WHO Laboratory Biosafety Manual Updates

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World Health Organization

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WHO Laboratory Biosafety Manual

- Having served for global biosafety community
  - Hereinafter, "WHO Manual"
  - "*For more than ~~20~~ 30 years, since it was first published in 1983, the Laboratory Biosafety Manual has provided practical guidance on biosafety techniques for use in laboratories at all levels.*" – WHO web site
- The 3rd edition translated into >10 UN official and other languages
  - WHO still receives queries for new languages
  - Published in 2004: 10 years have passed in this fast-evolving field → Time for revision

http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

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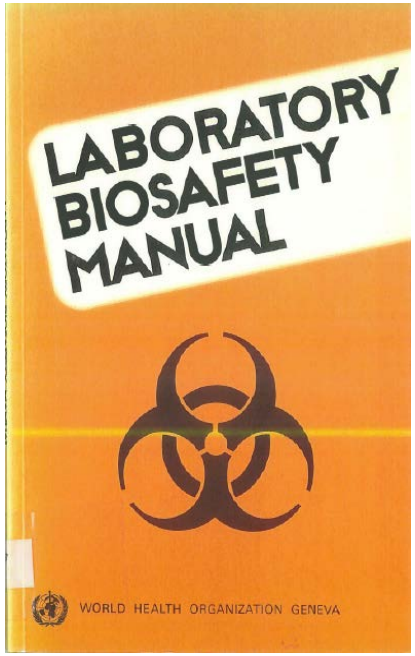
Things evolve

- WHO Manual (1st edition, 1983)
  - Risk Group: I, II, III and IV
  - "Laboratory Classification": Basic, Containment and Maximum Containment
    - "BSL" yet to be defined
  - PDCA cycle → review
- Technology
  - Common diagnostic methods
  - e.g. virus isolation → PCR
    - PCR first demonstrated in 1983



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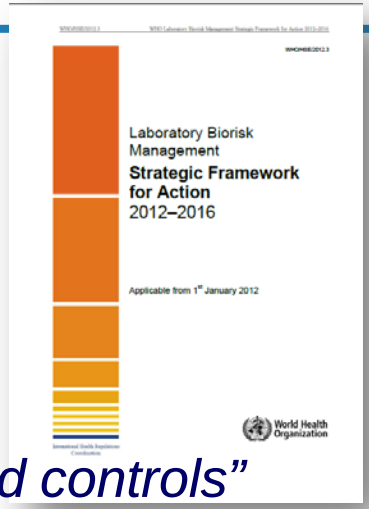
WHO Strategic Framework for Action 2012–2016

- WHO Extended Biosafety Advisory Group (BAG), 2010



- Regulatory and oversight mechanisms
  - *"Many countries remain without…"*
- Laboratory design and operating parameters
  - *"Often confusing"*
  - *"a lack of evidence to underpin many commonly used controls"*
- Universality of "solutions" questioned
  - *"Developing countries in particular often struggle to implement"*
  - *"effective supplier networks, maintenance provision and other basic measures" often unavailable*

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WHO Extended Biosafety Advisory Group (BAG) Meeting, Geneva, 24-25 November 2014

- Stakeholder meeting
- Review the 5-year plan

  ➔ Redefine organizational roles and functions of WHO
- Recommendations
  - Revision to the WHO Biosafety Manual is both a necessary and a priority
  - General agreement that a user needs survey would be beneficial to determine how the Manual can best suit their needs

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Review of the WHO Manual

- Discussion highlights:
  - Fundamental or progressive changes to manual
  - Prescriptive or performance-based requirements
  - Standard or guideline
  - Practical handbook or authoritative reference
  - Need for basic biosafety principles/criteria
  - Acknowledgement that WHO documents are considered the 'bible for users'
  - Need to promote local and green solutions with focus on energy conversation - move away from unsustainable outcomes
  - Acknowledgement that a graduated approach to compliance (whether by tier, step, etc.) can be beneficial
  - Useful to consider “appropriate technology” that provides equivalent safety with a limited cost

Our audience varies…

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Under construction…

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International Health Regulations – IHR (2005)

Legally binding for all 196 States Parties, international law

Requires countries to develop minimum core national and international surveillance and reporting capacities

Core capacity 8: Laboratory

- Policy and coordination
- Diagnostic capacity
- **Laboratory biosafety and biosecurity**
- Laboratory based surveillance

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Revision objectives

- Comprehensive revision
- Critical appraisal of biosafety practices (i.e. pathogen RG and BSL)
  - to be discussed below
- Risk-based
- Core/minimum requirements + suggestions for additional safety/security
  - provision of decision making instrument/flowchart
- Evidence-based
  - knowledge gap
    - what sort of evidence/experiments/research needed?
- Feasible and sustainable

WHO Laboratory Biosafety Manual

Reviewing/redefining key concepts

- Microorganism Risk Group
  - Risk Groups 1 to 4
- Biosafety level
  - Simple equation: helpful?
    - e.g. Ebola = RG4 = BSL4??
- →**Risk-based** approach
- → **Evidence-based** biosafety
- → Clear needs to define **core requirements**
  - realistic; better feasibility and sustainability

Risk Group 1: No or low individual and community risk

Risk Group 2: Moderate individual risk, low community risk

Risk Group 3: High individual risk, low community risk

Risk Group 4: High individual and community risk

Table 2. ***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 BSCs, double-ended autoclave (through the wall), filtered air

BSC, biological safety cabinet; GMT, good microbiological techniques (see Part IV of this manual)

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Review for the revision…1

- Scope
  - Audience
  - Biological materials, new technology
- Biosafety and biosecurity
- Approach
  - Setting out “core requirements”
- Focused areas
  - Good microbiological practices (GMP)
  - Risk assessment

Review for the revision…2

- Pathogen risk group (RG)
  - e.g. 1918 influenza: RG2 in some countries?
    - e.g. EU DIRECTIVE 2000/54/EC
- Biosafety level (BSL)
  - Physical containment (PC) level
  - Operational practices
  - BSL3+? BSL2**??
- Clear dissociation of RG and BSL
- Engineering and operational/administrative controls
  - Hierarchy of controls
  - Human factors (Human failure), e.g. validation

Areas missing/consideration

- Commissioning/Decommissioning
- Regulatory oversight mechanism
  - Reference to roles and functions of regulatory framework
  - to share best practices
- Field/emergency operations
  - Practically feasible operational guide
    - e.g. Ebola outbreak
- Common causes of accidents
- Risk communication

High containment facility

- Definition
- “Certification”
  - WHO standard?
- BSL3 assessment tool
- Mashrooming of BSL3s
  - Costing tool and checklist for planning
  - Recurring costs tend to be forgotten
- Construction, commissioning, operational/specific training

Derivatives/Supplementary publication

- Training tools
- "Monograph" – subject-specific booklet, such as:
  - BS in pathology lab
  - Research and production facilities
  - Animal facilities
  - Designing the labs
  - Waste management/waste segregation
    - clear guidance and solutions
  - Emergency procedures
  - Field/outbreak operations
  - Equipment and PPE - selection criteria
  - Disinfection, inactivation
  - Validation
  - Regulatory oversight mechanism
  - Accident/incident investigation, reporting, analysis
  - Risk communication
  - …

WHO Manual revision: Summary

- Comprehensive revision
  - Work plan drafted
    - a three-year project
    - consultation to various stakeholders planned
  - Manual (main text) + monographs
- Core requirements
  - Risk-based
    - clear decoupling of RG and BSL → decision-making instrument
    - Evidence-based
  - Aiming at practical feasibility and sustainability
  - User-oriented➔ suggestions much appreciated

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