Section 3 – Risk Assessment

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A. RISK ASSESSMENT AND ROUTES OF EXPOSURE

Risk assessment is a process used to identify the degree of risk to the laboratory worker, other personnel, and the environment. The degree of risk takes into consideration the virulence, pathogenicity, biological stability, and communicability of the organisms as well as the route of transmission. The following summarizes routes of transmission or infection.

1. Oral Infection

   A variety of organisms used in the laboratory are enteric pathogens and carry the prime risk of infection by ingestion. Examples are ova and parasites, Salmonella typhimurium, Hepatitis A virus, poliovirus, and enteropathogenic E. coli strains.

2. Respiratory Route Infection

   A variety of agents infect by the respiratory route. The major source of such infections is by aerosolization of biohazards. The more hazardous agents which cause respiratory infections are those which withstand drying such as Mycobacterium tuberculosis and Coccidioides immitis. Two hazards can be defined: the immediate risk from an aerosol which will be limited if the agent cannot withstand drying and the delayed risk (secondary aerosol) if the organism can withstand drying.

3. Puncture and Contact Infections

   A variety of agents are transmitted through puncture such as arthropod-borne virus infections, protozoal infections (malaria), human immunodeficiency virus (HIV), and HBV. However, those bacterial agents that can cause septicemia can also cause infections by injection, a phenomenon particularly dangerous when a rapidly growing and pathogenic organism is injected.

4. Fomites

   Fomites are particularly hazardous and subtle because the organisms are spread via deposition on surfaces. Careless handling of materials can lead to situations in which individuals unknowingly infect themselves by hand-to-mouth infection. The transmission of
organisms from fomites to the hands and then to the mucus membranes of the eyes or nose are other examples of the route of viral infections or ingestion.

Fomites can also be created by aerosols settling on laboratory furniture, apparatus, etc. Rapid dispersal of aerosols by high air flow is an indispensable means of preventing this problem. Creation of fomites from minor spills and droplets formed during transfer of cultures is a common hazard in laboratories. The reality of this problem can readily be appreciated by transferring a dye (e.g., crystal violet) as though it were a bacterial culture. The amount of dye scattered in the work area after several such manipulations is an excellent measure of the effectiveness of containment techniques.

The telephone provides a good example of a fomite. Ideally, no telephones should be included in a BSL-2 or BSL-3 laboratory as they are easily contaminated and interfere with concentration on work. Personnel must refrain from answering telephones when gloved or while conducting hazardous procedures. In the event that the telephone is handled by gloved personnel or is otherwise contaminated, it must be surface decontaminated at the end of the work day.

B. CLASSIFICATION BY RISK GROUPS AND BIOSAFETY CONTAINMENT LEVELS

The classification of human etiological agents into risk groups on the basis of hazard and the biosafety levels assigned to them are described below.

1. General Introduction to Risk Groups

Microorganisms have been classified according to degree of risk in terms of infectivity, pathogenicity, and the availability of preventive measures and effective treatments for the disease. The NIH Guidelines have established a classification and assigned human etiological agents into four risk groups on the basis of hazard. The risk groups correlate with, but do not always equate to, biosafety levels. A risk assessment will determine the degree of correlation between an agent’s risk group classification and biosafety level. The NIH Guidelines, Section II provides additional information on the differences and relatedness of risk groups and biosafety levels.

Risk Group I (RG-1) - Agents not associated with disease in healthy adult humans.

Risk Group II (RG-2) - Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available.

Risk Group III (RG-3) - Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).

Risk Group IV (RG-4) - Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk). There is no research with Risk Group IV agents at the UW.

2. General Introduction to Biosafety Containment Levels

Biosafety, when working with biohazards, is dependent on three elements: standard microbiological laboratory practices and techniques, safety equipment, and facility design. Combinations of these three elements are used to describe the four biosafety levels. Additional information is also available in the CDC/NIH BMBL.
**Biosafety Level 1 (BSL-1)** is suitable for work involving well-characterized agents not known to cause disease consistently in immunocompetent adult humans; such agents present minimal potential hazard to laboratory personnel and the environment.

**Biosafety Level 2 (BSL-2)** builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment.

**Biosafety Level 3 (BSL-3)** is applicable to research facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure.

**Biosafety Level 4 (BSL-4)** is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments; or a related agent with unknown risk of transmission.

There is no research requiring BSL-4 containment at the UW.

For more details regarding specific facility design elements for BSL-1, BSL-2, and BSL-3 laboratories, see Section 4.A on facility requirements.