

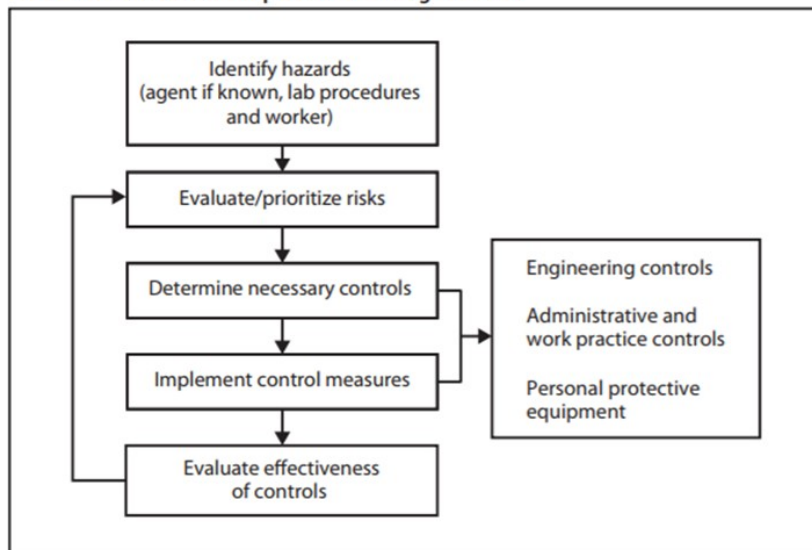
Assessing & Controlling Biological Material Risks

The below diagram outlines the basic steps in performing a risk assessment for procedures involving any lab hazard. For biosafety purposes, hazard identification needs to include:

1. The risk of the “parent” agent
2. The risk of the actual medium/material to be manipulated
3. The physical hazards associated with the procedure that could result in exposure/injury

When considering the hazards, a “what’s the worst thing that could go wrong” mindset should be employed when selecting hazard control measures.

FIGURE 1. Risk assessment process for biologic hazards



Hazard Identification

1. **What’s the risk of the “parent” agent?** Risk Group designation must be considered. Under a worst-case scenario, if the “parent agent” is present, or could become present through recombination, this risk must be considered when developing biocontainment procedures. Remember that in most cases, the RG designation, and the BSL designation will be the same.

Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are <i>often</i> available
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions <i>may be</i> available (high individual risk but low community risk)
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are <i>not usually</i> available (high individual risk and high community risk)

2. **What are the features/risks of the medium/materials to be manipulated?** Consideration should be given to the biological features of what you plan to work with:

- What format will the agent be present in?
- Modified agent? If yes, nature of modification? Possibility for recombination?
- Was the agent/material generated in a BSL-3 or 4 environments? If yes, is documentation available to support the material is contaminant-free?
- For clinical materials- anything “unique” about disease presentation in source?

Additionally, you must consider the format of materials that will be needed for the procedure:

- What are the maximum quantities required for the procedure?
- What is the maximum concentration required?

3. **What are the physical hazards associated with the procedure?** Lab equipment and manipulations are of equal importance when assessing risk. Almost all processing steps will increase the risk of exposing the person directly involved in the procedure, or spreading contamination to common surfaces that all persons in the lab may encounter. Common physical hazards associated with lab procedures include (but are not limited to):

- Live animals
- Sharps
- Glass
- Pressurized fluids
- Pressurized air (pneumatics)
- Temperature extremes (both hot and cold)
- Energized equipment/moving components (ex: shaker, vortex, centrifuge)

Evaluating the hazards/ selecting controls

When identifying and assessing the hazards, a “what’s the worst thing that could go wrong” mindset should be employed when selecting hazard control measures. Once both the biological and procedural hazards have been fully vetted, then action should be taken to:

1. Eliminate hazards when feasible (especially those that bear the greatest exposure risk);
2. Substitute less hazardous materials/equipment/techniques when possible;
3. Identify engineering and administrative controls that need to be employed to contain the exposure risk (for both personnel performing procedures, as well as those who may be present in the lab area):
 - engineering controls include all safety equipment designed to isolate or eliminate the hazard
 - administrative controls include restricted access, training/proficiency evaluation, disinfection and waste handling, use of PPE, etc.

Evaluating effectiveness of controls

Before any new procedure is carried out using “live” material, the exposure control methods should be evaluated for effectiveness.

A “test run” of a new process needs to be carried out using a NON-HAZARDOUS SIMULANT in order to determine if the procedure needs to be optimized for both scientific and safety reasons. Re-evaluation of a procedure needs to be carried out any time a spill or potential exposure incident occurs, or if a major component of the procedure is changed.