SAFETY MANUAL WRITING SAMPLE

1. BASIC PRINCIPLES

The complete manual addresses the relative risks of infectious microorganisms divided into risk groups (1, 2, 3, and 4). This classification for risk groups should be used exclusively in laboratory work.

Classification of infectious microorganisms to risk groups:

- 1 (does not convey any or is generally safe for the individual and public)

A small scale creature that is probably not going to cause illness in people or creatures.

- 2 (direct hazard for an individual, generally safe for the public)

A pathogen that can cause sickness in people or creatures, yet which is probably not going to be a genuine hazard to research facility laborers, the community, livestock or the earth. Introduction to research facilities and laboratories can cause genuine disease, yet there are in this way viable medicines and preventive measures, and the danger of spreading contamination is constrained.

- 3 (high hazard for the individual and the public)

A pathogen that generally causes a genuine illness that people or creatures, however normally don't spread starting with one contaminated individual then onto the next. There are precaution measures and compelling treatment.

- 4 (high hazard for the individual and the public)

A pathogen that causes genuine ailment in people or creatures and is effectively transmitted starting with one then onto the next, straightforwardly or in a roundabout way. Viable treatment and preventive measures are typically not accessible.

Laboratory facilities are defined as basic - level 1 of biosafety, basic - level 2 biosecurity, conservation (control) - level 3 of biosafety, and

maximum storage - level 4 of biosafety. The biosafety level determinants are based on the characteristics of the project, construction, capacity for

storage, equipment, procedures and workflows necessary to work with agents of different risk groups.

Countries (regions) should compile a national (regional) classification of microorganisms by risk groups, taking into account:

1. Pathogenicity of the organism.

2. The mode of transmission and the spread of the organism. These can be influenced by the existing levels of immunity of the local population, density and movement of the host population, presence appropriate vectors, as well as environmental hygiene standards.

3. Local availability of effective preventive measures. These may include: prevention through immunization or the use of antiserum (passive immunization); sanitary measures, i.e. hygiene of water and food; control of animal reservoirs or injecting vectors.

4. Local availability of effective treatment. This includes passive immunization, vaccination after exposure and use of antimicrobial, antiviral and chemotherapeutic agents, and the possibility of drug resistance should also be considered.

Assigning an agent to the level of biosafety for laboratory work must be based on risk assessment. Such an assessment will take into account the risk group as well as other factors in determining the appropriate level of biological security. For example, an agent classified in risk group 2 may, generally

speaking, require level 2 biological safety requirements, equipment, behavior, and procedures for the safe conduct of work. However, if certain experiments require the creation of a high concentration aerosol, then biological safety level 3 may be more suitable for providing the necessary degree of safety, since it provides a higher degree of aerosol control at the laboratory random site. The assigned level of biosecurity for the type of work to be performed is determined on the basis of a professional assessment based on risk assessment, not automatically, by determining the level of safety in the laboratory according to the determinants of the risk group of the pathogenic agent used in the work.

2. MICROBIOLOGICAL RISKA ASSESSMENT

The essence of applying biosafety is risk assessment. While there are many available aids in assessing the risk of a particular procedure or experiment, the most important component is a professional judgment. The risk assessment should be performed by individuals who are best acquainted with the specific characteristics of the organisms considered for use, the equipment and procedures to be used, the specimens' animals that can be used, as well as with storage equipment and available facilities. The laboratory director or chief researcher is responsible for the implementation of this adequate and timely risk assessments, as well as for close cooperation with the security committee of the institutions and staff responsible for biosafety, to provide the appropriate equipment and facilities available for the implementation of the work being considered. When done once, risk assessment should be routinely returned revise when necessary, taking into account the acquisition of new data of importance for the level of risk as well as other relevant new information from the scientific literature.

One of the most useful means available for carrying out an assessment of microbiological risk is the assembling of risk groups of microbial agents. However, simply relying on risk grouping for a particular agent is insufficient to carry out a risk assessment. Other factors to consider as appropriate are:

1. Pathogenicity of the agent and infectious dose
2. Potential exposure result
3. Natural Path of Infection
4. Other pathways of infection resulting from laboratory procedures (parenteral, air transfer, mouth-to-mouth)
5. Stability of the agent in the middle
6. The concentration of the agent and the volume of the concentrated material to be handled
7. The presence of an appropriate host (human or animal)
8. Available information from animal studies, reports on laboratory acquired infections and clinical reports
9. Planned activity in the laboratory (sonication, aerosolization, centrifugation, etc.).
10. Any genetic manipulation of an organism that can send a range of host agents or modify the response of the agent to known, effective regimens of treatment.
11. Local availability of effective prevention or therapeutic intervention.

Based on information verified during risk assessment, the level of biosafety can be determined for planned work, appropriate personal protective equipment selected and standard operating procedures (SOPs) that include other security interventions developed to ensure the safest possible performance of the work.