

Chapter 2 Biological Risk Assessment

2.1 Introduction

Risk assessment is a process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person's exposure to an agent, the likelihood that such exposure will cause a laboratory acquired infection (LAI), and the probable consequences of such an infection. The information identified by risk assessment will provide a guide for the selection of appropriate biosafety levels and microbiological practices, safety equipment, and facility safeguards that can prevent LAIs. The primary factors to consider in risk assessment and selection of precautions fall into two broad categories: agent hazards and laboratory procedure hazards. The agent summary statements contained in BMBL6 identify the primary agent and procedure hazards for specific pathogens and recommend precautions for their control. A review of the summary statement for a specific pathogen is the starting point for assessment of the risks of working with that agent and those for a similar agent.

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\) 6th Edition | CDC Laboratories](#)

2.2 Hazardous Characteristics of Agents

2.2.1 Principal Hazardous Characteristics

The principal hazardous characteristics of an agent are:

- Its capability to infect and cause disease in a susceptible human or animal host,
- Its virulence as measured by the severity of disease, and
- The availability of preventive measures and effective treatments for the disease

2.2.2 Risk Groups

The NIH Guidelines assigns human etiological agents into four risk groups on the basis of hazard. Agents are classified into four Risk Groups (RGs) according to their relative pathogenicity for healthy adult humans by the following criteria:

- Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans.
- Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

- Risk Group 3 (RG3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.
- Risk Group 4 (RG4) agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

2.2.3 Resources

- NIH Risk groups: [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(NIH Guidelines\)](#)
- NIH guidance for lentiviral vectors: [Major RAC concerns](#)
- ABSA risk database: [Riskgroups | my.ABSA.org - For the Biosafety and Biosecurity Professional](#)
- The Public Health Agency of Canada Pathogen Safety Data Sheets database: [Pathogen Safety Data Sheets - Canada.ca](#)

2.4 Risk Assessment of Other Agents

The end product of risk assessment is the assignment of an appropriate biosafety level (BSL) for an experiment. BSLs will be discussed in detail in Chapter 4. The initial risk assessment from the preceding resources should be followed by a thorough consideration of how the agent is to be manipulated. Agent factors to be considered in determining the BSL include:

- Virulence,
- Pathogenicity,
- Infectious dose,
- Environmental stability
- Route of transmission
- Communicability, operations, quantity,
- Availability of vaccine or treatment
- Gene product effects such as:
- Toxicity
- Physiological activity and
- Allergenicity

Any strain that is known to be more hazardous than the parent (wild-type) strain should be considered for handling at a higher BSL. Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the RG assigned to the parent strain.