Biosafety in Microbiological and Biomedical Laboratories-5th Edition

Impact on Influenza Research in the United States

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The BMBL Revision Process

- Government Steering Committee
  - Centers for Disease Control and Prevention
  - National Institutes of Health
- Guest Editors
- Working Groups
- Reviewers

BMBL Revision Process

- Update and Revise 4th Edition
- Not a major re-write
- General appearance and format will be retained
- Agent Summary Statements are being updated and revised

BMBL Revision Process

- Agent Summary Statements are added when:
  - Evidence of laboratory-acquired infection
  - Significant public health impact or interest

BMBL Revision Process

- Several New Chapters
  - Occupational Health and Medicine
  - General Concepts of Biosecurity
  - Biosafety Level 3(Ag)
- Emphasis added on Risk Assessment
- Additional Appendices

BMBL Revision Process

- Complex process
- Involves many people
  - Guest Editors 30
  - Contributors 70
  - Animal Biosafety Levels Workgroup 25
  - Biosafety Levels Workgroup 25
  - Biosafety Level 3 (Ag) 25
- Does not include reviewers

BMBL Revision Process

Expected Release Date

Summer 2005

Impact on Influenza Research ?

- Agent Summary Statement is being revised
- Control of Influenza is a continuing human and veterinary public health concern
- Department of Health and Human Services and Department of Agriculture are working closely to harmonize requirements for the conduct of scientific research

Factors of Interest to the Influenza Workgroup

- Pathogenicity of the viruses
- Route of transmission
- Agent stability (environmental)
- Infectious dose
- Virulence data from animal studies
- Availability of effective prophylaxis or therapeutic intervention

Factors of Interest to Influenza Workgroup

- Experience and skill of at-risk personnel
- Source of the virus (geographic)
- Potential risk to laboratory worker
- Pandemic potential
- Agricultural/economic risk

Risk Assessment Factors Applied to:

- Contemporary, circulating human influenza strains (e.g., H1/H3/B)
- Low pathogenicity avian influenza (LPAI) strains (e.g., H1-4, H6, H8-15)
- Non-contemporary human influenza (e.g., H2N2)
- Highly pathogenic avian influenza (HPAI)
- Research involving reverse genetics of the 1918 influenza strain

Recombinants vs. Reassortants

- The BMBL will bridge the gap left by the *NIH Guidelines for Research Involving Recombinant DNA Molecules* regarding experiments creating or using influenza reassortants.

Other Influenza reassortants or recombinants

- The gene constellation used
- Clear evidence of reduced virus replication in the respiratory tract of appropriate animal models compared with the replication of wild-type parent virus from which it was derived
- Evidence of clonal purity and phenotypic stability
- The number of years since a virus that was antigenically related to the donor of the hemagglutinin and neuraminidase genes last circulated

Occupational Health Considerations

- Personnel counseling and monitoring
- Availability of antiviral drugs for treatment and post-exposure prophylaxis
- Baseline serum storage
- Respiratory protection program