**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. 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.
	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 at the end of this worksheet.
4. Considerations with a light gray background color are procedure-specific. All other considerations pertain to the general laboratory unit/section/department and institution.

**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](#source_2_aphl_template_for_evd_testing) |
| Is there potential for aerosol generation during this procedure? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, what are the tasks with this potential?* |  | [2](#source_2_aphl_template_for_evd_testing) |
| 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? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Are centrifuge rotors sealed with O-rings to prevent aerosolization? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| ⮡ *If yes, are seals checked regularly? Is this documented?* |[ ] [ ] [ ]   |  |
| Is there a potential for a splash or spill of infectious material in this procedure? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| ⮡ *If yes, what is the potential and extent?* |  | [5](#source_5_sandia_biosafety_risk) |
| ⮡ *If yes, are stand-alone splash guards available?* |[ ] [ ] [ ]   |  |
| ⮡ *If yes, are PPE splash guards available (such as goggles or safety glasses)?* |[ ] [ ] [ ]   |  |
| Is absorbent material used for all procedures (on the bench or BSC) and disposed of after each use? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Are sharps used? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, what is the sharp (needle, blade, pipette tip, etc.)* |  | [2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, does the sharp include a safety device feature?* |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is there a policy in place for safe handling of sharps, including the use of sharps containers? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[2](#source_2_aphl_template_for_evd_testing) |
| Are proper practices for reducing percutaneous exposure identified in the laboratory procedures, taught, and verified on a regular schedule? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Is the use of needles and syringes limited to procedures for which there are no alternative methods? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is the resheathing of needles prohibited? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| ⮡ *If resheathing is absolutely required, does procedure utilize a needle resheathing device?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is the use of needle-cutting devices prohibited? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is there a large amount of breakable material (especially glassware) or items with sharp edges in this laboratory? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| ⮡ *If yes, what are the greatest concerns for breakage and sharp edges?* |  | [5](#source_5_sandia_biosafety_risk) |
| Does work include a Biological Safety Cabinet (BSC)? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, has the BSC been certified within the past year?* |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, are the air vents not blocked?* |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, is the sash used at the proper height and operable?* |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, is it a Class II BSC?* |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are BSCs used effectively including the following: |  | [1](#source_1_aphl_biosafety_checklist) |
| • Are BSCs free of clutter and both the front and back grates kept clear? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • Are closed centrifuge carriers opened only in the BSC? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • If there are vacuum lines in BSCs, are they protected with liquid trap or an in-line HEPA filter? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Are surfaces in the laboratory easy to decontaminate? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Are bench tops impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are chairs used in laboratory work covered with a nonporous material that is easily cleaned? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is there a policy in place for decontaminating surfaces after completion of work? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Are work surfaces decontaminated with an appropriate disinfectant after completion of work and after any spill or splash of potentially infectious material? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are instructions for disinfecting a laboratory work bench part of each SOP? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| ⮡ *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?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| 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? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are biosafety levels chosen based on risk assessments for every assay performed in your laboratory? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there controlled access to biosafety level 2, 3, and 4 laboratories? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Are eating, drinking, storing food or beverages, chewing gum, applying cosmetics, handling contact lenses, and smoking prohibited in the laboratory? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Does the laboratory have a sink for hand washing, preferably located near the laboratory exit? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is there a policy in place for hand washing? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[4](#source_4_cdc_mmwr_guidelines_for_safe) |
| ⮡ *If yes, does it require the washing of hands after working with potentially hazardous materials and before leaving the laboratory?* |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are hands always decontaminated prior to handling "Clean" objects, such as door handles and computer keyboards? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Are protective covers for computer keyboards used? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| ⮡ *If yes, are they easily cleanable and routinely disinfected along with the bench top, at least at the end of the work shift?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is there a policy restricting touching eyes, nose, mouth, and lips while in the laboratory? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is there a policy restricting placing pens, pencils, safety glasses, or other laboratory items in the mouth or against the lips? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is mouth pipetting prohibited? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is there a policy requiring flushing for a minimum of 15 minutes after all splashes to the eye? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is health monitoring performed in this Unit? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, what is the frequency and process?* |  | [2](#source_2_aphl_template_for_evd_testing) |
| Are gloves worn in the diagnostic laboratory considered potentially contaminated and placed into biohazard disposal containers when discarding? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is equipment decontaminated prior to being maintained or repaired? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| ⮡ *If yes, is the process documented and validated?* |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| 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? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are all biological agents in this laboratory inventoried? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |

**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? |[ ] [ ] [ ]   |  |
| Proper labeling: Are all containers labeled with the name of chemical? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is the fire department permit posted on the laboratory door? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is there an updated chemical inventory? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are (material) safety data sheets (SDS/MSDS) accessible to staff? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are incompatible chemicals segregated? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are flammable liquids stored in rated chemical cabinets? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are flammable liquids stored in flammable-rated refrigerators/freezers? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are excess chemicals stored in chemical storage room? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are compressed gas cylinders stored in laboratory? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| *⮡ If yes, are they properly secured?* |[ ] [ ] [ ]   |  |
| Are chemicals stored at eye-level? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are acids and bases stored in a cabinet? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are acids and bases stored in a labeled area? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are acids and bases stored free from metals? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are chemical fume hoods certified within past year? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Do chemical fume hoods have their sash closed when not in use? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is the exhaust air of chemical fume hoods not blocked by large equipment or containers? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are chemical fume hoods used for hazardous/toxic or flammable procedures? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |

**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.) |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Do staff receive annual PPE competency assessment? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| 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? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[5](#source_5_sandia_biosafety_risk) |
| ⮡ *If yes, does the written plan include instructions indicating PPE should be removed before exiting the laboratory?* |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[5](#source_5_sandia_biosafety_risk) |
| Is PPE appropriately stored in laboratory? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is PPE inspected prior to use and in good condition? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is all PPE (including gloves, safety glasses, respirators, laboratory coats, etc.) not worn outside of laboratory area? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing),4 |
| Are laboratory coats and gowns worn to prevent exposure of street clothing? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are laboratory coats available for all staff who may enter a laboratory? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is respiratory protection required? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, are users enrolled in a respiratory protection program?* |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are cryo or autoclave gloves used? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If autoclave gloves are used, are they thick, elbow-length, heat-resistant, and liquid-impervious?* |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are closed-toe shoes that cover entire foot worn in laboratory? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are gloves or bandages worn to protect non-intact skin? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are proper practices for reducing/eliminating contact exposure through broken skin identified in the laboratory procedures and taught and verified on a regular basis? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Are gloves worn when handling potentially contaminated materials, containers, equipment, or surfaces? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is there a written policy for when to change gloves? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Are gloves discarded after each use? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are various sizes of gloves provided? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are gloves provided made of different materials (e.g., nitrile, chloroprene) for employees who have skin sensitivity? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| 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)? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| 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? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |

**Emergency Preparedness**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Consideration** | **Yes** | **No** | **N/A** | **Comment** | **S** |
| Is emergency contact information posted? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is a first aid kit maintained? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are biological spill kits available, readily accessible to all laboratory personnel, and maintained? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, are personnel regularly trained in their use?* |[ ] [ ] [ ]   |  |
| Are chemical spill kits available, readily accessible to all laboratory personnel, and maintained? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, are personnel regularly trained in their use?* |[ ] [ ] [ ]   |  |
| 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. |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Is there a procedure in place if a potentially infectious aerosol release occurs outside a BSC? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| ⮡ *If yes, does the procedure include:* |  | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| *• Having all persons immediately vacate the laboratory unit where the spill occurred?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
|  *Referral of exposed persons for medical advice and evaluation?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| *• Informing the laboratory supervisor and biosafety officer of the situation immediately?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| *• 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?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| *• A further delayed entrance (e.g., up to 24 hours) if the laboratory does not have a central air exhaust system?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| *• Posting signs indicating that entry is forbidden?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| *• Decontamination, supervised by the biosafety officer, after the appropriate time?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| *• Appropriate PPE must be worn, which may include respirators?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| 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)? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Are staff aware of occupational injury procedures? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are the eye wash and shower stations flushed and checked weekly? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Does the institution conduct biosafety drills or exercises at predetermined intervals, including tabletop exercises, annual exercises, and exercises that include external responders? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[5](#source_5_sandia_biosafety_risk) |
| Are there procedures in place to detect safety breaches when they occur? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there a system to report safety breaches to laboratory leadership? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there a procedure specifying how biosafety breaches will be addressed and which staff are responsible for addressing them? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Are corrective actions implemented when breaches in biosafety are identified? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there an occupational health program? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there a medical surveillance program, including well-defined procedures and plans, in place in the event of exposure to an infectious agent? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[5](#source_5_sandia_biosafety_risk) |
| Are there procedures in place for preventative equipment maintenance to reduce/eliminate accidents or equipment failure? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| ⮡ *If yes, do these include equipment calibration, validation, and certification?* |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |

**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? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Have employee(s) completed unit-specific training? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Have employee(s) read and understand safety and health plans? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are biohazard signs posted by the entrance of laboratories where infectious agents are processed and tested and in other areas where indicated? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is the door sign up-to-date and posted? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Does equipment such as centrifuges, incubators, freezers involved in the use and storage of infectious materials have the biosafety label affixed? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is there a policy restricting the storage of food or beverages for human consumption in the laboratory? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are laboratory microwaves and refrigerators labeled with “Not for Food or Drink – Biohazard”? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is there an institutional biosafety plan? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Does the institution have comprehensive biosafety documentation, including biosafety policies, manuals, SOPs, and risk assessment and incident response information? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| 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? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Is there a designated Laboratory Biosafety Officer? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there an institutional biosafety committee or similar group? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Does the institutional biosafety committee or similar group meet at established time intervals? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| ⮡ *If yes, does the group discuss breaches in biosafety, corrective actions, maintenance issues related to biosafety, and pending certifications of equipment?* |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Are internal safety audits performed at least annually and after significant safety breaches? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there a written policy and/or a standard operating procedure (SOP) for performing risk assessments? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Do risk assessments consider both agent hazards and laboratory procedure hazards? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Has the person performing the risk assessment received training, and is the person experienced in risk assessments? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is a risk assessment performed when: |  | [1](#source_1_aphl_biosafety_checklist) |
| • New assays are introduced? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • New methods are introduced? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • Equipment is moved? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • New equipment is introduced? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • The potential for aerosolization is introduced? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • The potential for needlesticks is introduced? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • A laboratory is physically moved? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • A new pathogen is detected? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • Staffing changes? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Are risk assessments conducted annually for assays performed in the laboratory? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Do laboratory personnel receive training in the Biosafety Laboratory Competencies as outlined in the CDC’s MMWR, Guidelines for Biosafety Laboratory Competency? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Do all new personnel receive safety training before they begin working in their assigned laboratory? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there an annual biosafety training program for all personnel? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| ⮡ *If yes, do annual biosafety training programs include:* |  | [1](#source_1_aphl_biosafety_checklist) |
| *• Risk assessments?* |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| *• Biosafety level?* |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| *• Biosafety laboratory competencies?* |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| *• Occupational health?* |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there an annual training program on PPE that covers: |  | [1](#source_1_aphl_biosafety_checklist),[4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • When PPE is necessary |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • What PPE is necessary |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • 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 |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • Limitations of PPE |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • Proper care, maintenance, useful life, and disposal of PPE |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is there an annual blood borne pathogen training program for all personnel? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is documentation completed for employee training and competency assessment in medical waste handling for: |  | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • Constructing and properly labeling containers for medical waste that require assembly before their use? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • Disposing of medical waste in properly labeled containers? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • Use of appropriate supplies (e.g. containers, appropriate plastic bags, labeling)? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • 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)? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Do laboratorians who operate centrifuges have documented training and competency assessments on each type of centrifuge they operate? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| ⮡ *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?* |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are vaccines recommended for work in this Unit? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, how are employees informed of the vaccines?* |  | [1](#source_1_aphl_biosafety_checklist),[2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, what vaccines are recommended?* |  | [1](#source_1_aphl_biosafety_checklist),[2](#source_2_aphl_template_for_evd_testing) |
| ⮡ *If yes, are personnel offered appropriate vaccinations for working in their assigned laboratory?* |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist),[2](#source_2_aphl_template_for_evd_testing) |
| During pre-employment physical, is baseline serum collected as necessary to document potential occupational exposures? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there a needlestick and sharps injury prevention program? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Does the institution have an active shipping and receiving program with well-defined procedures and plans in place? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| ⮡ *If yes, have all individuals involved in packaging and shipping been trained and certified in the last two years?* |[ ] [ ] [ ]   |  |

**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? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are BSCs continually operated to provide some direction to potential aerosols in a previously constructed laboratory without directional room air? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are transport containers used? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is a BSC or similar containment device used for procedures with splash or aerosol potential? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are splash guards used at workstations when working with blood cultures and at workstations where the potential for splashing exists? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| For BSCs that vent to the outside, are outside vents placed away from the facility’s air intake units? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| If BSCs are used, are there procedures in place for proper use? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Are autoclaves located in a well-ventilated area or exhausted through a capture hood above them? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Does the mycobacteriology laboratory have its own autoclave? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are autoclave cycles validated before initial use for effective decontamination of the projected loads? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are autoclaves tested for efficacy using biological or chemical indicators on a regular basis? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Are the following certified at least annually: |  | [1](#source_1_aphl_biosafety_checklist) |
| • BSCs? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • Autoclaves? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • HVAC? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • HEPA Filters? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| • BSL-3 Suites? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |

**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](#source_4_cdc_mmwr_guidelines_for_safe) |
| • Waste-reduction or minimization program? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • Identification and definition of all categories of waste generated by the laboratory? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • For each category of waste generated, determination of applicability of federal, state, and local regulations? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • Segregation of all regulated waste to prevent access by the public or clients? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Establishment of a system for reporting and responding to all issues or problems regarding medical waste management? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| • Establishment of treatment and disposal processes, with disposal of regulated waste by a company meeting state and local licensure requirements? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Is there a policy in place for proper disposal of biomedical waste and sharps? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| Is there a decontamination facility or medical waste contract in place? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |
| Are chemical waste containers labeled with chemical name and percent of each chemical? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Are chemical waste containers properly sealed? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |
| Is contaminated waste stored properly and handled according to best practices? |[ ] [ ] [ ]   | [5](#source_5_sandia_biosafety_risk) |
| Is broken glass placed in appropriate receptacle? |[ ] [ ] [ ]   | [2](#source_2_aphl_template_for_evd_testing) |

**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? |[ ] [ ] [ ]   | [3](#source_3_cdc_assessment_tool_for_ebola) |
| 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? |[ ] [ ] [ ]   | [3](#source_3_cdc_assessment_tool_for_ebola) |
| 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? |[ ] [ ] [ ]   | [3](#source_3_cdc_assessment_tool_for_ebola) |
| ⮡ *If yes, does this include CBC, glucose, potassium, malaria exam, influenza test, and tests for liver function?* |[ ] [ ] [ ]   | [3](#source_3_cdc_assessment_tool_for_ebola) |
| Are protocols in place for handoff and placement of specimen tubes into appropriate containers for transport to hospital laboratory? |[ ] [ ] [ ]   | [3](#source_3_cdc_assessment_tool_for_ebola) |
| 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? |[ ] [ ] [ ]   | [3](#source_3_cdc_assessment_tool_for_ebola) |
| Is there a designated area for laboratory personnel to safely doff PPE? |[ ] [ ] [ ]   | [3](#source_3_cdc_assessment_tool_for_ebola) |
| Are protocols in place for cleaning and disinfection of laboratory surfaces and equipment, management of blood and body fluid spills, and exposure of staff? |[ ] [ ] [ ]   | [3](#source_3_cdc_assessment_tool_for_ebola) |
| Is a tracking system is in place for patient specimens that are transported to the laboratory? |[ ] [ ] [ ]   | [3](#source_3_cdc_assessment_tool_for_ebola) |
| Is a policy in place for safe short-term storage and disposal of Ebola patient specimens? |[ ] [ ] [ ]   | [3](#source_3_cdc_assessment_tool_for_ebola) |

**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? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| **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? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| **Documentation and Training** |
| Are trained employees required to have an annual respirator fit test if indicated? |[ ] [ ] [ ]   | [1](#source_1_aphl_biosafety_checklist) |
| **Engineering Controls** |
| Is the sink provided for hand washing able to be operated hands-free? |[ ] [ ] [ ]   | [4](#source_4_cdc_mmwr_guidelines_for_safe) |

**Sources**

1. APHL (Association of Public Health Laboratories) A Biosafety Checklist: Developing A Culture of Biosafety (April 2015)
	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
	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)
	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
	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)
	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.