ANNEX 4. BIOSAFETY GUIDELINES (*79*)

GENERAL PRINCIPLES

Laboratories are designated according to their design features and constriction and containment facilities (safety precautions and equipment) as Basic—Biosafety Level 1, Basic—Biosafety Level 2, Containment—Biosafety Level 3, and Maximum Containment—Biosafety Level 4.

Table A4.1 describes the risk groups and Table A4.2 relates them to the laboratory designations. Table A4.3 gives a summary of the four biosafety level requirements.

TABLE A4.1. Classification of infective microorganisms by risk group.

Risk Group 1 (no or very 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.

TABLE A4.2. Relationship of risk groups to biosafety levels, practices, and equipment.

Risk Group	Biosafety Level	Examples of labs	Lab practices	Safety equipment
1	Basic—Biosafety Level 1 (BSL-1)	Basic teaching	GMT[a]	None; open bench work
2	Basic—Biosafety Level 2 (BSL-2)	Primary health services; primary level hospital; diagnostic, teaching, and public health	GMT plus protective clothing; biohazard sign	Open bench plus BSC[b] for potential aerosols
3	Containment—Biosafety Level 3 (BSL-3)	Special diagnostic	As BSL-2 plus special clothing, controlled access, directional air flow	BSC and/or other primary containment for all activities
4	Maximum Containment—Biosafety Level 4 (BSL-4)	Dangerous pathogen units	As BSL-3 plus airlock entry, shower exit, special waste disposal	Class III BSC or positive pressure suits, double-ended autoclave, filtered air

[a] GMT = good microbiological technique.
[b] BSC = biological safety cabinet.

Each country should draw up a classification by risk group of the microorganisms encountered within its boundaries, based on the following factors:

- Pathogenicity of the organism.
- Mode of transmission and host range of the organism. These may be influenced by existing levels of immunity, density and movement of the host population, presence of appropriate vectors, and standards of environmental hygiene.
- Availability of effective preventive measures. These may include prophylaxis by immunization or administration of antisera; sanitary measures, e.g., food and water hygiene; control of animal reservoirs or arthropod vectors; and restrictions on the importation of potentially infected animals or animal products.
- Availability of effective treatment. This includes passive immunization, postexposure vaccination, and use of antimicrobials and chemotherapeutics, taking into consideration the possibility of the emergence of resistant strains.

In assessing the various criteria for classification, it is also important to take into account conditions prevailing in the geographical area in which the microorganisms are handled. Individual governments may decide to prohibit the handling or importation of certain pathogens except for diagnostic purposes.

In the preparation of lists it is recommended that, where appropriate, additional information be given about the advisability of wearing gloves and eye protection and, in the case of some Risk Group 3 pathogens, whether or not a biological safety cabinet is required.

Existing classifications, made by different countries and official organizations, may be useful for the preparation of new classifications and guidelines. One such set of guidelines for hantavirus pulmonary syndrome is available from the U.S. CDC.

Genetically engineered microorganisms may be placed in the risk groups that are appropriate for their recipients and donors, and handled at the relevant biosafety level. Various national and international codes and guidelines for work with genetically engineered organisms are available and can help guide local efforts.

TABLE A4.3. Summary of biosafety levels.

	Biosafety Level			
	1	2	3	4
Isolation of laboratory	No	No	Desirable	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
Inward air flow	No	Desirable	Yes	Yes
Mechanical via building system	No	Desirable	Desirable	No
Mechanical independent	No	No	Desirable	Yes
Filtered air exhaust	No	No	Yes	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Effluent treatment	No	No	No	Yes
Autoclave:				
On site	Yes	Yes	Yes	Yes
In laboratory room	No	No	Yes	Yes
Double-ended	No	No	Desirable	Yes
Biological safety cabinets:				
Class I or II	No	Yes	Yes	Desirable
Class III	No	No	Desirable	Yes