



Vision: To be the Healthiest State in the Nation

Biosafety Risk Assessment: General Considerations Worksheet

This is intended to be used in conjunction with the “Conducting a Biosafety Risk Assessment” Standard Operating Procedure. This worksheet is meant to be used in the “Analysis of Overall Procedural Considerations” step and will aid in the evaluation of overall procedural considerations, including ones specific to the procedure being considered, the laboratory unit/section/department, and the institution.

Overview

1. For considerations listed in a yes/no/N/A format, choose one of the three answers and provide a comment if desired.
 - 1.1. If a consideration isn’t applicable to the procedure, laboratory unit/section/department, or institution in question, choose “N/A” (not applicable).
2. For free-response considerations, write in the appropriate answer.
 - 2.1. If a consideration isn’t applicable to the procedure, laboratory unit/section/department, or institution in question, write “N/A” (not applicable).
3. The **source** providing the origin of each consideration is included in the last column (**‘S’**). The number of the source corresponds to one of the sources in the Sources section below.

Sources

1. APHL (Association of Public Health Laboratories) A Biosafety Checklist: Developing A Culture of Biosafety (April 2015)
 - 1.1. http://www.aphl.org/AboutAPHL/publications/Documents/ID_BiosafetyChecklist_42015.pdf
2. APHL (Association of Public Health Laboratories) Template for Public Health Laboratory Risk Assessment for Ebola Virus Disease (EVD) Testing
 - 2.1. <http://www.aphl.org/aphlprograms/preparedness-and-response/documents/aphl-template.pdf>
3. CDC (Centers for Disease Control and Prevention) Assessment Tool for Ebola Treatment Centers and Assessment Hospitals 5-18-2015 (v17)
 - 3.1. See <http://sos.ri.gov/documents/publicinfo/omdocs/minutes/1293/2015/41778.pdf> for an example of where this can be found and its intended audience.
4. CDC (Centers for Disease Control and Prevention) MMWR (Morbidity and Mortality Weekly Report) Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories
 - 4.1. <http://www.cdc.gov/mmwr/pdf/other/su6101.pdf>
5. Sandia Report SAND2010-6487 Biosafety Risk Assessment Methodology (Susan Caskey et al., printed October 2010)
 - 5.1. <http://biosecurity.sandia.gov/BioRAM/Biosafety%20Risk%20Assessment%20Report.pdf>

These resources are the product of research from respected biosafety sources that were combined to help create a biorisk program. Please follow your own professional judgement, your institution's established guidelines, and any applicable local, state, and federal requirements.



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Procedure-specific

These considerations apply to all laboratory units/sections/departments.
 They apply to the specific procedure(s) being assessed.

Consideration	Yes	No	N/A	Comment	S
Biological Safety					
Is there potential for aerosol generation during this procedure?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
↳ If yes, what are the tasks with this potential?					2
Is all the equipment used in this procedure with a potential to generate infectious aerosols (e.g. vortex mixer, centrifuge, sonicator) isolated or sealed in a manner to prevent aerosol escape (e.g. tubes sealed with caps or other covering prior to mixing with a vortex mixer, sealed centrifuge rotor cups, equipment in BSC or in a biobubble, etc) prior to use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Is there a potential for a splash or spill of infectious material in this procedure?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
↳ If yes, what is the potential and extent?					5
↳ If yes, are stand-alone splash guards available?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
↳ If yes, are PPE splash guards available (such as goggles or safety glasses)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are sharps used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
↳ If yes, what is the sharp (needle, blade, pipette tip, etc.)?					2
↳ If yes, does the sharp include a safety device feature?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Does work include a Biological Safety Cabinet (BSC)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
↳ If yes, has the BSC been certified within the past year?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
↳ If yes, are the air vents not blocked?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
↳ If yes, is the sash used at the proper height and operable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
↳ If yes, is it a Class II BSC?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Personal Protective Equipment					
Is respiratory protection required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
↳ If yes, are users enrolled in a respiratory protection program?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Engineering Controls					
Are transport containers used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2



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Biological Safety

These considerations apply to all laboratory units/sections/departments that may handle biological specimens.

Consideration	Yes	No	N/A	Comment	S
What is the biosafety level (BSL) in this unit? (BSL-1, BSL-2, BSL-3, N/A)					2
Are centrifuge rotors sealed with O-rings to prevent aerosolization?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
↳ If yes, are seals checked regularly and documented?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Is absorbent material used for all procedures (on the bench or BSC) and disposed of after each use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Is there a policy in place for safe handling of sharps, including the use of sharps containers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,2
Are proper practices for reducing percutaneous exposure identified in the laboratory procedures, taught, and verified on a regular schedule?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Is the use of needles and syringes limited to procedures for which there are no alternative methods?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is the resheathing of needles prohibited?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
↳ If resheathing is absolutely required, does procedure utilize a needle resheathing device?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is the use of needle-cutting devices prohibited?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is there a large amount of breakable material (especially glassware) or items with sharp edges in this laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
↳ If yes, what are the greatest concerns for breakage and sharp edges?					5
Are BSCs used effectively including the following:					1
• Are BSCs free of clutter and both the front and back grates kept clear?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• Are closed centrifuge carriers opened only in the BSC?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• 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"/>		1
Are surfaces in the laboratory easy to decontaminate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Are bench tops impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are chairs used in laboratory work covered with a nonporous material that is easily cleaned?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is there a policy in place for decontaminating surfaces after completion of work?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1



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Consideration	Yes	No	N/A	Comment	S
Are work surfaces decontaminated with an appropriate disinfectant after completion of work and after any spill or splash of potentially infectious material?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are instructions for disinfecting a laboratory work bench part of each SOP?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
↳ If yes, do these include what PPE to wear, how to clean surfaces, what disinfectant to use, disinfectant contact time, and how to dispose of cleaning materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are disinfectants recommended for environmental surfaces (such as EPA-registered disinfectants effective against hepatitis B virus, HIV, and other bloodborne pathogens or a 1:10 dilution of household bleach) used for disinfecting surface areas?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are biosafety levels chosen based on risk assessments for every assay performed in your laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is there controlled access to biosafety level 2, 3, and 4 laboratories?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Are eating, drinking, storing food or beverages, chewing gum, applying cosmetics, handling contact lenses, and smoking prohibited in the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,4
Does the laboratory have a sink for hand washing, preferably located near the laboratory exit?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is there a policy in place for hand washing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,4
↳ If yes, does it require the washing of hands after working with potentially hazardous materials and before leaving the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,4
Are hands always decontaminated prior to handling "Clean" objects, such as door handles and computer keyboards?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Are protective covers for computer keyboards used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
↳ If yes, are they easily cleanable and routinely disinfected along with the bench top, at least at the end of the work shift?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is there a policy restricting touching eyes, nose, mouth, and lips while in the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is there a policy restricting placing pens, pencils, safety glasses, or other laboratory items in the mouth or against the lips?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is mouth pipetting prohibited?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4



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Consideration	Yes	No	N/A	Comment	S
Is there a policy requiring flushing for a minimum of 15 minutes after all splashes to the eye?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is health monitoring performed in this Unit?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
↳ <i>If yes, what is the frequency and process?</i>					2
Are gloves worn in the diagnostic laboratory considered potentially contaminated and placed into biohazard disposal containers when discarding?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is equipment decontaminated prior to being maintained or repaired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
↳ <i>If yes, is the process documented and validated?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Have laboratory directors and supervisors assessed the exposure risks associated with use of laboratory documents and reference materials in the dirty areas of the laboratory and developed use policies to minimize those risks?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are all biological agents inventoried?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5



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Chemical Safety

These considerations apply to all laboratory units/sections/departments.

Consideration	Yes	No	N/A	Comment	S
Is regular training conducted in hazard communication and chemical hygiene?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Proper labeling: Are all containers labeled with the name of chemical?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Is the fire department permit posted on the laboratory door?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Is there an updated chemical inventory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are (material) safety data sheets (SDS/MSDS) accessible to staff?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are incompatible chemicals segregated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are flammable liquids stored in rated chemical cabinets?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are flammable liquids stored in flammable-rated refrigerators/freezers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are excess chemicals stored in chemical storage room?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are compressed gas cylinders stored in laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
<i>↳ If yes, are they properly secured?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are chemicals stored at eye-level?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are acids and bases stored in a cabinet?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are acids and bases stored in a labeled area?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are acids and bases stored free from metals?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are chemical fume hoods certified within past year?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Do chemical fume hoods have their sash closed when not in use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Is the exhaust air of chemical fume hoods not blocked by large equipment or containers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are chemical fume hoods used for hazardous/toxic or flammable procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2



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Personal Protective Equipment

These considerations apply to all laboratory units/sections/departments.

Consideration	Yes	No	N/A	Comment	S
Is basic personal protective equipment (PPE) provided for all personnel working in the laboratory? (Basic PPE includes gloves, laboratory coats or gowns, protective eyewear or face protection, etc.)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Do staff receive annual PPE competency assessment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Is there a formal PPE program in place, including well-defined written procedures for donning, doffing, storing, and maintaining PPE, including laboratory coats, gloves, protective eyewear, face shields, N95 and/or PAPRs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,5
↳ If yes, does the written plan include instructions indicating PPE should be removed before exiting the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,5
Is PPE appropriately stored in laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Is PPE inspected prior to use and in good condition?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Is all PPE (including gloves, safety glasses, respirators, laboratory coats, etc.) not worn outside of laboratory area?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2,4
Are laboratory coats and gowns worn to prevent exposure of street clothing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are laboratory coats available for all staff who may enter a laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Are cryo or autoclave gloves used?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
↳ If autoclave gloves are used, are they thick, elbow-length, heat-resistant, and liquid-impervious?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are closed-toe shoes that cover entire foot worn in laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are gloves or bandages worn to protect non-intact skin?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are proper practices for reducing/eliminating contact exposure through broken skin identified in the laboratory procedures and taught and verified on a regular basis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Are gloves worn when handling potentially contaminated materials, containers, equipment, or surfaces?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is there a written policy for when to change gloves?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Are gloves discarded after each use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are various sizes of gloves provided?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4



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Consideration	Yes	No	N/A	Comment	S
Are gloves provided made of different materials (e.g., nitrile, chloroprene) for employees who have skin sensitivity?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are extra-safe glove practices employed while using sharps (e.g. needles, scalpels, etc.), including wearing two pairs of latex or nitrile type gloves or wearing heavy gloves (e.g. leather or thick rubber gloves)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Are eye and face protection (goggles, mask, face shield, or other splatter guard) used whenever a splash or spray event could occur, includes opening containers and pipetting, manipulating, aliquoting, or testing specimens, cultures, biological agents, or other hazardous materials outside the BSC?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4



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Emergency Preparedness

These considerations apply to all laboratory units/sections/departments.

Consideration	Yes	No	N/A	Comment	S
Is emergency contact information posted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Is a first aid kit maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are biological spill kits available, readily accessible to all laboratory personnel, and maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,2
↳ <i>If yes, are personnel regularly trained in their use?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Are chemical spill kits available, readily accessible to all laboratory personnel, and maintained?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,2
↳ <i>If yes, are personnel regularly trained in their use?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Does the lab have validated and exercised spill response procedures, including spill response kits (which contain appropriate PPE, cleaning items, and other required items), training on spill response, plans for validation of spill cleanup, spill response SOPs, and spill response decontamination mechanisms including waste validation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Is there a procedure in place if a potentially infectious aerosol release occurs outside a BSC?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
↳ <i>If yes, does the procedure include:</i>					4
• <i>Having all persons immediately vacate the laboratory unit where the spill occurred?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• <i>Referral of exposed persons for medical advice and evaluation?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• <i>Informing the laboratory supervisor and biosafety officer of the situation immediately?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• <i>Instructions to ensure no one enters the room for at least 30 minutes to allow aerosols to be carried away and heavier particles to settle?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• <i>A further delayed entrance (e.g., up to 24 hours) if the laboratory does not have a central air exhaust system?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• <i>Posting signs indicating that entry is forbidden?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• <i>Decontamination, supervised by the biosafety officer, after the appropriate time?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• <i>Appropriate PPE must be worn, which may include respirators?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are there standard operating procedures in place for unexpected or catastrophic incidents, including the release of or exposure to an infectious agent (e.g. Incident response plans)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Are staff aware of occupational injury procedures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2



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Consideration	Yes	No	N/A	Comment	S
Are the eye wash and shower stations flushed and checked weekly?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Does the institution conduct biosafety drills or exercises at predetermined intervals, including tabletop exercises, annual exercises, and exercises that include external responders?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,5
Are there procedures in place to detect safety breaches when they occur?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is there a system to report safety breaches to laboratory leadership?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
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"/>		1
Are corrective actions implemented when breaches in biosafety are identified?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is there an occupational health program?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is there a medical surveillance program, including well-defined procedures and plans, in place in the event of exposure to an infectious agent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,5
Are there procedures in place for preventative equipment maintenance to reduce/eliminate accidents or equipment failure?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
↳ If yes, do these include equipment calibration, validation, and certification?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5



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Documentation and Training

These considerations apply to all laboratory units/sections/departments.

Consideration	Yes	No	N/A	Comment	S
Have employee(s) completed right-to-know training?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Have employee(s) completed unit-specific training?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Have employee(s) read and understand safety and health plans?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are biohazard signs posted by the entrance of laboratories where infectious agents are processed and tested and in other areas where indicated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is the door sign up-to-date and posted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Does equipment such as centrifuges, incubators, freezers involved in the use and storage of infectious materials have the biosafety label affixed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Is there a policy restricting the storage of food or beverages for human consumption in the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are laboratory microwaves and refrigerators labeled with "Not for Food or Drink – Biohazard"?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Is there an institutional biosafety plan?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Does the institution have comprehensive biosafety documentation, including biosafety policies, manuals, SOPs, and risk assessment and incident response information?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Does the institution periodically review the biosafety program, including assessing opportunities for improvement and any needs for changes to the system, procedures, policies, and objectives?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Is there a designated Laboratory Biosafety Officer?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is there an institutional biosafety committee or similar group?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Does the institutional biosafety committee or similar group meet at established time intervals?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
↳ If yes, does the group discuss breaches in biosafety, corrective actions, maintenance issues related to biosafety, and pending certifications of equipment?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Are internal safety audits performed at least annually and after significant safety breaches?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is there a written policy and/or a standard operating procedure (SOP) for performing risk assessments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1



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Consideration	Yes	No	N/A	Comment	S
Do risk assessments consider both agent hazards and laboratory procedure hazards?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Has the person performing the risk assessment received training, and is the person experienced in risk assessments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is a risk assessment performed when:					1
• New assays are introduced?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• New methods are introduced?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• Equipment is moved?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• New equipment is introduced?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• The potential for aerosolization is introduced?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• The potential for needlesticks is introduced?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• A laboratory is physically moved?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• A new pathogen is detected?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• Staffing changes?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Are risk assessments conducted annually for assays performed in the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Do laboratory personnel receive training in the Biosafety Laboratory Competencies as outlined in the CDC's MMWR, Guidelines for Biosafety Laboratory Competency?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Do all new personnel receive safety training before they begin working in their assigned laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is there an annual biosafety training program for all personnel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
↳ If yes, do annual biosafety training programs include:					1
• Risk assessments?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• Biosafety level?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• Biosafety laboratory competencies?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• Occupational health?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is there an annual training program on PPE that covers:					1,4
• When PPE is necessary?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,4
• What PPE is necessary?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,4
• How to properly put on (don), take off (doff), adjust, and wear PPE including laboratory coats, gloves, protective eyewear, face shields, N95 and/or PAPRs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,4
• Limitations of PPE?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,4
• Proper care, maintenance, useful life, and disposal of PPE?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,4
Is there an annual blood borne pathogen training program for all personnel?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1



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Consideration	Yes	No	N/A	Comment	S
Is documentation completed for employee training and competency assessment in medical waste handling for:					4
• Constructing and properly labeling containers for medical waste that require assembly before their use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• Disposing of medical waste in properly labeled containers?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• Use of appropriate supplies (e.g. containers, appropriate plastic bags, labeling)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• Following all federal, state, and local regulations regarding waste management (i.e. handling of medical waste; immediate disposal of medical waste; storage of medical waste; transportation of medical waste, which includes any required Department of Transportation labeling (e.g. the word "Biohazard" and the universal biohazard symbol) of transport containers; and final disposal of medical waste)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Do laboratorians who operate centrifuges have documented training and competency assessments on each type of centrifuge they operate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
↳ If yes, does the documented instruction for each centrifuge type include proper instrument startup and shutdown, emergency procedures and shutdown, balancing of tubes, use of safety cups and covers, rotor and container selection, requirements for high-speed and ultracentrifuges, and container fill-height limitations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are vaccines recommended for work in this Unit?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,2
↳ If yes, how are employees informed of the vaccines?					1,2
↳ If yes, what vaccines are recommended?					1,2
↳ If yes, are personnel offered appropriate vaccinations for working in their assigned laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1,2
During pre-employment physical, is baseline serum collected as necessary to document potential occupational exposures?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is there a needlestick and sharps injury prevention program?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4



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Consideration	Yes	No	N/A	Comment	S
Does the institution have an active shipping and receiving program with well-defined procedures and plans in place?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
↳ <i>If yes, have all individuals involved in packaging and shipping been trained and certified in the last two years?</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		



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Engineering Controls

These considerations apply to all laboratory units/sections/departments.

Consideration	Yes	No	N/A	Comment	S
Is there directional inward airflow from the main laboratory into the microbiology laboratory in newly constructed diagnostic laboratories?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are BSCs continually operated to provide some direction to potential aerosols in a previously constructed laboratory without directional room air?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is a BSC or similar containment device used for procedures with splash or aerosol potential?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are splash guards used at workstations when working with blood cultures and at workstations where the potential for splashing exists?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
For BSCs that vent to the outside, are outside vents placed away from the facility's air intake units?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
If BSCs are used, are there procedures in place for proper use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Are autoclaves located in a well-ventilated area or exhausted through a capture hood above them?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Does the mycobacteriology laboratory have its own autoclave?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are autoclave cycles validated before initial use for effective decontamination of the projected loads?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are autoclaves tested for efficacy using biological or chemical indicators on a regular basis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Are the following certified at least annually:					1
• BSCs?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• Autoclaves?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• HVAC?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• HEPA Filters?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
• BSL-3 Suites?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1



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Waste Management

These considerations apply to all laboratory units/sections/departments.

Consideration	Yes	No	N/A	Comment	S
Does the institution have a waste management plan that includes:					4
• Waste-reduction or minimization program?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• Identification and definition of all categories of waste generated by the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• For each category of waste generated, determination of applicability of federal, state, and local regulations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• Segregation of all regulated waste to prevent access by the public or clients?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• Establishment of a system for reporting and responding to all issues or problems regarding medical waste management?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
• Establishment of treatment and disposal processes, with disposal of regulated waste by a company meeting state and local licensure requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Is there a policy in place for proper disposal of biomedical waste and sharps?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Is there a decontamination facility or medical waste contract in place?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4
Are chemical waste containers labeled with chemical name and percent of each chemical?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Are chemical waste containers properly sealed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2
Is contaminated waste stored properly and handled according to best practices?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		5
Is broken glass placed in appropriate receptacle?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		2



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Hospital with Potential Ebola (EVD) Specimen

These considerations apply to all hospital laboratory units/sections/departments that may handle a specimen that could contain Ebola virus.

Consideration	Yes	No	N/A	Comment	S
Are protocols in place to send specimens for Ebola testing to the nearest Laboratory Response Network (LRN) laboratory capable of testing for Ebola?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3
If the hospital is using a commercial Ebola virus test, are paired specimens submitted to an LRN facility or CDC for definitive Ebola virus testing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3
Is the hospital prepared to provide a timely and minimum menu of testing to ensure patient care is not compromised while patients undergo assessment and prior to availability of Ebola laboratory testing results?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3
↳ If yes, does this include CBC, glucose, potassium, malaria exam, influenza test, and tests for liver function?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3
Are protocols in place for handoff and placement of specimen tubes into appropriate containers for transport to hospital laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3
Have personnel who process primary patient specimens, when Ebola is a concern, demonstrated competency in donning and doffing PPE and processing specimens while wearing PPE?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3
Is there a designated area for laboratory personnel to safely doff PPE?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3
Are protocols in place for cleaning and disinfection of laboratory surfaces and equipment, management of blood and body fluid spills, and exposure of staff?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3
Is a tracking system in place for patient specimens that are transported to the laboratory?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3
Is a policy in place for safe short-term storage and disposal of Ebola patient specimens?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		3



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BSL-3 (Biosafety level 3)

These considerations apply to all biosafety level 3 laboratory units/sections/departments.

Consideration	Yes	No	N/A	Comment	S
Biological Safety					
Is there a policy (SOP) in place for inactivating BSL-3/4 agents prior to moving them to BSL-2 for testing?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Personal Protective Equipment					
Are respirators or PAPRs available to appropriately trained staff to use in BSL-3 laboratories and/or when working with organisms requiring their use?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Documentation and Training					
Are trained employees required to have an annual respirator fit test if indicated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		1
Engineering Controls					
Is the sink provided for hand washing able to be operated hands-free?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		4