Revision of the BMBL

Where are we now and where are we going?

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• 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
• 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
• 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?
• 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