National Institutes of Health
Office of Management

Revision of the BMBL

Where are we now and where are we going?

Deborah E. Wilson, DrPH, SM (NRCM), CBSP
Rear Admiral, US Public Health Service (Ret.)
Director, Division of Occupational Health and Safety

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Biosafety in Microbiological and Biomedical Laboratories (BMBL)

- First Edition – 1984
- Co-published by the Centers for Disease Control and Prevention and the National Institutes of Health
- Cornerstone of biosafety practice in the United States and relied heavily upon around the world
- Performance-based set of guidelines
- Is not a regulatory document
- Referred to in various USG regulations as a guidance document

How are we proceeding?

- **Fifth Edition officially published in 2009**
- **Over 200 scientific and technical contributors**
- **Critique – Scientific Community was not involved in the revision leading to the BMBL 5th Edition**
- **To address this criticism, CDC and NIH engaged the National Academies of Sciences, Engineering, and Medicine (NAS) to solicit the broadest scientific community input**

NAS Approach

- **Established a Committee on Soliciting Stakeholder Input for Revision of the BMBL**

  Dr. Robert Ellis - Colorado State University

  Dr. Debra Hunt - Duke University

  Dr. Thomas Ksiazek – University of Texas Medical Branch, Galveston

Approach to Broadly Reach Stakeholders

- **NAS conducted a Virtual Town Hall Meeting**
  - April 4 through May 20, 2018
- **Stakeholders were asked to share thoughts on the BMBL, in general and its individual sections and appendices**
- **Specifically, stakeholders were asked what information should be added, revised or deleted**
- **Major themes from the virtual town hall meeting were developed for further discussion at a Workshop held at NAS on May 12, 2016**
- **Workshop was webcast and further comments, thoughts, and participation solicited**

Additional Information Sought by CDC/NIH

- **Should the BMBL remain performance based or should it become more prescriptive in nature?**
- **To what degree does the BMBL be revised – is a major revision needed or just a minor one?**
- **What new information or special topics should be included in the BMBL?**
- **What new Agent Summary Statements should be included in the 6th Edition?**
- **Are the Agent Summary Statements adequate; are they useful; what information should be added to them?**

A little more about the process…

- **Thoughts, comments, recommendations were summarized by NAS and provided to the CDC/NIH for consideration**
- **Summarized input was provided to Primary Authors for consideration during revision**
- **Primary Authors were established based on scientific and/or technical expertise**
  - Contributors

Where are we now?

- **Which sections will be revised (moderate or major)?**
  - Fungal Agents
  - Parasitic Agents
  - Viral Agents (SARS → Human coronaviruses; poliovirus- to reflect eradication efforts and address containment issues)
  - Toxins
  - Appendix A - Primary Barriers – reflect changes in NSF 49 and addition of new type of BSCs
  - Appendix D – Agricultural Pathogen Biosafety
  - Appendix F – Select Agents and Toxins

  - Appendix I – Guideline for Work with Toxins of Biological Origin
- **New Material**
  - Appendix on Clinical Laboratories
  - Appendix on Inactivation and Validation of Microbial Agents
  - Appendix on Large Scale Production
  - Appendix on Laboratory Sustainability