

Operation Directions Governing Management of Infectious Biological Materials, Ministry of Health and Welfare

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1. To assure the effectiveness of management of infectious biological materials and the biosafety of laboratories, this set of Operation Directions is specifically formulated to regulate the control, transportation and packing of infectious biological materials, the requirements of biosafety levels of laboratories, and levels and management of biosafety accidents in laboratories.
2. Infectious biological materials can be classified into the following three categories:
 - (1) Infectious pathogens: refer to pathogenic microorganisms (such as bacteria, viruses, fungi, parasites, etc.) that may cause infections or diseases in humans, and their cultures (medium);
 - (2) Derivatives of pathogens: refer to the purified and isolated components of pathogens (such as nucleic acid, plasmid, protein, etc.), or their secreted products (such as biotoxin);
 - (3) Materials confirmed to contain pathogens or their derivatives: refer to positive specimens of patients of infectious diseases that have been laboratory confirmed to contain certain pathogens, their components or their secretions (such as blood, sputum, urine, etc.)
3. When the infectious biological materials are pathogens, they can be classified, by their pathogenicity, routes of transmission, types of hosts, and availability of preventive measures and cure, into Risk Group 1 (RG1) through Risk Group 4 (RG 4) microorganisms. Lists of microorganisms by risk groups are provided in Appendix 1 through Appendix 4.
4. When the infectious biological materials are biotoxins, by the possibility of being used as biological agents, they are grouped and controlled as

shown in Appendix 5.

5. In the transportation of infectious biological materials, they should be adequately packed and labeled comply with Appendix 6 to avoid leakage in transit.
6. Laboratories refer to places where infectious biological materials are used. They are classified, by their operational practices, personal protective equipment, safety equipment and facilities, into Biosafety level 1 (BSL-1) through Biosafety level 4 (BSL-4) laboratories as per Appendix 7:
 - (1) BSL-1 laboratory: used mainly for the operation of infectious biological materials that is known not to cause diseases in humans;
 - (2) BSL-2 laboratory: used mainly for the operation of infectious biological materials that induces diseases in humans through skin wounds, ingestions, mucosal exposures;
 - (3) BSL-3 laboratory: used mainly for the operation of infectious biological materials that may induce serious or potentially fatal diseases in humans by exposure through inhalation;
 - (4) BSL-4 laboratory: used mainly for the operation of infectious biological materials that may produce high infectious aerosol to induce serious and fatal diseases in humans for which no vaccines or cure are yet available.
7. Biosafety accidents of laboratories are classified into high, medium and low levels by the areas and degrees of leakage of infectious biological materials. Regulations governing the reporting, examples and management of biosafety accidents in laboratories at various levels of biosafety are given in Appendix 8.