

- Stability of biological material in the environment
- Concentration of biological material and amount to be manipulated
- Presence of a suitable host
- Information available from animal studies and reports of laboratory-acquired infections or clinical reports
- How the biological material will be used (concentration, sonication, aerosolization, centrifugation, etc.)
- Any genetic manipulation of the organism that may extend the host range of the agent or alter the agent's sensitivity to known, effective treatment regimens
- Local availability of effective prophylaxis or therapeutic interventions

In situations where the information is insufficient to perform a risk assessment, the following conservative approach should be used:

- Universal precautions should always be followed, and barrier protections applied (Gloves, gowns, eye protection), regardless of the origin of the samples.
- Biosafety level 2 should be the minimum requirement for the handling of specimens.

Biological expression systems consist of vectors and host cells. When conducting a risk assessment of these systems, consider whether the following concerns apply:

- Does the expression of the DNA sequences derived from pathogenic organisms increase the virulence of the genetically modified organism (GMO)?
- How well-characterized are inserted DNA sequences?
- Do gene products have potential pharmacological activity?
- Do gene products code for toxins?
- Will a human oncogene be inserted, or will a tumor suppressor gene be silenced?

3.6 BLOODBORNE PATHOGENS

The federal government issued the OSHA BBP Standard (29 CFR 1910.1030) in December 1991. The primary purpose of the BBP Standard is to minimize the risk of occupational exposures to blood and other bodily fluids and protect workers from the infectious diseases associated with them. In addition to HIV and the hepatitis viruses, the BBP Standard covers a wide variety of bloodborne infectious agents that can cause disease. Some of the included agents are simian immunodeficiency virus and the

biological agents that cause syphilis, malaria, babesiosis, brucellosis, leptospirosis, relapsing fever, arboviral infections, Creutzfeldt-Jacob disease, and viral hemorrhagic fevers.

Sources of potential exposures to BBP include human blood and a variety of potentially infectious materials (PIMs). The OSHA definition of human blood includes whole blood, blood products, and blood components. PIMs include body fluids, such as saliva, semen, vaginal, cerebrospinal, synovial, pleural, peritoneal, pericardial, amniotic fluids, anybody fluid in which visible blood is present, and any unfixed tissue or organ from a human either living or dead. Cell or tissue cultures, organ cultures, or media containing HIV, HBV, or HCV are also included.

OSHA has designated the term “standard precautions” as the approach for controlling against infections from BBP. The concept is that all human blood and PIMs are treated as if they contain HIV, HBV, or other BBP. In the laboratory environment, BL2 practices and containment are required for activities involving BBP.

All personnel with potential occupational exposures to BBP must receive annual training in accordance with the BBP Standard. Supervisors are responsible for ensuring that all employees with potential occupational exposures to BBP participate in this training.

3.7 EXPOSURE CONTROL PLAN

The BBP Standard requires that an Exposure Control Plan (ECP) be written and implemented and that a copy of the ECP be made available to employees. The ECP includes several required elements, policies, and procedures that are designed to eliminate or minimize BBP exposures. The purposes of the plan are to:

- Protect staff and students from the health hazards associated with BBP.
- Coordinate appropriate treatment and counseling in the event of a BBP exposure incident.

The following procedures have been implemented to identify individuals that have occupational exposures to BBP. Each staff member is classified as either exposed or unexposed and is informed of their classification by respective supervisors.