Enhancing Health and Security for All

WHO Laboratory Biosafety Manual (LBM) Revision Update

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2nd OIE Global Conference on Biological Threat Reduction

OTTAWA, CANADA
31 Oct–2 Nov 2017

WORLD ORGANISATION FOR ANIMAL HEALTH
Protecting animals, preserving our future
Presentation overview

• Background
• Key concepts
• Aiming to achieve
• Risk (hazard) groups
• Biosafety levels
• Core Requirements, Heightened Control Measures, High Containment
• Way forward
WHO Laboratory Biosafety Manual (LBM)

- LBM has served the global biosafety community for more than 30 years with practical guidance on biosafety

  - Risk Group: I, II, III and IV
  - "Laboratory Classification": Basic, Containment and Maximum Containment
    - "BSL" yet to be defined

- Technology
  - Common diagnostic methods
  - e.g. virus isolation, electron microscope
    → PCR  PCR first demonstrated in 1983
LBM Evolution

- BSL 1-4

- Rapidly advancing technology

- The current 3rd edition has been translated into >10 UN official and other languages and WHO continues to receive requests for translation into other languages

- Published in 2004, 13 years have passed in this fast-evolving field


• Key Recommendation 2014
  – Revision to the WHO Biosafety Manual is both a necessary and a priority

• Key Recommendation 2016
  – General agreement for the proposed modifications to the manual, the revision of which remains a priority
Our audience varies...
Pragmatism?

Next Service / Certification date: Soonest
Issues in space and work flow
Issues in space and work flow
Pathogen (Hazard) versus Process (Likelihood)

Pathogen + Process = Risk

[Likelihood + severity of harm]
Biosafety Level 3?
Facility

• Sustainability:
  – Funding for construction vs. operational costs
  – Staff
  – Scientific programme

• Technical challenges
Good Microbiological Practices and Procedures (GMPP)

- Emphasis on risk assessment and training rather than engineering controls in GMPP

- The best designed and most engineered laboratory is only as good as its least trained worker

- Human factors are generally the cause of LAIs rather than malfunctions of engineering controls
Proposed Way Forward

• Ensure a practical, risk- and evidence-based approach to biosafety

• Flexibility

• Uphold good microbiological practices/procedures

• Encourage sustainable facilities
How?

• Refocusing on good microbiological practices and procedure

• Emphasising the importance of competence and on-going on-the-job training

• Highlighting what risk assessment is and how it should be performed

• To remove Risk Groups and Biosafety Levels at the global level to allow appropriate and practical measures are in place to mitigate the risk(s) identified
Concept

Risk (Hazard) groups ≠ Biosafety level
Factors affecting consequence

High severity or mortality plus:

- Low infectious dose
- High communicability
- Airborne route of transmission
- No preventive or therapeutic treatment available
- History of laboratory-acquired infection
- Exotic epidemiology (non-endemic)
- Highly susceptible population (e.g. immunocompromised, naïve)
- Increasing virulence
Procedures with high likelihood of exposure

- Producing and using large volumes and high titres
- Procedures that might have the potential to generate aerosols e.g. sonication, or deliberate generation of aerosols
- Infecting animals
- Using sharps
- Necropsy where infection is suspected
Procedures with low likelihood of exposure

- Use of agar plates (e.g. streaking, spreading)
- Serial dilution
- Preparing/staining slides
- Nucleic acid extraction
- Inactivation
- Use of autoanalysers
- ELISA
- PCR
- Rapid diagnostic tests
Risk assessment

High

Consequence of exposure or release

Likelihood of exposure

Core Requirements
(equivalent BSL2 minus BSC)

Heightened Control Measures (HCM)
(equiv. BSL2 + HCM e.g. BSC, extra PPE, containment up to and including BSL3)

Maximum Containment

(equiv. BSL4)
Core Requirements

• “Core requirements” refers to a combination of elements to be implemented and used as a minimum requirement for safe working during the majority of laboratory procedures.
  – codes of conduct
  – competent and appropriately trained staff
  – the laboratory facility/equipment
  – good microbiological practices and procedures.

• Core requirements will be fundamental to safe working practices of any facility.
Heightened Control Measures

Control Measures to be increased with...

...increased risk
# Heightened Control Measures: Examples

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Process</th>
<th>Routes of exposure</th>
<th>Example controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mycobacterium tuberculosis</td>
<td>Diagnostic via PCR</td>
<td>- Aerosol</td>
<td>- Gloves, (RPE)</td>
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<tr>
<td></td>
<td></td>
<td>- Splash</td>
<td>- Work within a BSC prior to inactivation using validated methods</td>
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<tr>
<td></td>
<td></td>
<td>- Contact</td>
<td>- BSC work surface disinfection post use</td>
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<tr>
<td>Brucellosis</td>
<td>Culture</td>
<td>- Splash</td>
<td>- Double gloves, facial protection, RPE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Aerosol</td>
<td>- Work within a BSC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Work surface disinfection on test completion</td>
</tr>
</tbody>
</table>
Maximum Containment

Highest control

Example of when maximum containment might be required:

• Eradicated diseases such as smallpox

• Procedures with high likelihood of exposure and impact of release to the environment:
  – Unknown agents of potential high consequence
  – Known pathogens of high consequence
Plan of Action

- To create a central core document with
- Additional monographs that go into detail on several key aspects including
  - Risk assessment,
  - Biosafety programme management,
  - Laboratory design and maintenance,
  - Biological safety cabinets and isolators,
  - PPE,
  - Decontamination and waste management, and
  - Emergency/outbreak response
- Publication of a position paper prior to release of the LBM to outline the rationale for the changes
Acknowledgements

Editorial Committee:

Marianne Heisz, Public Health Agency, Canada
Allan Bennett, Public Health England, UK
Stuart Blacksell, Mahidol-Oxford Tropical Medicine Research Unit, Thailand
Michelle McKinney, National Institute of Health, USA
Kathrin Summermatter, Institute of Virology and Immunology, Switzerland
Catherine Makison Booth, Health & Safety Laboratory, UK

Global Partnership Program (GPP), Global Affairs Canada
Biosecurity Engagement Program (BEP), U.S. Department of State
Thank you

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