

**IOWA STATE UNIVERSITY
Institutional Biosafety Committee**

**Frequently Asked Questions about
Risk Assessment and Personal Protective Equipment**

What is a risk assessment?

A risk assessment is an important responsibility performed by principal investigators (PIs) to identify the hazards that may be encountered in the lab. Examples include but are not limited to, characteristics of a known infectious or potentially infectious agent or material, unique hazards associated with recombinant or synthetic nucleic acids, hazards that can result from work using non-biological materials and equipment, a person's exposure to an agent, and the likelihood that such exposure will cause an acquired infection, and the probable consequences of such an infection.

What steps should be evaluated as part of the risk assessment when working with biological materials?

The items to be evaluated in a risk assessment include:

1. *Pathogenicity* of the infectious or suspected infectious agent, including disease incidence and severity (i.e., mild morbidity versus high mortality, acute versus chronic disease). The more severe the potential disease, the higher the risk.
2. *Route of transmission*—for example, parenteral, airborne, or by injection. This may not be definitively established for newly isolated agents. Guidance in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) indicates that when information is incomplete and a subjective judgment is required, it is generally advisable to use a conservative approach and implement universal precautions. Agents that are transmitted through aerosolization have a higher risk to personnel, as they have caused many documented laboratory infections. Note: When definitive information is not available, the IBC will generally use the more conservative approach.
3. *Agent stability*—the agent's ability to survive over time in the environment. Factors such as route of transmission, temperature, humidity, ultraviolet light, and chemical disinfectants should be considered.
4. *Infectious dose*—the infectious dose can vary from one to hundreds of thousands of units.
5. *Concentration*—the number of infectious organisms per unit volume. The volume of concentrated material being handled is also important.
6. *Origin*—refers to geographic location (e.g., domestic or foreign); host (e.g., infected or uninfected human or animal); or nature of source (potential zoonotic or associated with a disease outbreak). From another perspective, this consideration can include the potential of agents to endanger American livestock and poultry.
7. *Recombinant or synthetic nucleic acid molecules*—consideration of the same factors used in risk assessment of the wild-type organism should be used. The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* are the key guidance for assessing risk and establishing an appropriate biosafety level.
8. *Availability of an effective prophylaxis* or therapeutic intervention. The most common form of prophylaxis is immunization with an effective vaccine. Postexposure prophylaxis may include administration of a vaccine, immunoglobulins, antibiotics, or antiviral medications.

9. *Medical surveillance*—may include serum banking, monitoring employee health status, and participating in post-exposure management.
10. *Experience and skill* of personnel performing procedures.
11. *Safety equipment*—the laboratory director or principal investigator is responsible for reviewing available equipment and ensuring that the necessary safety equipment is available and properly operating.
12. *Personal Protective Equipment (PPE)*—the laboratory director or principal investigator is responsible for reviewing available PPE and ensuring that the necessary PPE is available and properly utilized and stored.
13. *Review of the risk assessment*—review of the risk assessment with a subject matter expert, biosafety professional, the IBC chair, or IBC member is always helpful.

(The preceding list was adapted from *Biosafety in Microbiological and Biomedical Laboratories*, 6th Edition.)

How do I use the information gained from the risk assessment?

A risk assessment is required as part of the completion of the application for IBC approval. The risk assessment should be used to select the biosafety level and the PPE in the application for IBC approval. The risk assessment should also be used to inform personnel about the hazards of working with biological or biohazardous materials and the need for proficiency in the use of selected safe practices and containment equipment. A thorough and careful risk assessment also protects individuals not associated with the project, such as other occupants of the building and the public.

What is a biosafety level?

Biosafety level refers to containment. Containment takes into account types of facility safeguards (negative versus positive pressure), safety equipment used (autoclaves, biosafety cabinets), and safe microbiological work practices.

What biosafety levels are used at ISU?

There are four biosafety levels; however, only three are used at ISU. Biosafety level 4 requires specialized facilities not available at ISU. A brief description of the three levels follows:

Biosafety Level 1 practices, safety equipment, and facility design and construction are appropriate for undergraduate and secondary educational training and teaching laboratories, and for other laboratories in which work is done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans.

Biosafety Level 2 practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous, moderate-risk agents that are present in the community and associated with human infections of varying severity.

Biosafety Level 3 practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, or research facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission and which may cause serious and potentially lethal infection.

What guideline(s) does the ISU IBC use to evaluate proposed biosafety levels?

The IBC uses the biosafety guidelines outlined in the *Biosafety in Microbiological and Biomedical Laboratories* (US Department of Health and Human Services, Center for Disease Controls and National

Institutes of Health) and the *NIH Guidelines* in determining the biosafety level(s) applicable for each project.

What are Risk Groups?

The National Institutes of Health (NIH) Guidelines has information and classifies according to Risk Groups as shown in the table below.

Risk Group 1	Risk Group 2	Risk Group 3	Risk Group 4
<u>NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules</u>			
Agents are not associated with disease in healthy adult humans	Agents are associated with human disease which is rarely serious and for which preventative or therapeutic interventions are <i>often</i> available	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)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not <i>usually</i> available (high individual risk and high community risk)

Additional reference sources include the risk classification criteria for the World Health Organization, Australia, Canada, and European Union and can be found at <https://my.absa.org/Riskgroups>.

How do the risk groups relate to the assigned biosafety levels?

Risk groups correlate with the biosafety level but do not equate to biosafety levels. A risk assessment determines the degree of correlation between an agent’s risk group classification and biosafety level. For example, Hepatitis B is a Risk Group 2 organism, but, depending on the quantity and activities used in the laboratory, it may need to be worked under Biosafety Level 3 containment.

Biosafety Level 1	Biosafety Level 2	Biosafety Level 3	Biosafety Level 4
<u>CDC/NIH Guidelines—Biosafety in Microbiological and Biomedical Laboratories</u> 6 th Edition			
Suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans and that present minimal potential hazard to laboratory personnel and the environment.	Suitable for work with agents associated with human disease and pose moderate hazards to personnel and the environment.	Suitable for work with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure.	Required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening diseases that are frequently fatal, agents for which there are no vaccines or treatments, or work with a related agent with unknown risk of transmission

What kind of PPE should personnel wear while decontaminating and using chemicals (i.e., ethanol or bleach) stated on the IBC protocol?

Laboratory personnel must follow the chemical Safety Data Sheets (SDS) for each chemical they are using. The PPE could be different than the one required for working with biological materials.

Does the risk assessment and PPE have to be documented in laboratory SOPs?

The risk assessment and selection of appropriate PPE *must* be documented in laboratory standard operating procedures developed for the experiment or laboratory operation. For more information about developing standard operating procedures refer to Section B of the ISU Laboratory Safety Manual, <https://publications.ehs.iastate.edu/labsm/> . SOP information/development can also be found [here](#).

How do I know if the proposed biocontainment level has been approved?

When the IBC approves the protocol, the committee administrator communicates the approval of the application to the Principal Investigator. The approved biosafety containment levels are selected in the application. The PI must follow the IBC's determinations and is expected to adhere to the precautions specified in the approved protocol.

Do I have to wear the PPE indicated in my application the whole time I am in the laboratory?

The risk assessment drives the need for PPE in the laboratory. The IBC expects that appropriate PPE will be worn when working with a biohazard. PIs should document in their laboratory standard operating procedures (SOPs) the appropriate PPE required by individuals working in the laboratory.

Will an ISU Biosafety Officer ask about use of PPE during an inspection?

The ISU BSO may request the lab SOPs, and investigators should also provide a copy of these SOPs to all personnel including undergraduate and graduate students. Investigators are responsible for ensuring that PPE requirements are communicated and followed by all personnel working in the laboratory.

What is the role of the ISU Biosafety Manual?

NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules require that a biosafety manual be prepared and adopted. Personnel must be advised of special hazards and are required to read and follow the instructions on practices and procedures. ISU has developed a [University Biosafety Manual](#) which describes the practices and procedures that must be followed for work with any biological hazard.

Is there a university policy on the use of PPE?

There is a university policy regarding PPE that can be found at <http://policy.iastate.edu/policy/equipment/protective/>. The policy requires that, at a minimum, the following must be worn when working with chemicals, biological, and radioactive materials:

- Laboratory coats (or other protective clothing such as aprons, scrubs, coveralls, etc.)
- Safety glasses or goggles
- Gloves resistant to the material used
- Appropriate footwear (closed at the heel and toe)

This policy requires stricter practices than listed in the BMBL because it addresses Occupational Safety and Health Administration (OSHA) and other federal agency requirements. As noted in other FAQs, “completion of a hazard assessment or SOPs may allow individual laboratory PPE requirements to be determined and justified by a laboratory supervisor or principal investigator.”

Can additional PPE be worn in laboratories?

PIs may use more than the minimum required PPE for their project. Additional items that will be utilized should be listed in the application.

Frequently Asked Questions about Laboratory Safety

What is the role of the ISU Laboratory Safety Manual (LSM)?

The [ISU LSM](#) provides a comprehensive view of the ISU requirements for work in the laboratory. The LSM focuses on all the hazards (biological, chemical, radiological, physical, and electrical) that may be encountered at any ISU laboratory facility.

Where can I find more information about laboratory safety?

[Environmental Health and Safety \(EH&S\)](#) maintains and regularly updates information that has most of the items that would be needed for various types of research labs on campus.