ChABSA Scientific Symposium
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Challenges of Designing and Building a Biocontainment Laboratory in Latin America

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Main Topics

- Analyze the main changes in the new LBM by the WHO
- Compare the LBM 3 (part I) vs LBM 4 (section 3 and monograph #2)
- How these changes impact Latin American countries

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What Changes?

LBM 3

- Risk group definition
- Biosafety levels definition

LBM 4

- Definition of risk groups risk assessment based
- Biosefety levels risk assessment based

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LBM 3 part I

Source: WHO Laboratory Biosafety Manual. – 3rd ed. WHO/CDS/CSR/LYO/2004.11

Table 1. ***Classification of infective microorganisms by risk group***

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.

Table 3. ***Summary of biosafety level requirements***

	BIOSAFETY LEVEL			
	1	2	3	4
Isolation[a] of laboratory	No	No	Yes	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
— inward airflow	No	Desirable	Yes	Yes
— controlled ventilating system	No	Desirable	Yes	Yes
— HEPA-filtered air exhaust	No	No	Yes/No[b]	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Anteroom	No	No	Yes	—
Anteroom with shower	No	No	Yes/No[c]	No
Effluent treatment	No	No	Yes/No[c]	Yes
Autoclave:				
— on site	No	Desirable	Yes	Yes
— in laboratory room	No	No	Desirable	Yes
— double-ended	No	No	Desirable	Yes
Biological safety cabinets	No	Desirable	Yes	Yes
Personnel safety monitoring capability[d]	No	No	Desirable	Yes

[a] Environmental and functional isolation from general traffic.
[b] Dependent on location of exhaust (see Chapter 4).
[c] Dependent on agent(s) used in the laboratory.
[d] For example, window, closed-circuit television, two-way communication.

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LBM 3 part I

Source: WHO Laboratory Biosafety Manual. – 3rd Edition WHO/CDS/CSR/LYO/2004.11

Figure 2. A typical Biosafety Level 1 laboratory. (graphics kindly provided by CUH2A, Princeton, NJ, USA)

Figure 3. A typical Biosafety Level 2 laboratory. (graphics kindly provided by CUH2A, Princeton, NJ, USA). Procedures likely to generate aerosols are performed within a biological safety cabinet. Doors are kept closed and are posted with appropriate hazard signs. Potentially contaminated wastes are separated from the general waste stream.

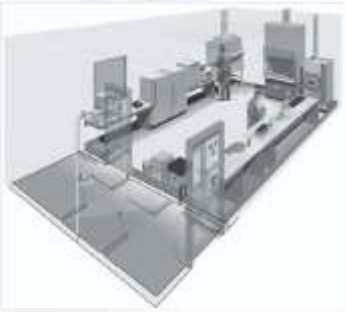

Figure 4. A typical Biosafety Level 3 laboratory. (graphics kindly provided by CUH2A, Princeton, NJ, USA). The laboratory is separated from general traffic flow and accessed through an anteroom (double door entry or basic laboratory – Biosafety Level 2) or an airlock. An autoclave is available within the facility for decontamination of wastes prior to disposal. A sink with hands-free operation is available. Inward directional airflow is established and all work with infectious materials is conducted within a biological safety cabinet.

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LBM 4 foreword/ Section 9 NATIONAL/INTERNATIONAL BIOSAFETY OVERSIGHT

Source: Laboratory Biosafety Manual, Fourth Edition. Geneva: World Health Organization; 2020 (Laboratory Biosafety Manual, Fourth Edition and associated monographs). License: CC BY-NC-SA 3.0 IGO.

Previous versions of the manual described the classification of biological agents and laboratories in terms of risk/hazard groups and biosafety/containment levels. While this may be a logical starting point for the handling and containment of biological agents, it has led to the misconception that the risk group of a biological agent directly corresponds to the biosafety level of a laboratory. In fact, the actual risk of a given scenario is influenced not only by the agent being handled, but also by the procedure being performed and the competency of the laboratory personnel engaging in the laboratory activity.

[1] 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 personnel, 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. Source: WHO Laboratory Biosafety Manual, 3rd edition (2004).

Table 9.1 Approaches for developing national biosafety regulations as part of a national legislative framework for biosafety

APPROACH	METHOD
Activity-based	The development of regulations that apply to the types of work being performed on a biological agent (rather than the biological agent itself). For example, regulations developed for all work involving recombinant DNA.
List-based	The development of one or more sets of national regulations and an accompanying list of all the biological agents for which those regulations apply.
Risk or hazard group	Biological agents are classified into "risk" or "hazard groups" based upon each agent's characteristics and epidemiological profile. The higher the risk or hazard group, the higher the likelihood that the agent will cause and spread infection in humans or animals in the country, and/or the more severe the consequences of that infection will be to individual and public health, if it were to occur. Regulations are then developed that apply to each of the risk or hazard groups. Classical definitions for risk groups 1 to 4 can be seen in footnote 1.

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LBM 4 Section 2 Risk Assessment

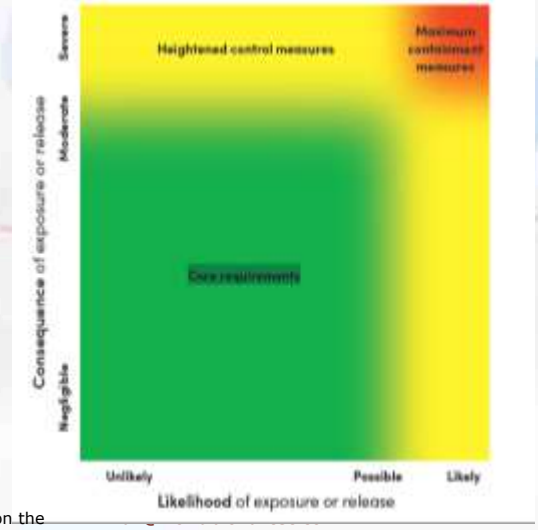
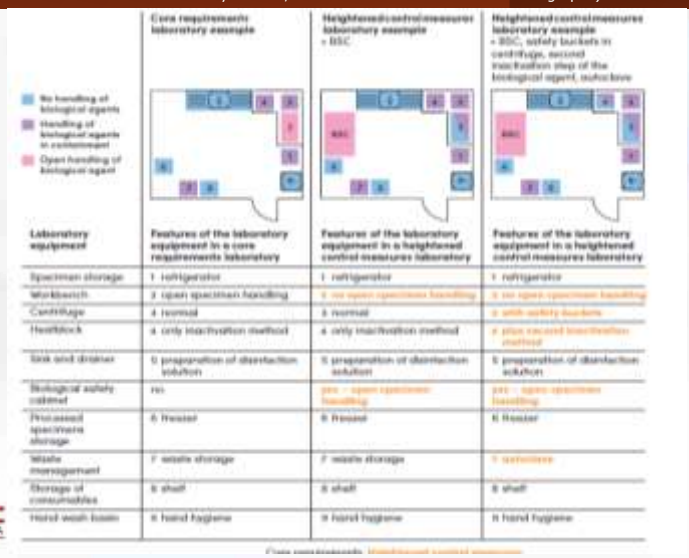


Figure 2.2 Risk control measures needed based on the likelihood and consequence of exposure or release

LBM 4 Monograph 2 LABORATORY DESIGN AND MAINTENANCE



LBM section 4 HEIGHTENED CONTROL MEASURES

- "…There are many different risk control measures available to address a single type of risk, and the selection of the most appropriate and effective measure will depend on local circumstances. Where national regulations exist, there may be compulsory, predefined lists of risk control measures to be used."… pg. 49

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What is Happening in Latin America

- There are no national guidelines nor regulations.
- Lack of biocontainment knowledge and expertise in laboratory design.
- Limited budget.
- Unlike the United States, the biosafety culture in Latin America is not strong.
- The decision makers usually do not have a scientific background.
- There is no culture of risk analysis or assessment.

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What is Happening in Latin America

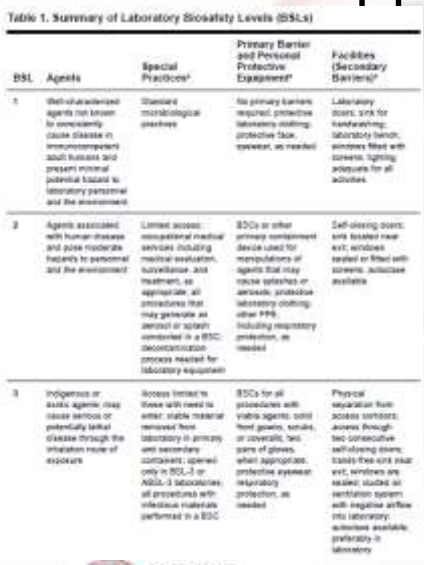

Table 1. Summary of Laboratory Biosafety Levels (BSLs)

BSL	Agents	Special Practices[a]	Primary Barrier and Personal Protective Equipment[b]	Facilities (Secondary Barriers)[c]
1	Well-characterized agents not known to consistently cause disease in immunocompetent adult humans and present minimal potential hazard to laboratory personnel and the environment	Standard microbiological practices	No primary barriers required; protective laboratory clothing; protective face, eyewear, as needed	Laboratory doors; sink for handwashing; laboratory bench; windows fitted with screens; lighting adequate for all activities
2	Agents associated with human disease and pose moderate hazards to personnel and the environment	Limited access; occupational medical services including medical evaluation, surveillance, and treatment, as appropriate; all procedures that may generate an aerosol or splash conducted in a BSC; decontamination process needed for laboratory equipment	BSCs or other primary containment device used for manipulations of agents that may cause splashes or aerosols; protective laboratory clothing; other PPE, including respiratory protection, as needed	Self-closing doors; sink located near exit; windows sealed or fitted with screens; autoclave available
3	Indigenous or exotic agents; may cause serious or potentially lethal disease through the inhalation route of exposure	Access limited to those with need to enter; viable material removed from laboratory in primary and secondary containers; opened only in BSL-3 or ABSL-3 laboratories; all procedures with infectious materials performed in a BSC	BSCs for all procedures with viable agents; solid front gowns, scrubs, or coveralls; two pairs of gloves, when appropriate; protective eyewear; respiratory protection, as needed	Physical separation from access corridors; access through two consecutive self-closing doors; clothes-free sink near exit; windows are sealed; ducted air ventilation system with negative airflow into laboratory; autoclave available, preferably in laboratory

Biosafety in Microbiological and Biomedical Laboratories, 6th Edition
Section IV—Laboratory Biosafety Level Criteria

- International guidelines like WHO Laboratory Biosafety Manual, 4th Edition and CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 6th Edition are not restrictive. The WHO LBM 4 presents a different point of view. These LBM and BMBL no longer speak the same language.

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What is Happening in Latin America

Table 3. Risk precaution levels, associated laboratory activities and risk assessment for tuberculosis (TB) laboratories

Risk level of TB laboratory[a]	Laboratory activities	Assessment of risk
Low risk	Direct sputum-smear microscopy; preparation of specimens for use in an automated nucleic acid amplification test cartridge (such as the Xpert MTB/RIF assay)	Low risk of generating infectious aerosols from specimens; low concentration of infectious particles
Moderate risk	Processing and concentration of specimens for inoculation on primary culture media; direct DST (for example, line-probe assays on processed sputum)	Moderate risk of generating infectious aerosols from specimens; low concentration of infectious particles
High risk (TB-containment laboratory)	Culture manipulation for identification; DST or line-probe assays on cultured isolates	High risk of generating infectious aerosols from specimens; high concentration of infectious particles

DST, drug-susceptibility testing.

[a] The risk level refers to how likely it is that someone in the laboratory will become infected with TB as a result of procedures performed in the laboratory.

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Source: Tuberculosis Laboratory Biosafety Manual. ISBN 978 92 4 150463 8.

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