

Summary of Biosafety Guidelines To Be Used In Biomedical Laboratories

This is a summary of biosafety guidelines to be used in microbiological and biomedical laboratories working with biohazards. These guidelines deal with characterization of the biohazards and the methods of containment to insure that minimal risk is involved in experimental work. More detailed information is available in the documents CDC-NIH [Biosafety in Microbiological and Biomedical Laboratories \(BMBL\)](#), HHS Publication No. 93-8395 and NIH [Guidelines for Research Involving Recombinant DNA \(NIH Guidelines\)](#). Copies of these publications are available on-line through the University's Institutional Biosafety Committee (IBC) homepage links (<http://www.cc.rochester.edu:80/Admin/EHAS/ibcpage.htm>).

Biohazards are defined as biological agents or substances present in or arising from the work environment, which may be a hazard to the health or well-being of the worker or community. Examples of biohazards are infectious organisms such as bacteria and viruses, some recombinant DNA, zoonoses (diseases which occur primarily in animals but may be transmitted to humans), and primary cell cultures that are initiated with tissues from infected humans or animals. Recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Containment of biohazards refers to safe methods for managing infectious agents in the laboratory environment to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment. Factors to be considered in determining the level of containment include agent factors such as: virulence, pathogenicity, infectious dose, environmental stability, route of spread, communicability, operations, quantity, availability of vaccine or treatment, and gene product effects. The most important element of containment is strict adherence to standard microbiological practices and techniques. Appropriate facility design and engineering features, safety equipment, and management practices supplement this. Four biosafety levels (BSL's) define those conditions under which the agent can be safely handled.

The purpose of the NIH Guidelines is to specify practices for constructing and handling recombinant DNA molecules and the organisms and viruses containing recombinant DNA. To facilitate these guidelines, biological agents known to infect humans as well as selected animal agents and known to pose theoretical risks if inoculated into humans are classified on the basis of hazard into four risk groups. These Risk Groups are organized according to the biohazard's relative pathogenicity for healthy adult humans.

The investigator must make an initial risk assessment. Decisions on the appropriate containment for an experiment include a thorough consideration of the agent itself and how it is to be manipulated. The objective of physical containment is to confine biohazards and to reduce the potential for exposure. BSL's are set according to the organisms being manipulated. Lists of specific agents and their BSL classification can be found in the CDC and NIH publications. For experiments involving recombinant DNA, the BSL required for containment is generally equivalent to the Risk Group classification of the agent but may be raised or lowered as a result of other considerations involved in the experiment. Therefore, experiments involving the introduction of recombinant DNA

into Risk Group 1 agents will usually be conducted at Biosafety Level 1 (BL1) containment. The same is true for recombinant DNA introduction into Risk Group 2, 3, and 4 agents that will be conducted at BL2, BL3, and BL4 containment, respectively. **Note: The CDC and OSHA (Occupational Health and Safety Administration) have defined work with infectious HIV on a laboratory-scale as biosafety level 2 plus. Biosafety level 2 + is a hybrid level requiring at the minimum the use of a biosafety level 2 facility with containment equipment and the practices of biosafety level 3.**

In conclusion, a final assessment of risk is based on considerations of the agent itself, how it is to be manipulated, and the level of containment involved. The relationship of biosafety levels and risk groups is summarized in a table on the reverse side. The Institutional Biosafety Committee must approve the risk assessment and the biosafety level of experimental work involving biohazards and recombinant DNA. **To initiate Institutional Biosafety Committee approval, review the instructions outlined on the IBC homepage (<http://www.cc.rochester.edu:80/Admin/EHAS/ibcpage.htm>) and contact Janet Ives (IBC Biosafety Officer) at x5-3241.**

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Biosafety Levels	Agents	Laboratory Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to cause disease in healthy adults Examples: * Bacillus subtilis * Adeno-associated virus types 1 - 4	* Standard Microbiological Practices * Decontaminate lab waste	None required	* Open bench top * Sink required
2	Associated with human disease; hazards result from auto-inoculation, ingestion, mucous membrane exposure Examples: * Hepatitis B virus * Papovaviruses	BL1 practice plus: * Limited access * Biohazard warning signs * “Sharps” precautions * Biosafety manual defining any needed decontamination or medical surveillance policies	* Open bench plus biosafety cabinet * PPE’s: lab coats, gloves, face protection	BL1 plus: * Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences Examples: * Mycobacterium tuberculosis	BL2 practice plus: * Controlled access * Decontamination of all waste * Decontamination of lab clothing before laundering * Baseline serum	* Biosafety cabinet (Class I, II, III) and/or other primary containment for all activities * PPE’s: protective lab clothing, gloves, respiratory protection as needed	BL2 plus: * Physical separation from access corridors * Self-closing double-door access * Exhausted air not recirculated * Negative airflow into laboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease; aerosol-transmitted lab infections; or related agents with unknown risk of transmission Examples: * Lassa virus * Ebola virus	BL3 practice plus: * Clothing change before entering * Shower on exit * All material decontaminated on exit from facility	* Maximum containment equipment used for all procedures (i.e. Class III biosafety cabinet or partial containment equipment in combination with positive pressure personnel suit)	BL3 plus: * Separate building or isolated zone * Dedicated supply /exhaust, vacuum, and decon systems * Other requirements outlined in CDC/NIH BMBL

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