

Annex 2-A: Topics covered in ISO 15190: 2003 Medical laboratories – Particular requirements for safety

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Annex 2-B: Risk Groups and Biosafety Levels

Table 1: Risk Groups

Risk Group 1 (no or low individual and community risk)

A microorganism that is unlikely to cause human or animal disease.

Risk Group 2 (moderate individual risk, low community risk)

A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

Risk Group 3 (high individual risk, low community risk)

A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.

Risk Group 4 (high individual and community risk)

A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.

Countries (regions) should draw up a national (regional) classification of microorganisms, by risk group, taking into account:

1. Pathogenicity of the organism.
2. Mode of transmission and host range of the organism. These may be influenced by existing levels of immunity in the local population, density and movement of the host population, presence of appropriate vectors, and standards of environmental hygiene.
3. Local availability of effective preventive measures. These may include: prophylaxis by immunization or administration of antisera (passive immunization); sanitary measures, e.g. food and water hygiene; control of animal reservoirs or arthropod vectors.
4. Local availability of effective treatment. This includes passive immunization, post exposure vaccination and use of antimicrobials, antivirals and chemotherapeutic agents, and should take into consideration the possibility of the emergence of drug-resistant strains.

Biosafety Levels¹

Laboratory facilities are designated as basic – Biosafety Level 1; basic – Biosafety Level 2; containment – Biosafety Level 3; and maximum containment – Biosafety Level 4. Biosafety level designations are based on a composite of the design features, construction, containment facilities, equipment, practices and operational procedures required for working with agents from the various risk groups. Table relates but does not “equate” risk groups to the biosafety level of laboratories designed to work with organisms in each risk group.

Table . Relation of risk groups to biosafety levels, practices, and equipment.

Risk Group	Biosafety Level	Laboratory Type	Laboratory Practices	Safety Equipment
1	Basic Biosafety Level 1	Basic Teaching Research	GMT	None open bench work
2	Basic Biosafety Level 2	Primary health services diagnostic services research	GMT plus protective clothing biohazard sign	Open bench plus BSC for potential aerosols
3	Containment Biosafety Level 3	Special diagnostic services, research	As Level 2 plus special clothing, controlled access, directional airflow	BSC and/or other primary devices for all activities
4	Maximum containment Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSC double-ended autoclave (through the wall), filtered air

Key: BSC, biological safety cabinet; GMT, good microbiological techniques

¹ WHO Laboratory Biosafety Manual Available from URL:
<http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>

Biosafety Levels²

SUMMARY OF RECOMMENDED BIOSAFETY LEVELS FOR INFECTIOUS AGENTS

BSL	AGENTS	PRACTICES	PRIMARY BARRIERS AND SAFETY EQUIPMENT	FACILITIES (SECONDARY BARRIERS)
1	Not known to consistently cause diseases in healthy adults	Standard Microbiological Practices	None required	Laboratory bench and sink required
2	<ul style="list-style-type: none"> Agents associated with human disease Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure 	BSL-1 practice plus: <ul style="list-style-type: none"> Limited access Biohazard warning signs "Sharps" precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies 	Primary barriers: <ul style="list-style-type: none"> Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials PPEs*: <ul style="list-style-type: none"> Laboratory coats; gloves; face protection as needed 	BSL-1 plus: <ul style="list-style-type: none"> Autoclave available
3	<ul style="list-style-type: none"> Indigenous or exotic agents with potential for aerosol transmission Disease may have serious or lethal consequences 	BSL-2 practice plus: <ul style="list-style-type: none"> Controlled access Decontamination of all waste Decontamination of laboratory clothing before laundering Baseline serum 	Primary barriers: <ul style="list-style-type: none"> Class I or II BSCs or other physical containment devices used for all open manipulation of agents PPEs: <ul style="list-style-type: none"> Protective laboratory clothing; gloves; respiratory protection as needed 	BSL-2 plus: <ul style="list-style-type: none"> Physical separation from access corridors Self-closing, double-door access Exhaust air not recirculated Negative airflow into laboratory
4	<ul style="list-style-type: none"> Dangerous/exotic agents which pose high risk of life-threatening disease Aerosol-transmitted laboratory infections have occurred, or related agents with unknown risk of transmission 	BSL-3 practices plus: <ul style="list-style-type: none"> Clothing change before entering Shower on exit All material decontaminated on exit from facility 	Primary barriers: <ul style="list-style-type: none"> All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit 	BSL-3 plus: <ul style="list-style-type: none"> Separate building or isolated zone Dedicated supply and exhaust, vacuum, and decontamination systems Other requirements outlined in the text

² *Biosafety in Microbiological and Biomedical Laboratories* CDC and NIH, 5th ed. Available from URL: http://www.cdc.gov/OD/ohs/biosfty/bmb15/BMBL_5th_Edition.pdf