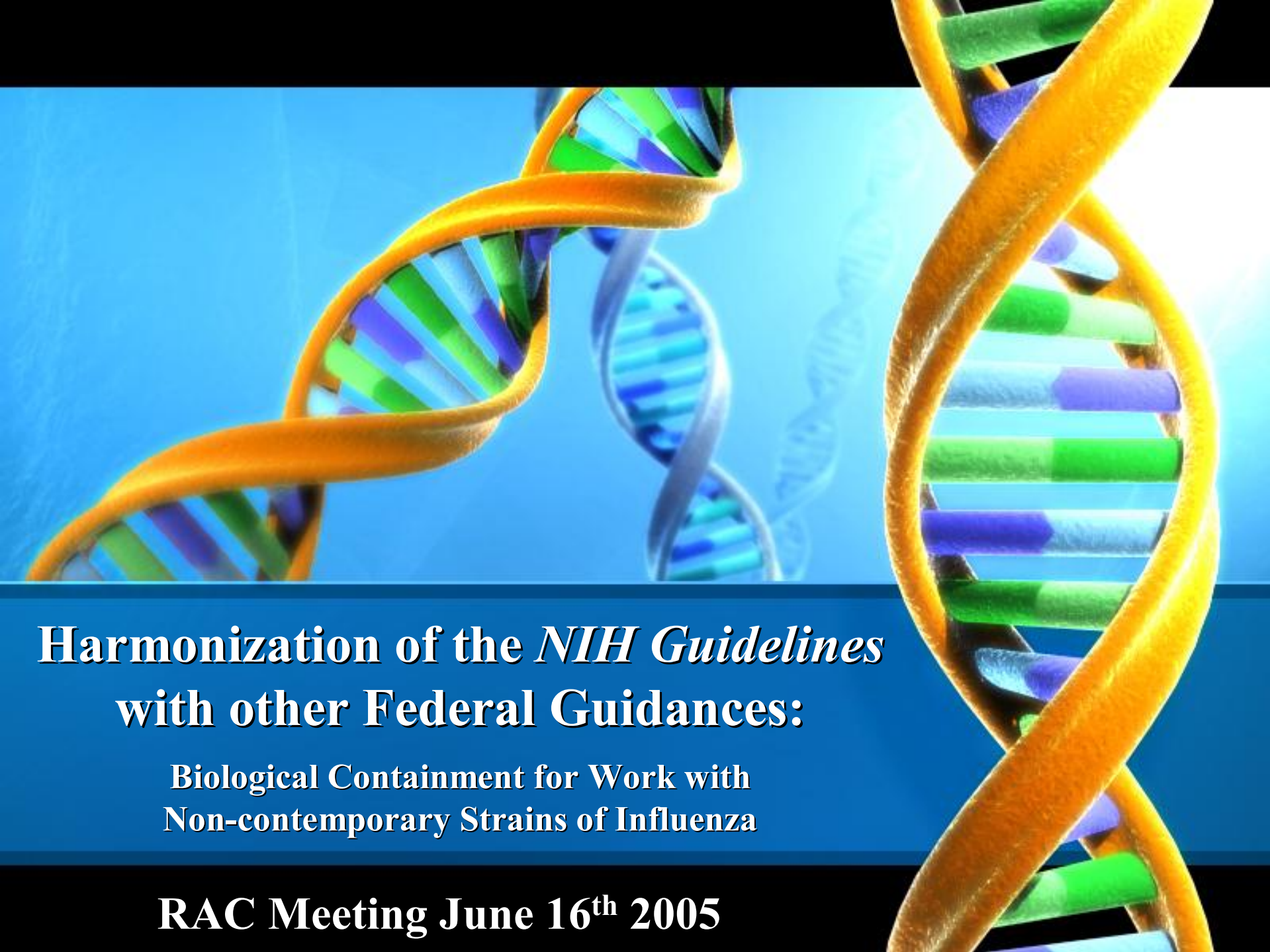




Harmonization of the *NIH Guidelines* with other Federal Guidances:

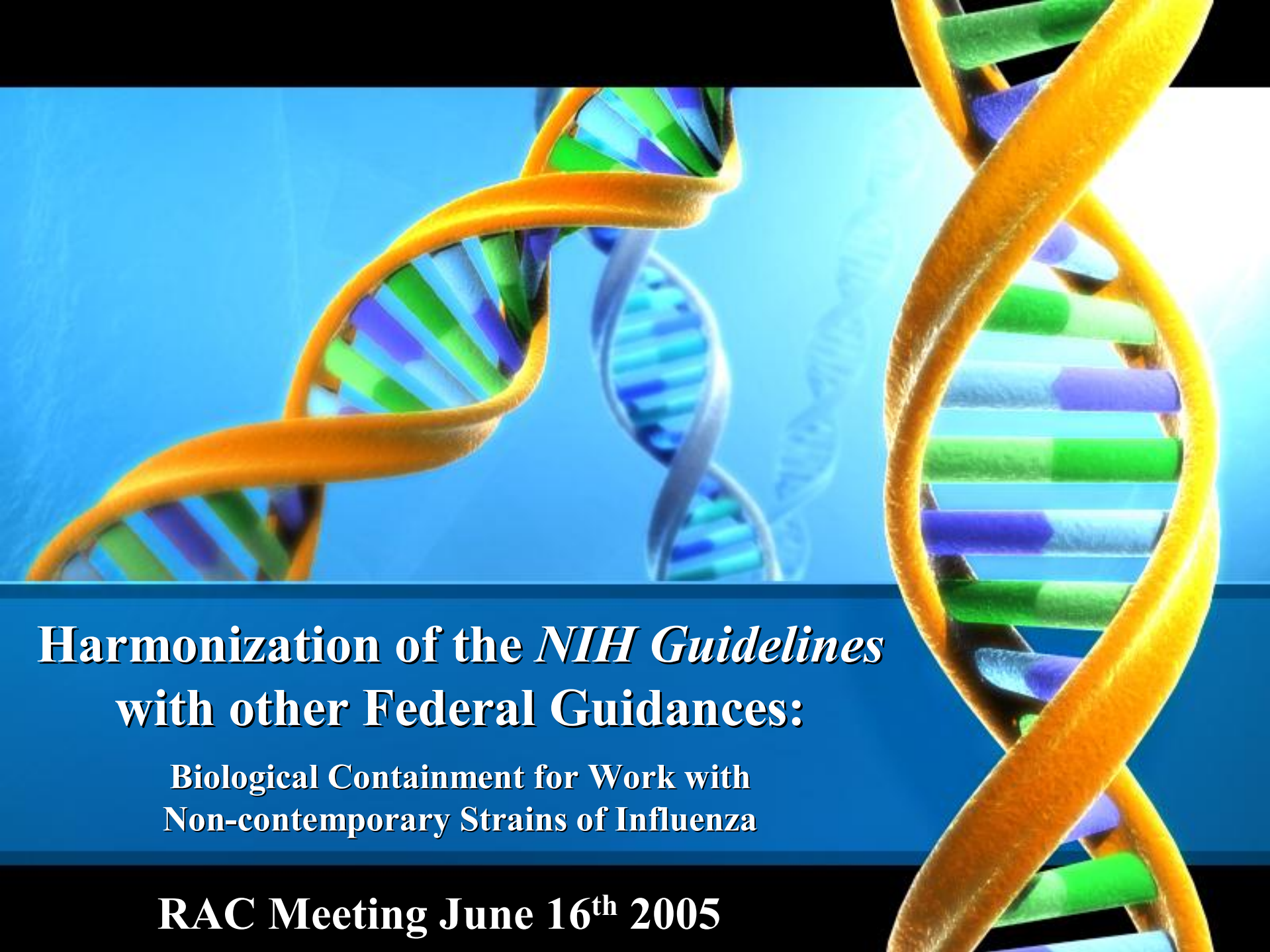
Biological Containment for Work with
Non-contemporary Strains of Influenza

RAC Meeting June 16th 2005

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Harmonization of the *NIH Guidelines* with other Federal Guidances:

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Risk Groups and Containment Levels

■ Risk Groups

- | | |
|------------|--|
| RG1 | Agents are not associated with disease in healthy adult humans. |
| RG2 | Agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are <i>often</i> available. |
| RG3 | Agents are associated with serious or lethal human disease for which preventive or therapeutic interventions <i>may be</i> available. |
| RG4 | Agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are <i>not usually</i> available. |

■ Containment levels

- ❑ Containment level often equivalent to the Risk Group
- ❑ Containment level may be raised or lowered depending on a comprehensive risk assessment.



Current Recommendations

- **Appendix B-II-D. Risk Group 2 (RG2) – Viruses**
 - **Orthomyxoviruses**
 - **Influenza viruses types A, B, and C**
 - **Other tick-borne orthomyxoviruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)**
- **Containment levels higher than the Risk Group classification may be appropriate.**
 - **Biosafety Level 3 containment is appropriate for research with non-contemporary strains.**



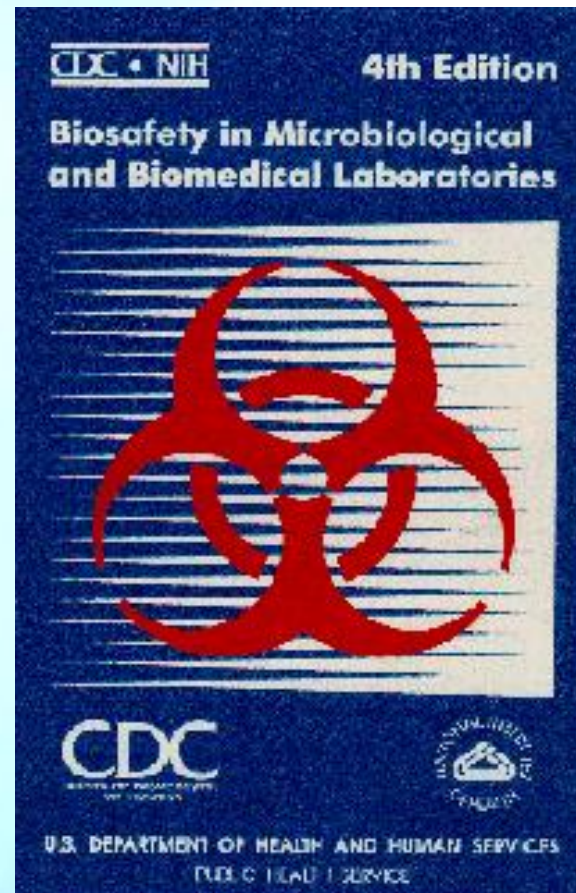
New Recommendations

- **May 3, 2005 - CDC announced an increase in the recommended containment level (from Biosafety Level 2 to Biosafety Level 3) for laboratories working with non-contemporary strains.**
 - **Pandemic potential**
 - **Lab worker and public safety**



New Recommendations

- **Fall 2005 - CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (5th Edition) will recommend a similar increase in containment level for:**
 - ❑ **Non-contemporary human influenza strains**
 - ❑ **Research involving reverse genetics of the 1918 influenza strain**
 - ❑ **Highly Pathogenic Avian Influenza (H5N1).**



Next Steps

- **Specify that the Risk Group classification for non-contemporary strains of Orthomyxoviruses (including H2N2, H5N1 Highly Pathogenic Avian Influenza virus, and 1918 Influenza virus) is Risk Group 3.**
- **Provide additional specific biosafety recommendations for research with non-contemporary strains of Orthomyxoviruses, in keeping with the recently publicized CDC recommendation and the revised language for the 5th edition of the BMBL.**

(Contemporary strains of Orthomyxoviruses will retain their classification as Risk Group 2 agents)



Change to Appendix B-II-D Risk Group 2 (RG2) – Viruses

Proposed Change to Existing Text:

Orthomyxoviruses

- Influenza viruses types A, B, and C **except non-contemporary human strains (including H2N2 and 1918 Influenza virus), and highly pathogenic avian influenza virus (H5N1), (see Appendix B-III-D, Risk Group 3 (RG3) – Viruses and Prions)**
- Other tick-borne orthomyxoviruses as listed in the reference source (see Section V-C, *Footnotes and References of Sections I through IV*)



Change to Appendix B-II-D

Risk Group 3 (RG3) – Viruses and Prions

Text To Be Added:

Orthomyxoviruses

- Non-contemporary human strains of influenza viruses (including H2N2 and 1918 Influenza virus) and highly pathogenic avian influenza virus (H5N1).**



Change to Section II-A-3

Comprehensive Risk Assessment

- **Important considerations**
 - **Number of years since an antigenically related virus last circulated**
 - **Potential for presence of a susceptible population**
 - **Significant pandemic potential**
 - **Significant agricultural and economic implications.**
 - **Availability of risk assessment data**



Addition to Section II-A-3

Comprehensive Risk Assessment

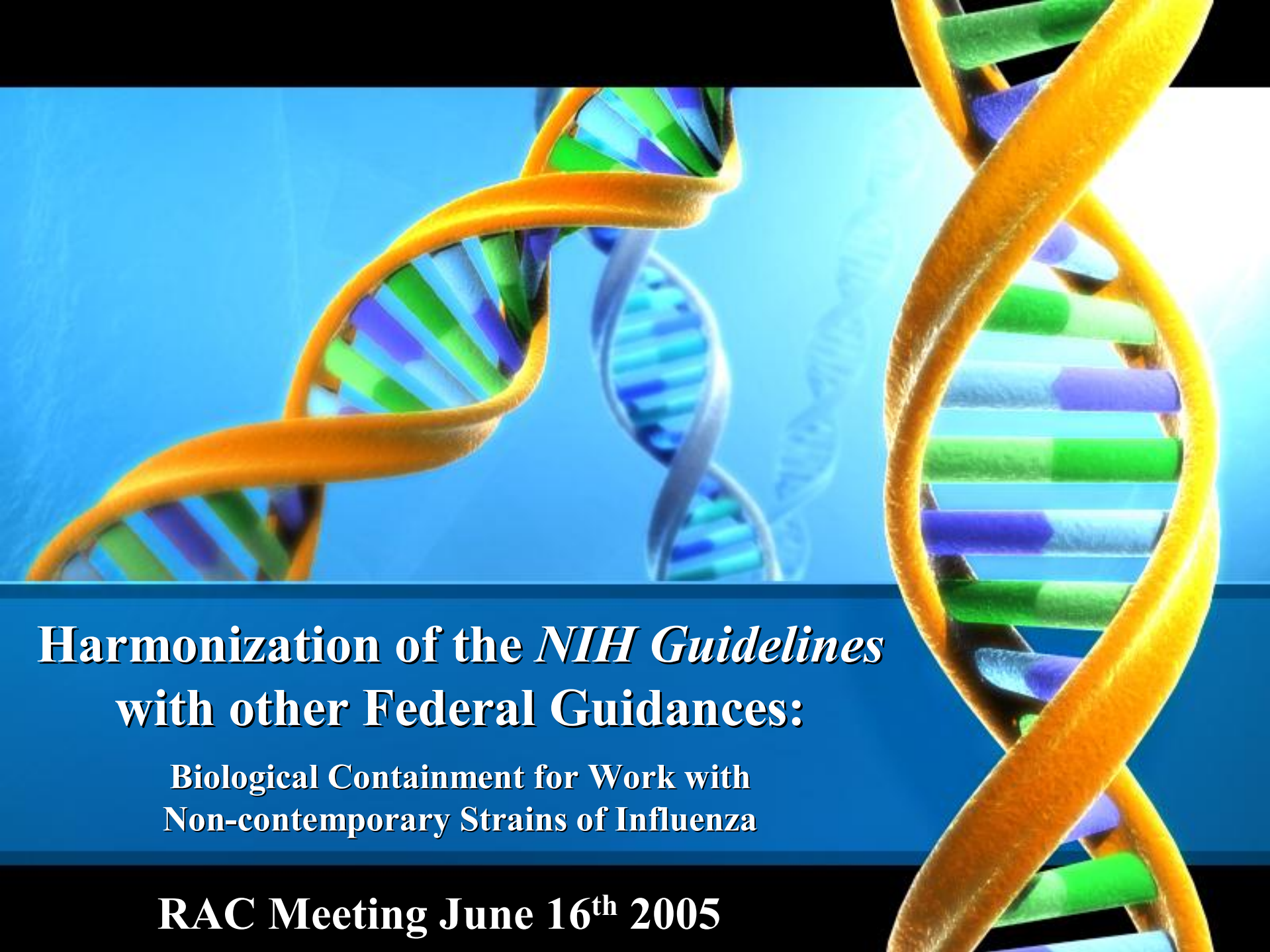
- **Biosafety Level 3 and Animal Biosafety Level 3 practices, procedures and facilities**
- **Large laboratory animals such as nonhuman primates should be housed in primary barrier systems in ABSL-3**
- **Rigorous adherence to additional respiratory protection and clothing change protocols**
- **Use of negative pressure, HEPA-filtered respirators or positive air-purifying respirators (PAPRS)**
- **Use of HEPA filtration for treatment of exhaust air**
- **Amendment of personnel practices to include personal showers prior to exiting the laboratory.**



Summary

- **The NIH will be revising the *NIH Guidelines* classification of non-contemporary strains of influenza to reflect new guidance from the CDC regarding the recommended containment for these agents.**
 - **The classification for non-contemporary strains of Influenza in Appendix B of the *NIH Guidelines* will be Risk Group 3**
 - **Specific biosafety recommendations for research with non-contemporary strains of Influenza will be added to Section II-A-3 of the *NIH Guidelines***
 - **Contemporary strains of Influenza will retain their classification as Risk Group 2 agents**





Harmonization of the *NIH Guidelines* with other Federal Guidances:

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HPAI

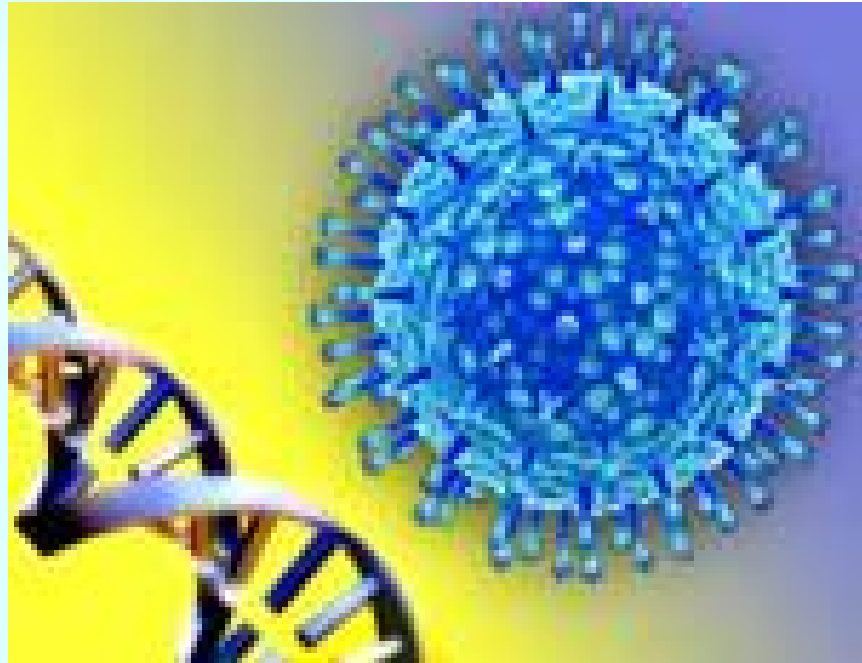
- The definition of Highly Pathogenic Avian Influenza (HPAI):
 - Any influenza virus that kills at least 75% of eight 4 to 6 to week-old chicks within 10 days of inoculation with a 1:10 dilution of infectious allantoic fluid;
 - Any H5 or H7 that does not meet the criteria above but has an amino acid sequence at the hemagglutinin cleavage site that is compatible with HPAI; or
 - Any influenza virus that is not an H7 or H5 and kills one to five chickens and grows in cell culture in the absence of trypsin.



Resources

**Fourth National NIH
Safety Symposium
Safety Considerations
in Recombinant DNA
Research with
Pathogenic Viruses**

September 21-22, 2004



www4.od.nih.gov/oba/RAC/SSSept04/resources.htm