

## Being Watchful of Biosafety Challenges for diagnostic and research labs in India

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**Biosafety is defined by WHO as a 'strategic and integrated approach to analyse and manage relevant risk to human, animal, plant life and health and associated risk to the environment'. In other words, the biosafety process is to eliminate biological or chemical contamination affecting humans, animals, plants, and the environment. Biosafety is those processes that ensure such operations are conducted in a safe, secure, and reliable manner. The biological surety programme is generally concerned with biological agents having a high risk for adverse medical consequences upon release outside of proper containment. Biosecurity is the process employed for ensuring biological agents are properly safeguarded against theft, loss, diversion, unauthorized access, or use/release.**



A biosafety laboratory is an essential requirement for any experimental research programme on any potential pathogenic organisms or infectious ailments. A lot of research activities are focussed on the study of microbial pathogens, which poses a potential risk to related research fellows in R&D labs. In addition, there is the risk that dangerous microbes under study might escape from the laboratory and pose a risk to public health. For example, in the past, a highly pathogenic avian influenza H5N1 has escaped out of containment.

Pathogens have been categorised based on the degree of risk they carry, both to laboratory crew and to the general public too. The assessment depends not only on the virulence of the microorganism but also on whether an effective vaccine exists and/or effective antimicrobial/antiviral therapy is available. Where an effective vaccine exists, laboratory workers should be immunized, and precautions should be taken to physically contain the microbes under study.

The risk is classified in four levels. Level one assumes no risk and level four is for the most virulent pathogens for which no effective immunization or antimicrobial therapy exists.

Biosafety challenges should be handled with utmost care with no compromise. It is not the responsibility of the technical team daily working inside the laboratory alone, but it starts from the laboratory construction and commissioning, thus involving all departments involved in any laboratory construction, operation, maintenance, etc. Only with the support of all departments, Biosafety protocols can be implemented in a pathogen handling laboratory successfully, without giving an opportunity to biosafety challenges such as a pathogen outbreak. Biosafety challenges not only include pathogen outbreaks but also include challenges that arise due to handling and disposal of hazardous chemicals which will sometimes affect the environment too.

## **Major challenges in Biosafety**

**Biological Hazard:** Risk of uncontrolled exposure to a condition that causes a disease. It may be exposure to the pathogen causing infectious diseases or any chemical substances that induce or support infection or any other form of health challenges.

**Biocontainment:** Challenges in the prevention of infectious pathogens leaking from R&D or testing laboratories or isolated wards in which the patient is admitted.

**Bio protection:** Challenges in the prevention of loss, theft, misuse, or intentional release of the pathogen bypassing the security or illegal access to facilities as above or material theft, data theft, etc.

**Guidelines:** Challenges that arise due to not following the guidelines due to negligence or no proper understanding of the workflow or due to any human error.

**Good Laboratory Practices:** Challenges that arise due to not implementing good laboratory practices and the above-mentioned factors due to lack of proper training, negligence in handling experiments, not implementing the above due to any poor coordination of other departments like construction, operation, maintenance, etc.

**Preanalytical:** Challenges in poor handling of sample collection and transportation. A potential pathogen not handled properly during sample collection may outbreak within the hospital environment. Improper transportation may cause breakage of the sample container and lead to an endemic or pandemic. Samples not transported in recommended conditions may lead to false-negative results.

Lab acquired infections are in vogue and potential accidental leakage also are really critical around the world. There was public news about suspected lab leakage of the Covid-19 virus from Wuhan area, which might be the starting point of a great pandemic. So, Biosafety measures and policies are of utmost importance to human safety. The formation of aerosols during the processing time of microorganisms can pose great threats to scientists and humanity, which is the primary purpose of the policies as well as Biosafety cabinets or any other safety measures. Thermal and chemical burns, skin absorption chemicals, inhalation of toxic fumes, skin cuts etc are some of the physical hazards.

In India, Biosafety regulations are enforced under Environmental Protection Act to prevent the leakage of biological materials, unintentional exposure of chemicals to the workforce, intentional or unintentional leakage of genetic mutants, etc. In the second class of biological risks, India has intentionally set up an exhaustive list of Biosafety guidelines and the same has been regulated by the Department of Biotechnology. Although the implementation of Biosafety guidelines falls under the guidance of the Ministry of Science and Technology, Ministry of Environment, and Forest and Climate Change.

It is true that a lot of research is undertaken by the Indian Council of Medical Research (ICMR) as well as the Indian Council of Agricultural Research (ICAR). Both the research bodies are set up under the Ministry of Health and Family Welfare and the Ministry of Agriculture and Farmers' Welfare. The involvement of multiple departments practically generates a lot of confusion in the field. Besides, the regulatory process as such is not that transparent and it's influenced by activist groups, which often delays the approval of biotechnology-derived products.

### ***In the molecular biology segment, the following precautions and protective measures are to be taken:***

- All samples are to be considered highly infectious and to be handled with care according to ICMR and NABL guidelines.
- There are Biosafety guidelines to be followed in a pathogen detection laboratory using Molecular technologies for Research and Development and to be followed very strictly according to the pathogen handled.

These guidelines are for preserving the sample integrity and protecting the laboratory environment and the technical team to avoid infection by the pathogen due to biosafety challenges and thus prevent any outbreak in the society.