



National Institutes of Health  
*Office of Management*

# Revision of the BMBL

## Where are we now and where are we going?

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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 5<sup>th</sup> 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**

- **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**

- **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**

- **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 6<sup>th</sup> Edition?**
- **Are the Agent Summary Statements adequate; are they useful; what information should be added to them?**

- **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

- **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