

General Principles of Biological Safety Risk Assessment

According to the CDC's Biosafety in Microbiological and Biomedical Laboratories, 5th edition, the following factors must be considered when conducting a risk assessment to determine appropriate biocontainment practices:

1. **The pathogenicity (ability to cause disease) of the infectious or potentially infectious agent.** As a part of this, infectious dose, severity of the disease, history of laboratory-acquired infections and incidence in the community must be evaluated. In terms of risk, a lower infectious dose, greater disease severity, past history of lab-acquired infections, etc. are all associated with a higher risk level.
2. **The availability of effective prophylaxis and/or treatment.** Identify and outline available pre-exposure prophylaxis (i.e., effective vaccines) and post-exposure prophylaxis, including passive immunizations and treatment options. Although greater disease severity often correlates with a higher biosafety level, the assignment of the biosafety level must also be determined within the context of therapeutic intervention, available vaccines, susceptibility to antibiotics or antiviral agents, etc. (Knudsen 2001).
3. **The immune status of the employee.** The outcome of infection is ultimately determined by interaction with the host, with immune status directly connected to susceptibility. Opportunistic pathogens and agents that are a part of normal microbial flora which are of no or low concern to healthy adults can cause disease in immunocompromised individuals (Fleming 2000). Therefore, underlying conditions and the risk to pregnant women (and their unborn baby) should be identified.
4. **The route of transmission of the infectious or suspected infectious agent.** Unless noted otherwise, it should be assumed that agents have multiple routes of transmission (Knudsen 2001). Parenteral (injection), oral (ingestion) and airborne (inhalation) routes must be considered, and for every agent, the potential for aerosol transmission must be evaluated. Aerosols are considered the most dangerous route of transmission because of the large number of personnel that can be infected and because most laboratory-acquired infections are known (or suspected) to be contracted via aerosol exposure (Knudsen 2001). The route of transmission in the community should also be noted.
5. **The agent's viability in the environment.** Identify factors (desiccation, exposure to sun or UV light, susceptibility to heat or chemical disinfectants, etc.) that affect the infectious agent's stability in the environment. There is a greater risk associated with organisms that can persist in the environment. Agent stability is also related to aerosol infectivity, in that inactivation of viable aerosols limits transmission via this route.
6. **The origin of the potentially infectious agent.** Evaluation of the origin should include host (e.g., symptomatic or asymptomatic animal), geographical location (e.g., domestic or foreign), association with zoonotic infection or disease outbreak and ability to endanger livestock. The host range of the agent should also be determined.
7. **The concentration of infectious organisms.** The risk is higher for manipulations of (highly) concentrated samples. In addition to concentration, the evaluation of the sample should include the menstruum (e.g., solid tissue, viscous blood or sputum, liquid medium, etc.) and the volume or amount of material being handled.
8. **The planned activities.** The activities should be evaluated for, among other things, their propensity to generate aerosols and how much handling of the sample materials is required. Examples of activities include sonication, centrifugation, those requiring or resulting in agent amplification and those involving sharps.
9. **The experience/skill level of at-risk personnel.** At-risk personnel directly handling the infectious or potentially infectious materials should be identified and their experience and skill level evaluated. Depending on the operation, at-risk personnel might also include maintenance workers, custodial staff, etc. If additional training is necessary to ensure safety, it should be considered.

The compilation of this information will be used in order to assign the biosafety level for a procedure and to identify corresponding work practices, engineering controls (i.e., containment devices) and personal protective equipment.