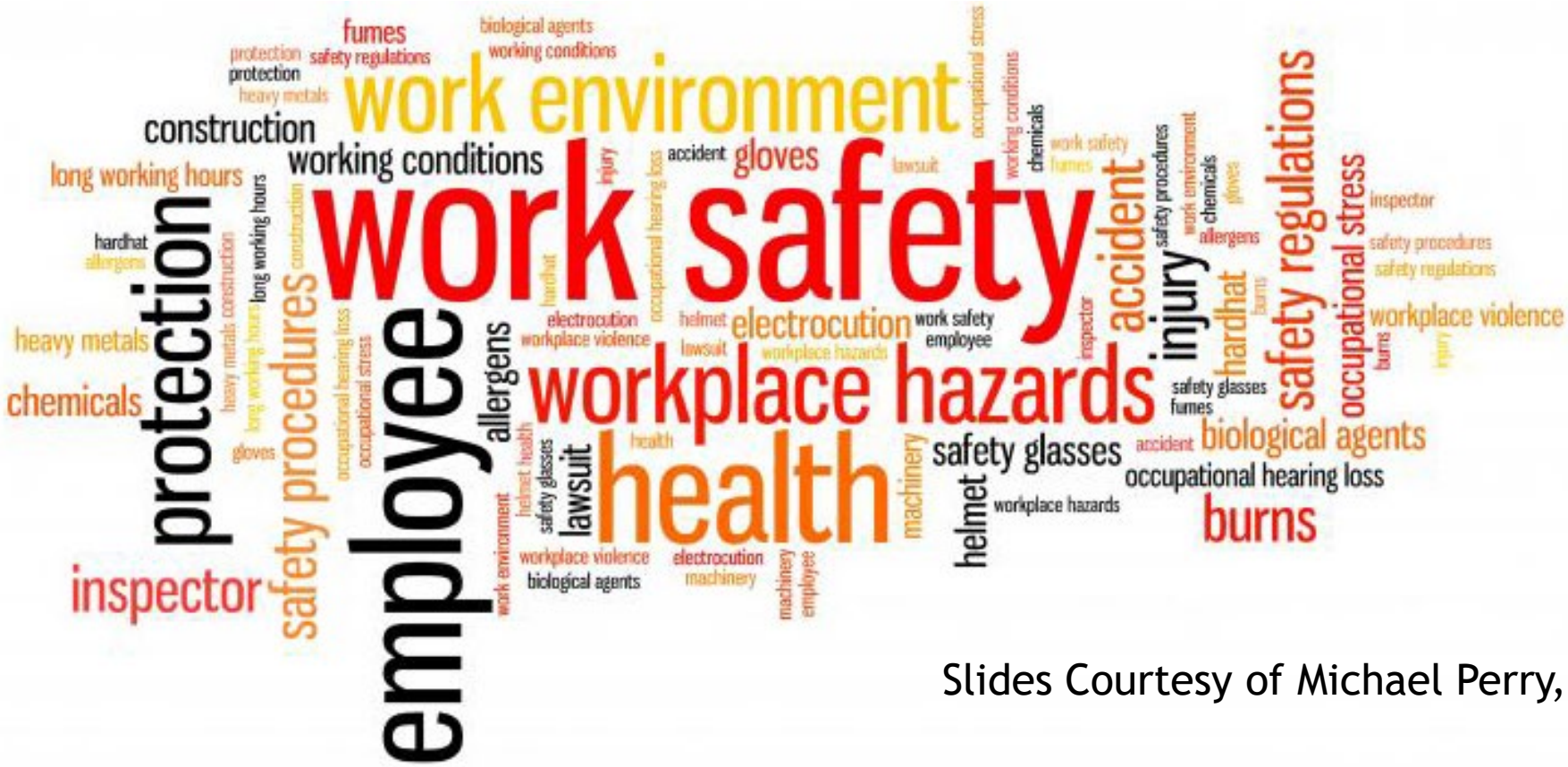
Developing Biosafety Competencies



Slides Courtesy of Michael Perry, Wadsworth Laboratories

Objectives

Use the tools provided to:

- Incorporate the identified biosafety competencies into:
  - the specified SOPs
  - your institutional technical competency assessment program

Recommendations of the Advisory Committee to the Director Concerning Laboratory Safety at CDC 13 January 2015

"Observational competence occurs at the local lab level; however, except for clinical labs, competency skills mapping and refresher training is not consistent. "

- **Recommendation:**
  - Establish a standardized lab safety training curriculum across CDC.
  - Establish standardized methods for competency skills mapping and refresher training.
  - Establish a fellowship/internship program to train scientists to serve as laboratory safety professionals who serve as liaisons between the labs and ESHCO or other central lab safety entity.

Training vs. Competency

Training

- **Read** and understand Biosafety Plan and Incident Response Plan
- **Review** Lab Specific SOPs

Competency

- **Assess** knowledge after a period of “hands on” experience
- **Assessment** through direct observation, oral, or written knowledge

Documentation - Forms

- Laboratory Training Checklist
- Used to document competency of core laboratory skills
- The same form will be used for individual initial training/competency assessment and annual competency assessment
- Detail each section of the form

Expectations for annual assessment and re-training

- Use the checklist for annual review of the core laboratory skills and any lab specific SOPs.
- Throughout the year, documentation is up to the training coordinator.
- At the annual review, add any new procedures to the checklist before completing the competency assessment.
- The checklist should be completed annually for each person and kept in an individual training file.
- Keep copies of completed checklists in a training folder for each lab employee so that when asked a complete and ongoing training record is available

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

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Supplement / Vol. 64 / No. 1
May 15, 2015

Competency Guidelines for Public Health Laboratory Professionals
CDC and the Association of Public Health Laboratories

https://www.cdc.gov/mmwr/pdf/other/su6401.pdf

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

General Tasks to incorporate Biosafety Competencies

1. Review the SOP
2. Perform the Risk Assessment (RA)
3. Identify mitigation strategies based on RA
4. Select applicable competencies from each domain based on the RA
5. Write competency into safety section of SOP
6. Determine how competencies will be assessed
7. Determine how competencies can be extended over time (3-5 years)
8. Review competencies annually and modify based on changes and identified issues

How to Assess Biosafety Competencies

- **CLIA**
  1. Direct observation of test performance
  2. Monitoring the recording and reporting of test results
  3. Review of intermediate test results or worksheets, QC, PT, and preventive maintenance records
  4. Direct observation of performance of instrument maintenance and function checks
  5. Assessment through performance of testing with previously tested specimens
  6. Assessment of problem-solving skills

- **Biosafety**
  1. Direct observation of biosafety practices
  2. Review of each exposure or potential exposure
  3. Review of biosafety practices during work procedures
  4. Direct observation of work in a biosafety cabinet
  5. Assessment through exercises and drills
  6. Assessment by quizzes

Safety and Technical Competency Example

New York State Department of Health Wadsworth Center Clinical Laboratory	QS-17.02FormA - Technical Training and Competency Assessment Form Effective Date: 07/01/15 1 of 11

Employee: _____

Laboratory: Biodefense

Assessment Procedure:

1. Direct observation by trainer /assessor
2. Observation for compliance with safety protocols
3. Direct observation of instrument maintenance and function checks, where applicable
4. Review of worksheets, QC, PM documentation
5. Monitoring the recording/reporting of test results
6. Assessment of test performance through previously analyzed samples or PT
7. Assessment of problem-solving skills

Molecular/Environmental Processing – Core (☑) Surge (☐)	
Molecular/Biothreat R/O	X
Ricin Toxin Testing	X

Follows SOP(s) for:
BDL-MANUAL-5003-05 (Lab Methods Manual)
BDL-MANUAL-5001-05 (Lab Biosafety Plan)
BDL-MANUAL-5002-07 (Lab Quality Manual)
BDL-MANUAL-5000-06 (Chemical Hygiene Plan)

Assessment Type:

- ☐ Annual Competency for Year: _____
- ☐ Initial Training
- ☐ 6 Month Competency Assessment
- ☐ Re-Training
- ☐ Other: _____

TASK	**Assessment Procedure** Record number of all procedures that apply to a given task. (1-7)	**Accession Number (IDR #) /Batch Number** of sample(s) used for assessment (if applicable)	**Trained/ Competent** Satisfactory (S) Unsatisfactory (U) Not Applicable (NA)	Date	Initials Trainee/ Tech	Initials Trainer/ Assessor	Comments
PRE-ANALYTIC							
Initial Processing and Accessioning of Specimens	1						
Schedules Appropriate tests in LIMS	1						
Generates Testing Labels	1						
Specimen Evaluation for Acceptance/Rejection	1, 2						

TASK	**Assessment Procedure** Record number of all procedures that apply to a given task. (1-7)	**Accession Number (IDR #) /Batch Number** of sample(s) used for assessment (if applicable)	**Trained/ Competent** Satisfactory (S) Unsatisfactory (U) Not Applicable (NA)	**Date**	**Initials Trainee/ Tech**	**Initials Trainer/ Assessor**	**Comments**
ANALYTIC							
Method: Molecular Assay/Biothreat Rule-Outs							
Knowledge and Compliance with SOP	1, 2, 4, 6, 7						
Env Processing	1, 2, 4, 6, 7						
Reagent Preparation	1, 4						
Adheres to Labeling/Expiration Date Requirements	1, 4						
Calibration/Quality Control	1, 3, 4, 6						
Programs Instruments	1, 4						
Proper Use/Maintenance of Equipment (ABI 7500)	1, 3, 4						
Temperature/CO_2	1, 3						
Gram Stain	1, 2						
Gamma Phage	1, 2						
Prepares Worksheet	1, 4						

Colony Morphology	1,2						
Heat Lysis	1, 2						
Master Mix and Plate Setup	1, 2, 6						
Tetracore	1, 2						
Streaking for Isolation	1, 2						
Troubleshooting/ Discrepancies	7						

TASK	**Assessment Procedure** Record number of all procedures that apply to a given task. (1-7)	**Accession Number (IDR #) /Batch Number** of sample(s) used for assessment (if applicable)	**Trained/ Competent** Satisfactory (S) Unsatisfactory (U) Not Applicable (NA)	**Date**	**Initials Trainee/ Tech**	**Initials Trainer/ Assessor**	**Comments**
ANALYTIC							
Method: Ricin Toxin Testing							
Knowledge and Compliance with SOP	1, 2, 4, 6, 7						
Prepares Worksheet	1, 4						
Reagent Preparation	1, 4						
Adheres to Labeling/Expiration Date Requirements	1, 4						
Calibration/Quality Control	1						
Programs Instruments	1, 4						
Proper Use/Maintenance of Equipment (Victor, Plate Washer, Compact)	1, 3, 4, 6						
Troubleshooting/ Discrepancies	7						

TASK	Assessment Procedure Record number of all procedures that apply to a given task. (1-7)	Accession Number (IDR #) /Batch Number of sample(s) used for assessment (if applicable)	Trained/ Competent Satisfactory (S) Unsatisfactory (U) Not Applicable (NA)	Date	Initials Trainee/ Tech	Initials Trainer/ Assessor	Comments
POST ANALYTIC							
Method: Molecular Assay/Biothreat Rule-Outs							
Analyzes Data/Controls	1, 5						
Completes worksheet(s)/Paperwork	1, 5						
Enters/Imports Results into LIMS	1, 5						
Recognizes Aberrant Results/Reports to Supervisor	2, 5, 6						
Recognizes Other Nonconforming Events	2, 5, 6						
Troubleshoots/ Discrepancies	7						
Method: Ricin Toxin Testing							
Analyzes Data/Controls	1, 5						
Completes worksheet(s)/Paperwork	1, 5						
Enters/Imports Results into LIMS	1, 5						
Recognizes Aberrant Results/Reports to Supervisor	2, 5, 6						
Recognizes Other Nonconforming Events	2, 5, 6						
Troubleshoots/ Discrepancies	7						

TASK	Assessment Procedure Record number of all procedures that apply to a given task. (1-7)	Accession Number (IDR #) /Batch Number of sample(s) used for assessment (if applicable)	Trained/ Competent Satisfactory (S) Unsatisfactory (U) Not Applicable (NA)	Date	Initials Trainee/ Tech	Initials Trainer/ Assessor	Comments
POST ANALYTIC							
Method: Quality System							
Adheres to the Wadsworth Center Quality System Documents	1, 2, 4, 6						
QC Sheets/Logs	1, 4, 5						
Method: Continuing Education							
Confidentiality	4						
Blood Borne Pathogens	4						
Hazard Communications	4						
Meets the minimum requirements of 12 hours CE	4						
See SAP Tier 1 Lab Staff Training Sheet for a list of completed trainings							

TASK	**Assessment Procedure** Record number of all procedures that apply to a given task. (1-7)	**Accession Number (IDR #) /Batch Number** of sample(s) used for assessment (if applicable)	**Trained/ Competent** Satisfactory (S) Unsatisfactory (U) Not Applicable (NA)	**Date**	**Initials Trainee/ Tech**	**Initials Trainer/ Assessor**	**Comments**
Method: Safety							
Adheres to the Wadsworth Center Safety Policies	1, 2, 6, 7						
Proper use/cleaning of BSC	1, 2, 3						
Bench clean-up	1, 2						
Spills	2, 4						
Emergency Exit from BSL2 and BSL3	2, 4						
Accident Reporting	2, 4						
911, BDL Director, RO Notifications	2, 4						
Security Awareness and Notification	2, 4						
Agent-specific hazards	2						
Understands exposure risks and Occupational health requirements	2						

TASK	Assessment Procedure Record number of all procedures that apply to a given task. (1-7)	Accession Number (IDR #) /Batch Number of sample(s) used for assessment (if applicable)	Trained/ Competent Satisfactory (S) Unsatisfactory (U) Not Applicable (NA)	Date	Initials Trainee/ Tech	Initials Trainer/ Assessor	Comments
Method: BSL-3							
Donning and Doffing PPE	1, 2						
PAPR Testing and Maintenance	1, 2						
Entry/Exit Log, Accident Log	1, 2						
2-Person Rule	1, 2						
Visitor Access Requirements	1, 2						
Autoclaving: Loading/unloading, indicators, run records, failures	1, 2						
Environmental Monitoring	6						
FreezerPro Inventory	1, 2						

TASK	Assessment Procedure Record number of all procedures that apply to a given task. (1-7)	Accession Number (IDR #) /Batch Number of sample(s) used for assessment (if applicable)	Trained/ Competent Satisfactory (S) Unsatisfactory (U) Not Applicable (NA)	Date	Initials Trainee/ Tech	Initials Trainer/ Assessor	Comments
Method: Additional Tasks							
Instrument-to-instrument matching							
Reagent lot approval for tests							
Approves quality control samples							
Review and sign logs (temperature, calibration, PM and maintenance documents)							
Method: Biothreat Inactivation							
Heat Killed Isolates							
Extracted Proteins							
Extracted Nucleic Acid: MasterPure & Qiagen							
Plating and 72 hr Growth Check							
Inactivation Log/Certificate							

Overall Assessment

Training: ☐ Completed ☐ Continue training **Competency:** ☐ Competent ☐ Needs improvement

Developmental Plan

Employee _____ Signature _____ Date _____

Trainer/Assessor _____ Signature _____ Date _____

Trainer/Assessor _____ Signature _____ Date _____

Lab Supervisor _____ Signature _____ Date _____

Section Assistant Director _____ Signature _____ Date _____

QA Officer review _____ Signature _____ Date _____

Method of Competency

1. Review the SOP, Risk Assessment and Mitigation
2. Go to the list of biosafety competencies
3. Select the appropriate Biosafety Competencies for the SOP
4. Select the biosafety competency that you want to use from each of the subdomains for a "competent" individual
5. In the SOP, write instructions based on competencies

BIOSAFETY COMPETENCIES TABLE

HAZARDS AND MITIGATION FROM BIOSAFETY RISK ASSESSMENT	SAFETY COMPETENCIES IDENTIFIED	WHAT IS NEEDED IN THE SAFETY SECTION OF THE SOP	SAFETY COMPETENCE ASSESSMENTS

Example : Monkeypox Nucleic Acid Procedures

SOP Excerpt: DNA Extraction

a. Prepare reagents according to manufactures protocol
b. Pipet 20 μL protease into the bottom of each microcentrifuge tube
c. Add 100 μL of each specimen to the appropriately labeled polypropylene tube.
d. Add 100 μL PBS
e. Add 200 μL of lysis buffer to each sample
f. Mix by vortexing for 15 seconds
g. Transfer the full volume of sample mixture to a clean vial.
h. Incubate at 56°C for 15 minutes
i. Centrifuge and add 200 μL ethanol (96-100%).
j. Vortex for 15 seconds
k. Close the cap and centrifuge spin column/collection tube assembly at 8000 RPM for 1 minute
l. Place each spin column in a clean 2 mL collection tube
m. Add 500 μL wash buffer 1
n. Centrifuge spin columns collection tube assembly at 8000 RPM for 1 minute.
o. Place spin column into collection tube.
p. Add 500 μL wash buffer 2
q. Centrifuge spin columns/collection tube assembly at full speed for 3 minutes
r. Place in clean collection tube and centrifuge spin columns at full speed for 1 minute.
s. Place each spin column in a clean sterile collection tube.
t. Add 100 μL elution buffer or PCR grade water
u. Incubate tubes at room temperature for 5 minuets
v. Centrifuge spin columns/collection tube assembly at 8000 rpm for 1 minute
w. Discard spin column
x. The DNA is now ready to be tested by the fluorogenic 5’ nuclease assay.

Example : Monkeypox Nucleic Acid Procedures

SOP Excerpt: rtPCR

Clean Room

a. All components of the mastermix will be added within this room.
b. No Template Controls (NTCs) will be added and capped tightly within this room.
c. Once mastermix has been loaded, loosely cap all wells with the optical strip caps. Only the NTCs should have their caps securely in place.
d. See Agent Specific SOPs for details on primer and probe concentrations.
    a. Include a minimum of two (2) No Template Controls (NTCs) per target.
    b. Include duplicate Positive Controls for each target.
    c. Include Inhibition Control Reactions for each sample. See agent specific protocols for specific reactions.
    d. All samples must be analyzed in duplicate as Neat (undiluted) extracts and as 1:10 dilutions for environmental samples.
e. Take the 96 well reaction plate to Addition Area

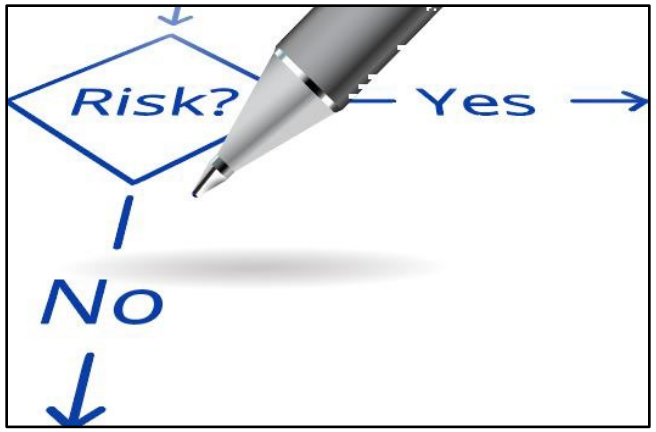
Sample Addition Area

a. Addition of extracted samples
b. Place extracted samples in rack
c. Add samples
    a. Add 5 µL of neat or 1:10 sample to appropriate wells
d. Securely cap wells with optical caps.
e. Visually inspect plate for air bubbles.

Positive Control Addition Area

a. Only previously extracted positive control material may be added to the reaction mixtures in this area. No unknown samples are permitted
b. Remove all Positive Control material from freezer
c. Add control material and tightly cap wells
    a. Add 5 uL of appropriate positive control to each specified well.
d. Securely cap wells with optical caps.
e. Return all positive control material to freezer immediately

Monkeypox Nucleic Acid Extraction Risk Assessment



Laboratory Section and Procedure: Molecular Procedure

Overview:

This is based on the tool developed by State Hygienic Laboratory at the University of Iowa. It is intended to guide laboratory staff through the risk assessment (RA) process for the work they regularly perform. Throughout this process, a mindset of "what COULD go wrong" should be maintained. The goal of the RA process is to identify and minimize all potential risks that may adversely affect 1) the health and safety of laboratory staff, 2) the health and safety of non-laboratory staff, 3) the health and safety of the general public, and 4) the quality of work being performed. For additional information on biosafety and the RA process, please refer to the list of resources provided in this document.

Step 1. Identify the hazards.

Please select ALL potential hazards listed below that could affect the laboratory section being assessed. Where appropriate, provide additional details describing specific hazards. If more space is needed, please attach extra page(s).

Biological
☐ Blood/Body fluid ☒ Bacteria ☒ Viruses ☐ Parasites ☐ Fungus ☐ Toxins ☒ Waste ☐ Other/Details: Enter other biological hazards or details here.
Chemical (Refer to the label and Safety Data Sheet (SDS) for the classification and management of all chemicals)
☐ Non-hazardous chemical(s) ☒ Hazardous Chemicals ☒ Waste ☐ Other/Details: Enter other chemical hazards or details here.
Radiological (includes ultraviolet light sources)
☐ External radiation sources (resulting from close proximity to, limited shielding of, or prolonged exposure to source) ☐ Internal radiation sources (e.g. resulting from ingestion, inhalation, inoculation, or skin absorption) ☐ Waste ☐ Other/Details: Enter other radiological hazards or details here.
Physical and Environmental
☒ Heat ☐ Cold ☐ Sharps ☐ Loud noise ☒ Electrocution ☐ Allergens ☐ Pinch/crush/scrape ☐ Repetitive movements (e.g. bending, crouching, pipetting) ☐ Heavy lifting ☐ Reaching ☐ Slip/trip/fall ☐ Other/Details: Enter other physical/environmental hazards or details here.
Procedure, Equipment, and Instrumentation
☒ Aerosols ☒ Splash/splatter/spray ☒ Vapors ☐ Steam ☒ Small volume spills ☐ Large volume spills ☒ Surface contamination ☐ Explosion (contents under pressure) ☐ Projectiles (e.g. failed centrifuge) ☐ Other/Details: Enter other procedure/equipment/instrumentation hazards or details here.
Facilities and Systems
☐ Electricity (e.g. power outage) ☐ Gas (e.g. interior lines) ☐ Pressurized gas (e.g. gas cylinders) ☒ Air handlers/HVAC ☐ Other/Details: Enter other facilities/systems hazards or details here.
Critical Incident
☐ Fire ☐ Severe weather ☐ Intruder ☐ Lockdown ☐ Evacuation ☐ Disruption ☐ Other/Details: Enter other critical incident hazards or details here.
People
☐ Students ☐ Visitors ☐ Staff ☐ Psychological/Stress ☐ Other/Details: Enter other people hazards or details here.
Other hazards and/or additional details (if more space is needed, please attach an additional page(s))
Please provide additional hazard details here.

Step 2. Assess the level of risk.

Use tables A through C below to assess the risk level associated with each hazard identified in Step 1, above.

Table A. Likelihood of hazard occurrence.

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

Table B. Consequence of hazard occurrence.

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

Table C. Based on the likelihood and consequence determined above, identify the risk level of each hazard using the Risk Assessment Matrix below.

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

Table D. Based on the assessed risk level for each hazard, determine whether additional control measures should be implemented.

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

Step 3. Identify control measures and complete the Laboratory Risk Management Worksheet.

Using the following guidance, complete the Laboratory Risk Management Worksheet found in Appendix A.

A. List the specific task being performed.
B. List the identified hazard associated with that task.
C. List the risk level determined for that hazard in Step 2, above.
D. Describe the control measure you will implement to eliminate or mitigate the risk. **Note:** Control measures should be implemented in accordance with the preferred **hierarchy of control** (see Table E below). If a lower level control measure (such as Administrative Controls or PPE) is to be implemented without higher level controls, it is important that the reasons are approved by supervisor.
E. List the risk level (refer to Steps 1 and 2) remaining with the described control measure in place.
F. Describe how the described control measure will be implemented (e.g. implement precautions into SOP and/or ensure employees are trained in hazards/precautions).
G. Describe how this control measure will be supervised (e.g. daily by supervisor, monthly by safety committee, annually by associate director).

NOTE: The Laboratory Risk Management Worksheet should be completed by laboratory staff who regularly perform the work being assessed. The completed worksheet should then be reviewed and signed by the section supervisor and the division associate director.

Table E. Hierarchy of Control Measures

Most Effective (High Level)	**Engineering/Design Controls**	**Elimination:** remove the hazard completely from the workplace or activity
		Substitution: replace a hazard with a less dangerous one (e.g. a less hazardous chemical)
		Redesign: make equipment or processes safer (e.g. raise a bench to reduce bending)
		Isolation: separate people from the hazard (e.g. perform work in biosafety cabinet)
	Administrative Controls	**Administration:** putting rules, signage, or training in place to make a workplace safer (e.g. blood borne pathogens training)
Least Effective (Low Level)	**Personal Protective Equipment (PPE)**	**PPE:** Protective clothing and equipment (e.g. gloves, lab coat, safety glasses, respirator)

Step 4. Monitor and review the control measures and complete the Risk Management Hotwash Worksheet.

After performing work with the implemented control measures identified in Step 3 above, complete the Risk Management Hotwash Worksheet found in Appendix B.

NOTE: The Risk Management Hotwash Worksheet should be completed by laboratory staff who regularly perform the work being assessed. The completed worksheet should then be reviewed and signed by the section supervisor and the division associate director.

Nucleic Acid Risk Assessment

Appendix A

PUBLIC HEALTH LABORATORY RISK MANAGEMENT WORKSHEET

For instructions on use of this form, see guidance information above. Determine risk levels using the Risk Assessment Matrix above.

LABORATORY SECTION AND/OR PROCEDURE: Molecular Non-culture Procedures | **DATE PREPARED: 08/2022**

PREPARED BY: Biosafety Competencies Workshop | **TITLE/POSITION:** Enter your title or position here.

A. TASK	B. HAZARD	C. INITIAL RISK LEVEL	D. CONTROL MEASURES	E. RESIDUAL RISK LEVEL	F. HOW TO IMPLEMENT (WHAT IS NEEDED)	G. WHO IS RESPONSIBLE
Centrifuging specimen	Opening tubes and pouring off supernatant - Biological exposure from aerosols, droplets, splashes, and splatter Tube breakage - Biological exposure; Percutaneous injuries Centrifuge - Electrical shock, electrical burns, other injuries	Medium	Engineering Controls: Certified Class II biological safety cabinet; sealed biosafety centrifuge cups and rotors; O-ring screw capped microcentrifuge tubes Administrative Controls: Annual certification for Class II biological safety cabinet; Annual maintenance and certification for centrifuge; Training Plan for Molecular SOP; Technical Competency Assessment for Molecular SOP; Vaccinations for Hepatitis B Virus and other pathogens; Respiratory Clearance Program for users of PAPRs Practices and Procedures: Molecular SOP; Biosafety Plan; Work in a certified Class II biological safety cabinet; Sealed biosafety centrifuge cups and rotors must be used; Samples are to be loaded inside a biological safety cabinet, transferred to the centrifuge, and reopened inside a biological safety cabinet after a period of settling time; Use O-ring screw capped tubes and ensure each cap is closed tightly PPE for BSL-2: Nitrile gloves; closed-front lab coat; safety glasses; solid-front, back-closing lab gown over lab coat when using biological safety cabinet PPE for BSL-3: Tyvek jumpsuit; double nitrile gloves; hair cover; shoe covers; HEPA filtered PAPR with full face hood	Low	Precautions and procedures are described in the Molecular SOP and Biosafety Plan. All staff are trained and competent in the procedures, and follow established lab practices. Staff are trained and competent in the use of the biological safety cabinet and donning/doffing PPE.	Laboratory Supervisor, Biosafety Staff, Occupational Health Staff
Nucleic acid extraction (pipetting, centrifuging, vortexing, heating)	Pipetting, centrifuging, vortexing, and heating - Biological exposure from aerosols, splashes, and splatter Pressure/vapors by heating -	High	As above, with additions listed below. Engineering Controls: Aerosol resistant tips for micropipettors; sealed biological transport containers Practices and Procedures: Chemical Hygiene Plan; Follow Standard Precautions and treat any human specimen as potentially infectious material; Perform all work prior to lysis step inside a certified Class II biological safety cabinet; Use micropipettors with aerosol resistant tips for fluids possibly containing nucleic acids; Make sure the O-ring is in place on	Low	As above, with the additions below. Precautions and procedures are described in the Chemical Hygiene Plan. Follow Standard Precautions.	Laboratory Supervisor

A. TASK	B. HAZARD	C. INITIAL RISK LEVEL	D. CONTROL MEASURES	E. RESIDUAL RISK LEVEL	F. HOW TO IMPLEMENT (WHAT IS NEEDED)	G. WHO IS RESPONSIBLE AND WHEN WILL IT BE DONE
	Chemical – skin, eye, and respiratory irritation, flammable Incubator or heating block - Burn injuries from hot surfaces; Electrical shock and electrical burns		each cap and close tightly to prevent aerosols from escaping during heating; Do not wet rims on filter tubes to ensure a tight seal; Filter extracts; Use biological transport containers to move tubes in and out of biological safety cabinet and between laboratory areas when not centrifuging			
Vortexing, while extracting specimens in BSL-2 laboratory	Vortexing - Biological exposure from aerosols and droplets Vortex mixer - Electrical shock and electrical burns	Medium	As above for Centrifuging specimen and Nucleic acid extraction.	Low	As above for Centrifuging specimen and Nucleic acid extraction.	Laboratory Supervisor
Vortexing, while extracting specimens in BSL-3 containment laboratory	Vortexing - Biological exposure from aerosols and droplets Vortex mixer - Electrical shock and electrical burns	Medium	As above for Centrifuging specimen and Nucleic acid extraction, with additions listed below. Engineering Controls: BSL-3 containment laboratory with BSL-3 HVAC system Practices and Procedures: Place vortex mixer in a certified Class II biological safety cabinet	Low	As above for Centrifuging specimen and Nucleic acid extraction, with addition listed below. Staff are trained and competent in BSL-3 laboratory operations.	Laboratory Supervisor
Pipetting, while extracting specimens in BSL-2 laboratory	Pipetting - Biological exposure from aerosols and droplets Micropipettor tips - Percutaneous injuries	Medium	As above for Centrifuging specimen and Nucleic acid extraction.	Low	As above for Centrifuging specimen and Nucleic acid extraction, with addition listed below. Staff are trained and competent in pipetting.	Laboratory Supervisor

A. TASK	B. HAZARD	C. INITIAL RISK LEVEL	D. CONTROL MEASURES	E. RESIDUAL RISK LEVEL	F. HOW TO IMPLEMENT (WHAT IS NEEDED)	G. WHO IS RESPONSIBLE AND WHEN WILL IT BE DONE
Pipetting, while extracting specimens in BSL-3 containment laboratory	Pipetting - Biological exposure from aerosols and droplets Micropipettor tips - Percutaneous injuries	Medium	As above for Centrifuging specimen and Nucleic acid extraction, with additions listed below. Engineering Controls: BSL-3 containment laboratory with BSL-3 HVAC system Practices and Procedures: If high risk biological agent is suspected, work must be performed in a BSL-3 containment laboratory.	Low	As above for Centrifuging specimen and Nucleic acid extraction, with additions listed below. Staff are trained and competent in pipetting and BSL-3 laboratory operations.	Laboratory Supervisor
Extraction, addition of chemical reagents	Aliquoting strong acids and organic solvents l – skin, eye, and respiratory irritation, flammable Opening tubes, pouring off supernatant, vortexing, and pipetting - Biological exposure from aerosols, splashes, and splatter; Chemical exposure	Low	As above for Centrifuging specimen and Nucleic acid extraction, with additions listed below. Engineering Controls: Certified chemical fume hood Administrative Controls: Chemical Safety Data Sheets for Molecular SOP reagents and decontamination chemicals; Chemical inventories where Molecular SOP is performed; Annual certification for chemical fume hood Practices and Procedures: Chemical Hygiene Plan; Limit volumes of chemicals handled in certified Class II biological safety cabinet Note: Risk of chemical exposure is low because of small volumes and low concentrations of chemical hazards.	Low	As above for Centrifuging specimen and Nucleic acid extraction, with additions listed below. Precautions and procedures are described in the Chemical Hygiene Plan. Staff are trained and competent in the use of the chemical fume hood and pipetting.	Laboratory Supervisor

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Competency Guidelines for Public Health Laboratory Professionals

CDC and the Association of Public Health Laboratories

Supplement

TABLE 9. (*Continued*) Public health laboratory competency guidelines: Safety domain

Safety subdomain: hazard control*

SHC 3.00. Personal Protective Equipment (PPE):* employs the selection, use, and care of personal protective equipment while being continually mindful of its limitations

Subcompetency	Beginner	Competent	Proficient	Expert
SHC 3.01. PPE selection	Describes appropriate PPE and its limitations for jobs assigned	Selects appropriate PPE for jobs assigned	Develops procedures for the appropriate selection of PPE	Ensures staff knowledge of procedures for the appropriate selection of PPE
SHC 3.02. PPE use	Describes specific PPE and its limitations for use with each laboratory procedure	Uses specific PPE for each laboratory procedure	Determines procedures for use of specific PPE	Ensures staff compliance with procedures for use of specific PPE
SHC 3.03. PPE inspection	Describes pre-and postinspection procedures for PPE	Implements pre-and postinspection procedures for PPE	Develops pre-and postinspection procedures for PPE	Ensures staff knowledge of pre-and postinspection procedures for PPE

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Applicable competencies for this SOP?

SOP	Potential Competencies
Perform work inside BSC	**SHC 1.00 Engineering controls** **SHC 2.00 Safe work practices** **SHC 3.00 Personal Protective Equipment (PPE)** • SHC 3.01 PPE selection • SHC 3.02 PPE use • SHC 3.03 PPE inspection
Extracting specimens from primary matrices	**SPH 2.00 Biological Materials** • SPH 2.01 Biological materials used in the laboratory • SPH 2.02 Hazards associated with biological materials handled in the laboratory • SPH 2.03 Control measures to be used when working with biological materials • SPH 2.04 Work practices to be used for working with biological materials • SPH 2.05 Hazards associated with laboratory procedures
Extracting isolates	Same as above
Extraction / PCR Chemicals • Ethanol • Proprietary Reagents (w/GuHCl) • Proteinase • Bleach • PCR Reagents	**SPH 4.00 Chemical Materials** • 4.01 chemicals used in lab • 4.02 hazards associated with chemicals used in lab • 4.03 controls measures to be used with chemicals in lab • 4.04 work practices to be used when using chemicals in lab

BIOSAFETY COMPETENCIES TABLE EXAMPLE

Monkeypox Nucleic Acid

HAZARDS AND MITIGATION FROM BIOSAFETY RISK ASSESSMENT	SAFETY COMPETENCIES IDENTIFIED	WHAT IS NEEDED IN THE SAFETY SECTION OF THE SOP	SAFETY COMPETENCE ASSESSMENTS

BIOSAFETY COMPETENCIES TABLE EXAMPLE
Monkeypox Nucleic Acid

HAZARDS AND MITIGATION FROM BIOSAFETY RISK ASSESSMENT	SAFETY COMPETENCIES IDENTIFIED	WHAT IS NEEDED IN THE SAFETY SECTION OF THE SOP	SAFETY COMPETENCE ASSESSMENTS
• Biological Hazards • Chemical Hazards • Engineering Controls • Administrative Controls • Practices and Procedures • PPE	Safety Subdomains • Potential Hazards • Hazard Control • Safety Communication and Training	• What procedures to perform in the BSC • Engineering controls • Administrative controls • Practices and procedures • PPE • Training needs	• Written or Oral Knowledge Assessment • Observation

BIOSAFETY COMPETENCIES TABLE
EXAMPLE: Monkeypox Nucleic Acid Extraction

HAZARDS & MITIGATION FROM BIOSAFETY RISK ASSESSMENT	SAFETY COMPETENCIES IDENTIFIED	WHAT IS NEEDED IN THE SAFETY SECTION OF THE SOP	SAFETY COMPETENCE ASSESSMENTS
• Biological Hazards: aerosolization, spill/splash, potential pathogens, Assessment of potential risk group (High, medium or low probability), aerosol tight rotor for centrifugation, Training on biological agents and methods • Chemical Hazard: -GuHCl, ethanol; Bleach; Chemical hygiene plan and SDS; Training on chemicals and methods • Engineering Controls: BSC, Fume hood • Practices and Procedures: Standard Precautions, Work inside BSC or fume hood, clean spills with 10% bleach and ethanol • PPE: Lab coat, safety glasses and chemical resistant gloves	**SHC 1.00 Engineering controls** **SHC 2.00 Safe work practices** **SHC 3.00 PPE** • SHC 3.01 PPE selection • SHC 3.02 PPE use • SHC 3.03 PPE inspection **SPH 2.00 Biological Materials** • SPH 2.01 Biological materials used in the laboratory • SPH 2.02 Hazards associated with biological materials handled in the laboratory • SPH 2.03 Control measures to be used when working with biological materials • SPH 2.04 Work practices to be used for working with biological materials • SPH 2.05 Hazards associated with laboratory procedures **SPH 4.00 Chemical Materials** • 4.01 chemicals used in lab • 4.02 hazards associated with chemicals used in lab • 4.03 controls measures to be used with chemicals in lab • 4.04 work practices to be used when using chemicals in lab	• Disposable instructions for hazardous chemical waste. • Extraction needs to be performed in a BSC, preferably ducted. • Double gloves and Lab Coat are needed for reagent preparation and extraction. • Disposable gloves, closed toe shoes, and lab coat are required for extraction. • Hazardous characteristics of chemicals – refer to SDS **Training Required:** • Unit Specific Training (Technical Test Training) • Lab Safety: Blood-Borne pathogen training, Biosafety, Chemical Safety • Biological Safety Cabinet	• Written or oral identification of Biological and Chemical Hazards • Written or oral identification of risk mitigation for hazards – engineering controls, admin, PPE, work practices. • Written or oral identification of proper spill procedures and proper reporting/notification and waste disposal procedure. • Observation of Proper use of the BSC, use of PPE and donning/doffing procedures, and setup and decontamination of workspace.