
International health regulations (IHR) and laboratory biosafety guidelines

UNICEF Webinar

Strengthening biosafety and biosecurity in clinical
laboratories

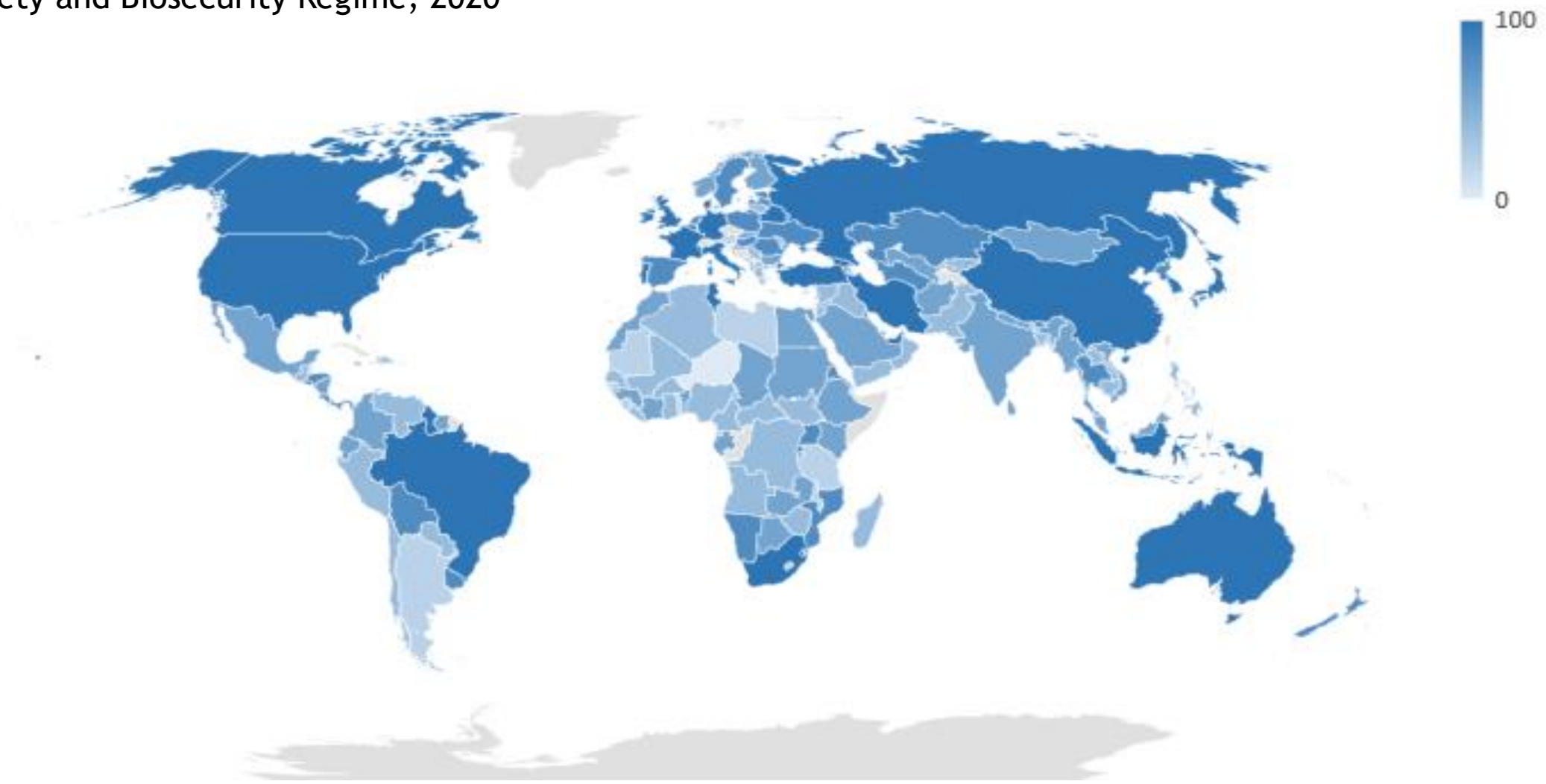
08 June 2022

Kazunobu Kojima



IHR State Party Self-Assessment Annual Reporting

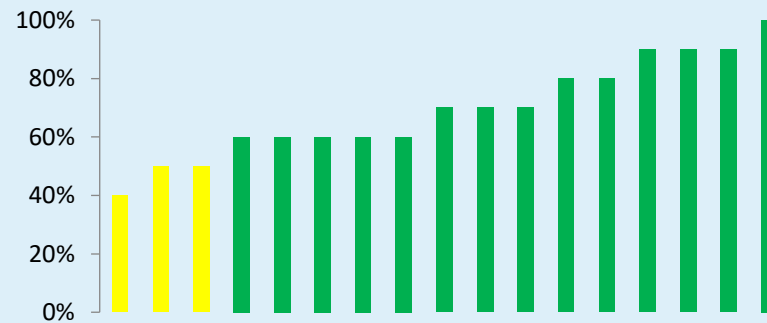
Biosafety and Biosecurity Regime, 2020



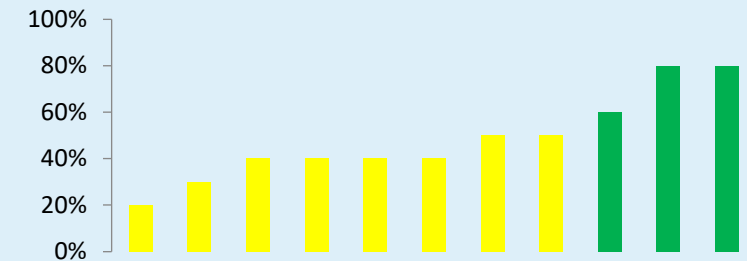
Joint External Evaluation (JEE) & Income Group Analysis

Biosafety and biosecurity

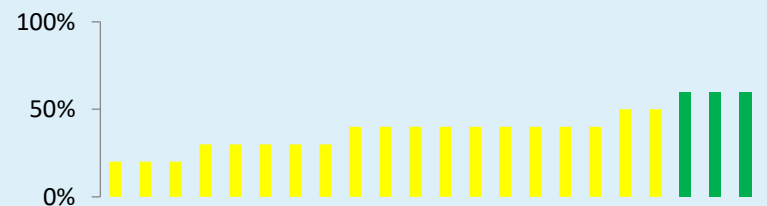
JEE Biosafety & Biosecurity (17 High Income Countries)



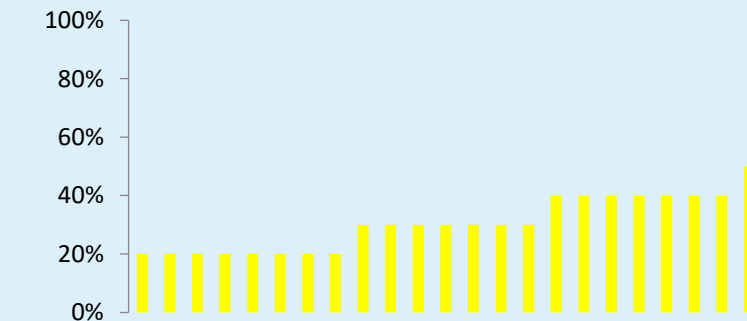
JEE Biosafety & Biosecurity (11 Upper Middle Income Countries)



JEE Biosafety & Biosecurity (23 Lower Middle Income Countries)



JEE Biosafety & Biosecurity (25 Low Income Countries)



Evidence- and risk-based approach in biosafety

Click to edit Master text styles

Second level

Third level

LABORATORY BIOSAFETY MANUAL
FOURTH EDITION
AND
ASSOCIATED MONOGRAPHS

LABORATORY BIOSAFETY MANUAL
FOURTH EDITION

- WHO Laboratory Biosafety Manual 4th Edition (LBM4)
- Equitable, flexible, locally applicable and therefore sustainable biosafety
- Allow better understanding and application of risk assessment
- Enhance and complement existing national regulations

WHO Laboratory Biosafety Manual

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**
- **Applicable to all laboratories irrespective of resources**
- **Equitable, flexible, locally applicable, and therefore sustainable biosafety**



WHO Laboratory Biosafety Manual 4th edition (LBM4) - ~~Site~~



“Core document”

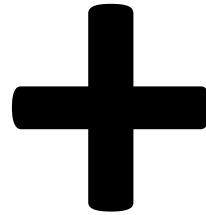
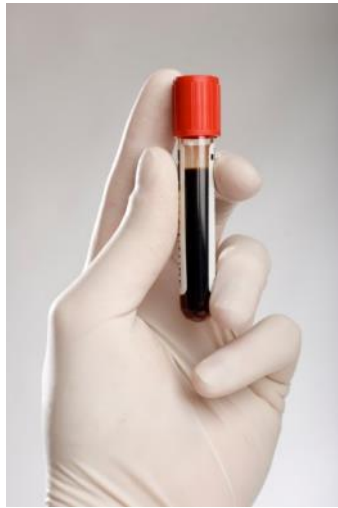
Supplementary monographs:

- Biosafety programme management
- Risk assessment
- Biological safety cabinets and other primary containment devices
- Personal protective equipment
- Laboratory design and maintenance
- Decontamination and waste management
- Outbreak preparedness and resilience

<https://www.who.int/publications/i/item/9789240011311>



Biological agent (Hazard) versus Process (Likelihood)



Biological agent

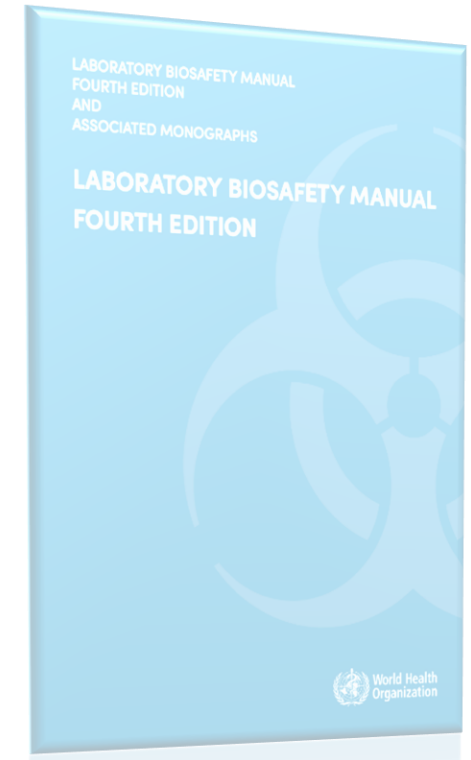
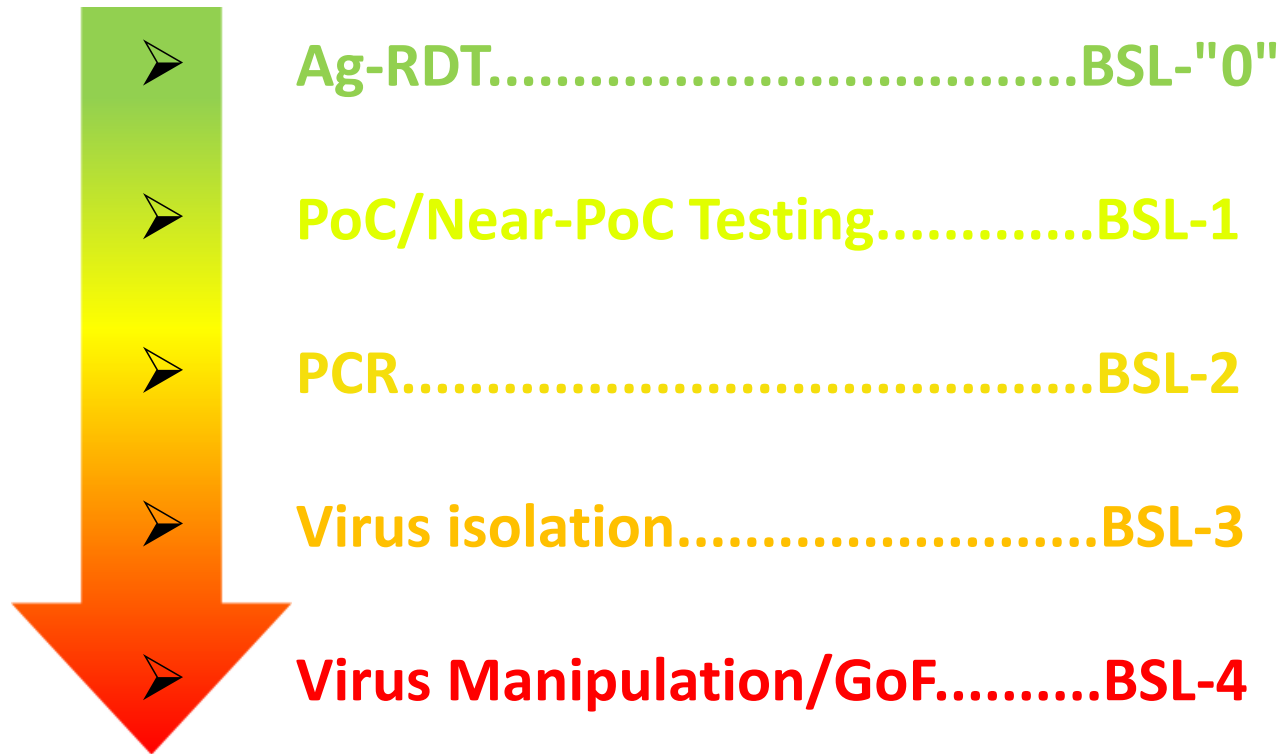
Process

Risk

[Likelihood + severity of harm (consequence)]

Risk-based approach?

SARS-CoV-2 (COVID-19) related assays and Assessed risks



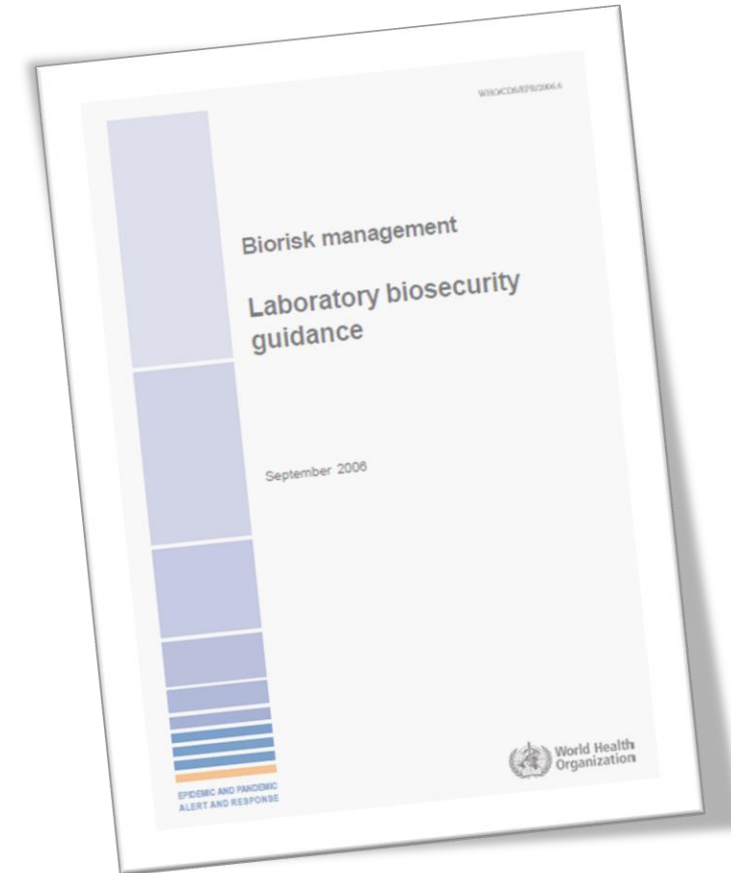
| | | Likelihood of exposure/release | | | | |
|----------------------------------|------------|--------------------------------|----------|----------|-----------|----------------|
| | | Rare | Unlikely | Possible | Likely | Almost certain |
| Consequences of exposure/release | Severe | Medium | Medium | High | Very high | Very high |
| | Major | Medium | Medium | High | High | Very high |
| | Moderate | Low | Low | Medium | High | High |
| | Minor | Very low | Low | Low | Medium | Medium |
| | Negligible | Very low | Very low | Low | Medium | Medium |

Revision of laboratory biosecurity guidance

Last edition published in 2006

Provide up-to-date technical information

- protecting, controlling and being accountable for valuable biological materials within laboratories
- preventing unauthorized access, loss, theft, misuse, diversion or intentional release
- taking into consideration the latest events and concerns relating to growing usage and accessibility to new technologies



Acknowledgement

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