WHO Laboratory Biological Safety Manual
4th edition (LBM4)
BWC Meeting of Experts on Review of Science and Technology (MX2)
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World Health Organization
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Health Emergencies Programme
IHR State Party Annual Reporting (SPAR): capacity 5.2
biosafety and biosecurity regime
Our audience varies...
WHO Laboratory Biosafety Manual 4th edition (LBM4) - *Elevator pitch*

- **Best practice sharing:** Evidence- and risk-based approach
  - Practical guidance for global audience
    - vis à vis ISO 35001 – management system standard
  - Not legally binding unlike International Health Regulations (IHR)
    - violation would not result in a ticket!
    - observance may enhance safety
- **de facto** regulatory document in some unregulated countries
- Referred by diverse sectors and countries
- Equitable, flexible, locally applicable, and therefore sustainable biosafety
Practicality & Sustainability

Pathogen Risk / Hazard Group

CANNOT / DOES NOT EQUATE

Biosafety / Containment Level
SARS-CoV-2 (COVID-19) related assays and Assessed risks

- Ag-RDT ............................................ BSL-"0"
- PoC/Near-PoC Testing .............. BSL-1
- PCR .................................................. BSL-2
- Virus isolation ............................ BSL-3
- Virus Manipulation/GoF .......... BSL-4
What is risk?

Hazard / Biological agent (Consequence) + Procedure/Activity (Likelihood) = Risk
Biological agent + Procedure = Risk

- **Severe** (e.g., high mortality that spreads to community)
- **Moderate** (e.g., treatable LAI)
- **Negligible** (e.g., infection unlikely)
- **Likely** (e.g., large volumes and high titre)
- **Possible** (e.g., vortex mixing)
- **Unlikely** (e.g., incubating agar plates)

**Consequence**

**Likelihood**

**Risk**

- **Very high**
- **Medium**
- **Very low**
Risk assessment process

Very high

Initial risk
Risk control measure applied

Residual risk of laboratory activity
Residual risk accepted

Start laboratory activity

Very low

Risk assessment process
Templates for risk assessment process

• Short and simplified template
  — for those new to the process and small laboratories with a well-defined, modest scope of work

• Long and detailed template
  — for large facilities with complex laboratory operations
  — training tool for risk assessment methodologies

• Exemplary risk assessments
  — two scenario-based examples for each template
Looking ahead

- **WHO biosecurity guidance document**
  - Being revised

- **WHO BioHub**
  - Biobank

- **WHO “model regulations”**
  - Regulatory guidance published

- **WHO SAGO**
  - For searching origin of novel pathogens

- **74th World Health Assembly**
  - LBM4 well received
  - Further guidance/support requested
Safeguarding biosafety and biosecurity in laboratories

- WHO biosafety homepage
  - https://www.who.int/activities/safeguarding-biosafety-and-biosecurity-in-laboratories

- WHO Laboratory Biosafety Manual 4th edition (LBM4)
  - https://www.who.int/publications/i/item/97892400113
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