Position

Biosafety practices in the nation's laboratories must be enhanced through implementing routine risk assessments and standardized training, identification of true risk and best practices, development of consensus standards and guidelines, and improved reporting of exposure events.

leadership to promote a culture of biosafety in their laboratories.

4. APHL will work with public health laboratories to provide outreach and training to other laboratories within their jurisdictions that are implementing biosafety practices and guidelines.
5. APHL will assist public health laboratories educating the public about the principles of

Questions

Email: Michael-pentella@uiowa.edu