

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.

RISK ASSESSMENT

Yes	No	Not Applicable		RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a written policy and/or a standard operating procedure (SOP) for performing risk assessments?	Biological Risk Assessment Guidelines can be found on pages 7-12 of CDC's Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Do risk assessments consider both agent hazards and laboratory procedure hazards?	An example Risk Assessment form can be found on CDC's Biosafety Website .	It is recommended that at a minimum risk assessments include: <ul style="list-style-type: none"> an assessment of risks associated with specimen source and likely organisms method of transmission, route of exposure, infectivity and infectious dose test requested from submitter epidemiological information such as symptoms, travel history, and occupation risk factors and experience of individual performing the assay when assays require inactivating BSL-3/4 agents and bringing them out to a BSL-2 for testing
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Has the person performing the risk assessment received training and are they experienced in risk assessments?		Examples of trainings include the American Society of Clinical Pathology's "Using Risk Analysis to Assess Biosafety" and the American Biological Safety Association's " ABSA Advanced Biosafety Training Series Module 1 "
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is a risk assessment performed when: <ul style="list-style-type: none"> new assays are introduced? new methods are introduced? equipment is moved? new equipment is introduced? the potential for aerosolization is introduced? the potential for needlesticks is introduced? a laboratory is physically moved? a new pathogen is detected? staffing changes? 		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are risk assessments conducted annually for assays performed in the laboratory?		

SELECTION OF SAFETY PRACTICES

BIOSAFETY LEVEL					
Yes	No	Not Applicable		RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are biosafety levels chosen based on risk assessments for every assay performed in your laboratory?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are biosafety levels selected based on the BMBL recommendations?	More information on the selection of biosafety level is available on pages 22-59 of CDC's BMBL 5th Edition	
ENGINEERING CONTROLS					
Yes	No	Not Applicable		RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there controlled access to biosafety level 2, 3, and 4 laboratories?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the following certified at least annually? <ul style="list-style-type: none"> • Biosafety Cabinets (BSCs) • Autoclaves • HVAC • HEPA Filters* • BSL-3 Suites 	More information can be found on page 311 of CCD's BMBL 5th Edition and on pages 32-35 of APHL's Mycobacterium tuberculosis: Assessing Your Laboratory .	Biosafety cabinets should be certified annually and also be certified when they are moved >18 inches, initially installed, and if they are repaired/serviced. *
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are BSCs used effectively including the following?: <ul style="list-style-type: none"> • Are BSCs free of clutter and the front grate kept clear? • Are closed centrifuge carriers opened only in the BSC? • If there are vacuum lines in BSCs are they protected with liquid trap or an in-line HEPA filter? 		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the eye wash and shower stations flushed and checked weekly?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are centrifuge rotors sealed with O-rings to prevent aerosolization?	More information is available in CDC's BMBL 5th Edition	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are autoclaves tested for efficacy using biological or chemical indicators on a regular basis?		The schedule for autoclave efficacy testing should be based on autoclave usage.

PERSONAL PROTECTIVE EQUIPMENT (PPE)					
Yes	No	Not Applicable		RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is basic PPE provided for all personnel working in the laboratory? (basic PPE includes gloves, laboratory coats or gowns, protective eyewear or face protection, etc)		The National Personal Protective Technology Laboratory at CDC has a webpage dedicated to considerations for selecting personal protective equipment and a webpage dedicated to respirator users .
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are laboratory coats available for all staff who may enter a laboratory?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a written policy for when to change gloves?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a written procedure for appropriate donning and doffing PPE including laboratory coats, gloves, protective eyewear, face shields, N95 and/or PAPRs?	CDC's Sequence for Putting on and Removing Personal Protective Equipment is available here . CDC's Personal Protective Equipment (PPE) DVD and Poster Package is available for purchase here .	The written plan should include instructions indicating PPE should be removed before exiting the laboratory.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are N95 respirators or PAPRs available to appropriately trained staff to use in BSL-3 laboratories and/or when working with organisms requiring their use?	Additional respiratory protection training is available on OSHA's website .	OSHA requires that laboratories have a written respiratory protection plan.

LABORATORY PRACTICES/POLICIES					
Yes	No	Not Applicable		RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a policy in place for hand washing?	An example policy can be found on page 30 of CDC's BMBL 5th Edition . CDC's Hand Hygiene in Healthcare Settings Interactive Trainings are available here	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a policy in place ensuring procedures that may induce aerosolization be performed in a biosafety cabinet (BSC)?	More information can be found on page 311 of CCD's BMBL 5th Edition	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a policy in place for safe handling of sharps?	More information can be found in OSHA's Bloodborne Pathogen Standard 1910.1030 .	An example Sharps Disposal Evaluation form can be found on OSHA's website .
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a policy in place for proper disposal of biomedical waste and sharps?	More information on disposal of biomedical waste can be found in the National Academies Biosafety in the Laboratory: Prudent Practices for Handling and Disposal of Infectious Materials (pages 34-45)	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a policy in place for decontaminating surfaces after completion of work?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are biological spill kits available and readily accessible to all laboratory personnel?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a policy (SOP) in place for inactivating BSL3/4 agents prior to moving them to BSL-2 for testing?		

BIOSAFETY LABORATORY COMPETENCIES

Yes	No	Not Applicable		RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Do laboratory personnel receive training in the Biosafety Laboratory Competencies as outlined in the CDC's MMWR, Guidelines for Biosafety Laboratory Competency?	CDC's MMWR, Guidelines for Biosafety Laboratory Competency can be found here	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are the Biosafety Laboratory Competencies used for annual staff reviews?		

SAFETY ORIENTATION AND TRAINING

Yes	No	Not Applicable		RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Do all new personnel receive safety training before they begin working in their assigned laboratory?	An example training schedule can be found on pages 51-53 of CLSI's Clinical Laboratory Safety; Approved Guideline-Third Edition .	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there an annual biosafety training program for all personnel?	Annual biosafety training programs can include: <ul style="list-style-type: none"> • Risk Assessments • Biosafety level • Biosafety Laboratory Competencies • Occupational Health • etc 	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there annual training program on appropriate donning and doffing of PPE including laboratory coats, gloves, protective eyewear, face shields, N95 and/or PAPRs based on the risk of a given procedure?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there an annual blood borne pathogen training program for all personnel?	More information can be found in OSHA's Bloodborne Pathogen Standard 1910.1030 .	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are personnel offered appropriate vaccinations for working in their assigned laboratory?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	During pre-employment physical, is baseline serum collected as necessary to document potential occupational exposures?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are trained employees required to have an annual N-95 respirator fit test if indicated?		

AUDITS, MONITORING AND SAFETY COMMITTEE

Yes	No	Not Applicable		RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there an institutional biosafety plan?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a designated Laboratory Biosafety Officer?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there an institutional biosafety committee or similar group?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Does the institutional biosafety committee or similar group meet at established time intervals?	Discussion items include, but are not limited to breaches in biosafety, corrective actions, maintenance issues related to biosafety, and pending certifications of equipment.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are internal safety audits performed at least annually and after significant safety breaches?	An example safety audit form can be found here .	The College of American Pathologists (CAP) recommends under GEN.73400 that a review of safety practices occur at least annually.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are biosafety drills and exercises performed at predetermined intervals?	Examples of drills and exercises can be found in the BMBL 5th Edition on page 112.	Drills and exercises can include: <ul style="list-style-type: none"> • loss or theft of materials • emergency response to accidents and injuries • incident reporting and identification of and response to security breaches
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are there procedures in place to detect safety breaches when they occur?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a system to report safety breaches to laboratory leadership?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a procedure specifying how biosafety breaches will be addressed and which staff are responsible for addressing them?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a system in place for performing root cause analysis of safety breaches?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are corrective actions implemented when breaches in biosafety are identified?		

ADMINISTRATIVE CONTROLS

Yes	No	Not Applicable		RESOURCES	COMMENTS
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Are biohazard signs posted by the entrance of laboratories where infectious agents are processed and tested and in other areas where indicated?		Biohazardous materials should be labeled as such.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a policy restricting eating, drinking, storing food, applying cosmetics and handling contact lenses to areas outside of the laboratory?		
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there an occupational health program?	Examples and minimum requirements can be found on pages 49-51 of CLSI's Clinical Laboratory Safety; Approved Guideline—Third Edition .	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Is there a medical surveillance program in place in the event of exposure to an infectious agent?		

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) is a national nonprofit dedicated to working with members to strengthen laboratories with a public health mandate. By promoting effective programs and public policy, APHL strives to provide public health laboratories with the resources and infrastructure needed to protect the health of US residents and to prevent and control disease globally.

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National Center for Immunization and Respiratory Diseases (IP)

Office of Surveillance, Epidemiology and Laboratory Services (OSELS)

National Center for HIV, Viral Hepatitis, STDs and TB Prevention (PS)

National Center for Zoonotic, Vector-borne, and Enteric Diseases (CK)

National Center for Environmental Health (NCEH)

Coordinating Office for Terrorism Preparedness and Emergency Response (CTPER)

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