individual species which are known to be the most important in terms of human infectivity. When such a genus is listed in Appendix B, the species and strains known to be non-pathogenic are meant to be excluded from the list. For parasites, the stages of the life cycle which are not infectious for humans are excluded.

Appendix B-I-D. Those agents not listed in Risk Groups 2-4 are not automatically or implicitly classified in Risk Group 1; a risk assessment must be conducted. The list in Appendix B is meant to serve as a general guideline for the risk group classification of microorganisms. Further guidance for microorganisms which are not specifically listed may be obtained from the Centers for Disease Control and Prevention, Office of Health and Safety (404–329–3883).

Appendix B-I-E. The list provided in Appendix B reflects the state of knowledge at the time it was prepared. The nomenclature reflects and is meant to be in conformity with the latest international agreements on taxonomy and nomenclature of agents at this time. The list is as complete as possible but necessarily not exhaustive. Additional information to be used to update the list in a timely manner shall include new agent summary statements published by the Centers for Disease Control as well as taxonomic changes to human pathogens. An annual review to incorporate the new agents and to correct the taxonomy has been offered through the ASM.

Appendix B-II. Risk Assessment

Appendix B–II–A. It is the responsibility of the Principal Investigator/supervisor to assess the risk associated with the handling of potentially biohazardous microorganisms and to ensure that the appropriate biosafety practices are employed prior to conducting any experiments or operations. A rough, qualitative risk assessment is used for an initial agent classification. However, it is to be followed by a quantitative risk

assessment of the specific strain of the agent, the immune status of the host relative to the agent in question and potential agent-host-activity interactions, such as those caused by aerosol production. For example, although cultures of the organism may be handled at BSL–2 for Risk Group 2 agents such as the dengue virus, when used for animal inoculation or transmission work it is handled at BSL–3. Similarly, such work with monkey pox, VEE or yellow fever viruses are carried out under BSL–4 containment.

Appendix B–II–B. The quantitative risk assessment described above is to be used to determine the Biosafety Level (BL), as described in Appendices G and K, which identifies the appropriate facilities, equipment, and work practices to be used for specific procedures carried out by a healthy adult individual (assessed for health status) with a specific biohazardous agent (assessed for virulence factors including antibiotic resistance to drugs of treatment). Factors to be considered in determining the level of containment include agent factors such as: Virulence, pathogenicity, stability, route of spread, communicability, the operation(s), quantity, and availability of vaccine or treatment. The higher risk agents also require more stringent biosafety practices and facilities as reflected in the Biosafety Level to which work is to be assigned (See Table 2 for the relation between risk groups and biosafety level). Although risk assessment is ultimately a subjective process, the CDC/NIH Guidelines in BMBL (See Appendix B-VI-D) have provided information about microorganisms based on the hazard they present and guidance for defining safe conditions for their use. Further information on specific biohazardous microorganisms is available in the Agent Summary Statements of the primary reference (See Appendix B–VI–D), from a publication of the American Public Health Association "Control of Communicable Diseases in Man" (See Appendix B-VI-

B) and from the CDC, e.g., the Office of Safety and Health and the Special Pathogens Branch. Changes to the agent which enhance or remove virulence factors should be considered by the Principal Investigator/supervisor and/or a local Institutional Biosafety Committee (IBC) which has the authority to raise or lower the containment level used for that agent. Published regulations or guidelines from Federal, State or local governments must also be taken into account.

Appendix B-II-C. When laboratory work is conducted with biological agents for which epidemiology and etiology are unknown or incompletely understood, it will be presumed that the work presents a biohazard similar to related agents until further information can be provided. This method was used by the Subcommittee on Arbovirus Laboratory Safety in assessing the risk of work with arboviruses for which risk information is inadequate or unavailable (See Table C of Appendix B). It is assumed that information needed for risk evaluation will be obtained prior to the large-scale use of such an agent.

Appendix B–II–D. Special consideration will be given to large-scale (greater than 10 liters of culture) and aerosol producing operations which may pose additional significant risks and thus may require additional containment (See Appendix K).

Appendix B–III. Risk Groups: Classification of Infectious Substances and Oncogenic Viruses on the Basis of Risk

The characteristics used for the qualitative risk assessment of biohazardous agents into the four Risk Groups of human etiologic agents are defined in Table 1 below, with each higher number representing an increased hazard. The information and interpretations below are from the CDC/NIH, BMBL (See Appendix B–VI–D) and the World Health Organization Laboratory Biosafety Manual (See Appendix B–VI–E).

TABLE 1.—CLASSIFICATION OF BIOHAZARDOUS AGENTS BY RISK GROUP (SEE APPENDIX B-VI-E)

- Risk Group 1 (No or very low individual and community risk) An agent that is unlikely to cause human disease. Well characterized agents not known to cause disease in healthy adult humans and of minimal potential hazard to laboratory personnel and the environment.
- Risk Group 2 (Moderate individual risk, low community risk) Agents which can cause human disease but are unlikely to be a serious hazard to workers, the community or the environment; laboratory exposures may cause serious infection but effective treatment and preventive measures are available and the risk of spread of infection is limited.
- Risk Group 3 (High individual risk, low community risk) Agents which usually cause serious human disease but do not ordinarily spread from one infected individual to another. Effective treatment or preventive measures are available.
- Risk Group 4 (High individual and high community risk) Agents which can cause serious human disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available.