Biosafety in Microbiological and Biomedical Laboratories: The Next Edition

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BMBL

- What is it?
- History
- 4th Edition
- Rewrite process
- New in the 5th Edition
- Timeline

BMBL

- Development of “Biosafety in Microbiological and Biomedical Laboratories”
  - First Edition: 1983, 4th Edition; 1999
  - Organized attempt at developing a standard of practice for working with infectious agents (not the first, but perhaps first on this scale)
  - Specifically describes combinations of microbiological practices, laboratory facilities, and safety equipment, and to recommend their use in four categories or biosafety levels of laboratory operation with selected agents infectious to humans.

BMBL: What is it?

- This publication describes the combinations of standard and special microbiological practices, safety equipment, and facilities constituting Biosafety Levels 1-4, which are recommended for work with a variety of infectious agents in various laboratory settings.

- These recommendations are advisory. They are intended to provide a voluntary guide or code of practice as well as goals for upgrading operations. They also are offered as a guide and reference in the construction of new laboratory facilities and in the renovation of existing facilities.

- However, the application of these recommendations to a particular laboratory operation should be based on a risk assessment of the special agents and activities, rather than used as a universal and generic code applicable to all situations.

BMBL as a Biosafety Tool

- Based on Individual Risk Assessment
- “Should” “Could” “May” “Recommended”
- Find: “Must” “Required”
- Flexible and adaptable
- Balance allowing the work to continue with allowing the work to proceed safely
- Multiple layers of guidance/regulations
  - BMBL…DHHS….NIH….Institute….Laboratory

BMBL: the 4th Edition

- Introduction
- Principles of Biosafety
- Laboratory Biosafety Level Criteria
- Vertebrate Animal Biosafety Level Criteria
- Risk Assessment
- Recommended Biosafety Levels for Infectious Agents and Infected Animals
- Bacteria, Fugal, Parasitic, Prions, Rickettsia, Viral, Arboviruses
- Appendix A: BSCs
- Appendix B: Immunoprophylaxis
- Appendix C: Transport
- Appendix D: Restricted Animal Pathogens
- Appendix E: Resources
- Appendix F: Select Agents
- Appendix G: IPM
- Appendix H: Human/NHP cells and tissues
- Appendix I: Biotoxins

BMBL: the 4th Edition

- Agent Summary Sheets: Guidance for specific agents
- 5th edition: more standardized format

Organism Name

INTRODUCTION

Description

Latin name of organism (genus and species)
Common names for organism (if relevant)
General Microbiology of organism (not disease)
Relevant natural history and clinical information (Infectious dose, etc.)

Occupational Infections

Brief history of laboratory associated infections and occurrence of occupational exposures
Modes of occupational transmission (if relevant)
Unique factors of occupational exposures, for example:

- Brief description of occupational acquired disease (incl. unique occupational factors)
- Body system most likely affected by occupational infection
  (Skin, GI, Muscular, Vision, Central Nervous Sys, Reproductive, etc.)

Natural Modes of Infection

Common names of disease
Brief description of naturally occurring disease (host range, geographic range, etc.)
Natural mode of infection/transmission

LABORATORY SAFETY

Organism risk factors in the lab (presence in what kinds of samples)
Modes of occupational transmission (if relevant, repeat if significant)
Risk in labs, and with animals
Unique information for laboratory handling (if a specific situation or procedure represents a severe risk)

Containment Recommendations

BE BRIEF and as general as possible – MINIMIZE NUMBER OF RECOMMENDATIONS
BRIEFLY justify special circumstances (increased bio-containment) if recommended
Do not forget Animal Biosafety Levels
Includes other recommendations (Greenhouse, Large scale, PPE, BSC use) if different/elevated risk from BSL

SPECIAL ISSUES

Unique Headings for each organism
Be Brief and relevant and remember we already have chapters for transport, security, etc.
Include relevant regulatory issues as needed (Is the organism a select agent? Does USDA/FDA/EPA have jurisdiction over this organism?)

IF YOU THINK IT IS IMPORTANT, INCLUDE IT!

BMBL: the 5th edition

- The Process
  - Late 2002: Formation of the Executive Steering Committee
    - CDC and NIH (total of 4 members)
    - Oversee process
    - Obtain and expend funding
    - Engaged Project Coodinator and Technical Editor
    - Determined needs, overall layout, new topics
    - Identified coordinating editors
    - Review all documents
    - Oversee the publication process

BMBL: the 5th Edition

- The Process:
  - Section identified (new or old)
  - Coordinating editor (CO) selected
  - CO organizes SME committee
  - Old sections: focus on update, not completely rewriting
  - CO organizes efforts, coordinates reviews, deadlines, etc.
  - CO sends draft document to Project Coordinator

BMBL: the 5th Edition

- Development time ranges from a few weeks to 2 years
- Some topics have single editors and small review groups: others have large groups
  - Arbovirus/Hemorrhagic fever virus section
    - 20 SME (CDC, NIH, USDA, UTMB, USAMRIID)
    - Now 600 viruses
    - New format
    - New agent summary statements
    - 2 years, 5 months, and counting……

BMBL: the 5th Edition

- Project Coordinator delivers documents to Steering Committee
- Steering Committee reviews for content, consistency, changes from 4th edition, etc.
- Steering Committee and Project Coordinator send changes back to CO or accepts document
- CO:
  - Accepts changes
  - May return to SMEs for further review

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- Accepted Document sent to Technical Editor
  - Internal consistency of reference format, acronyms, terminology, document format, etc.
  - Redundant check for content errors
- Edited document ready for post submission process

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- Currently, approximately 85% submitted and more than half of that has been fully reviewed
- New sections include:
  - Introduction to biosecurity
  - Decontamination
  - USDA standards (beyond Appendix D)
  - rDNA Issues
  - New Agent Summary Statements (SARS)
  - Occupational Medicine

BMBL: the 5th Edition

- Post Submission changes
  - Focus on intra-document consistency
  - Professional Indexing
  - Glossary Development

Questions?