Recognize the ISO 35001 BiorskManagement System Standardand its Key Factorsaa

It is critical for business, government, and academiato handle biological materials safely and securely. A vital component of accomplishing this isimplementing an ISO 35001 biorisk management system, which enables an organization to efficientlyrecognize, monitor, and control any biosafety orbiosecurity hazards associated with its operations.For a biorisk management system, ISO 35001 is thefirst International Standard. ISO 35001 standard wasfirst released in November 2019 and is applicable toall businesses that test, store, transport, operatewith, or dispose of hazardous biological products. Tocontrol and minimize any hazards associated withtheir use, it outlines the specifications and guidelinesfor laboratories and any other organization thatworks with biological agents. While many regional or national standards aid organizations in riskmanagement and compliance with legal obligations,ISO 35001 is the first to harmonize them to giveglobal best practices. The establishment of precisecriteriafor the management of biological agents isimperative for international laboratories, especiallythose inlow-resource nations. Users would benefitfrom the standard, Patricia notes, “, especially inmanycountries without any national policies orregulations in place”. The biorisk managementsystem, ISO35001:

- Establishes the biorisk management principlesthat allow laboratories and related facilities tomeet their biosafety and biosecurity goals
- Specifies the fundamental components of abiorisk management system framework to be integrated into a laboratory’s or otherassociated facility’s overall governance,strategy and planning, management, reportingprocesses, policies, values, and culture;
- It outlines a comprehensive bioriskmanagement procedure that reduces biorisk(biosafety and biosecurity risks); and directsthe application and usage of the standard, ifnecessary.

The biorisk management system was established ona management system approach, allowing an organization to efficiently detect, analyze, control, and evaluate the biosafety and biosecurity risks inherent to its activities. As a result, the paper aims to specify requirements that are compatible with the scope and nature of each organization. The foundation of the biorisk management system is the idea of continuous improvement, which is accomplished through a cycle of planning, executing, reviewing, and refining the procedures and activities that an organization takes to achieve its primary goals. The Plan-Do-Check-Act (PDCA) approach is used in this situation:

- Organisations utilize the PDCA model, an iterative process, to continuously improve their processes and products.
- Understanding and paying attention to the reasons behind nonconformities and occurrences is necessary for improving biorisk management.
- Improvements in performance and the management of biorisks result from systematic detection and correction of system flaws.

The following are some of the most crucial elements in developing and putting into practise an ISO 35001 biorisk management system standard:

- The dedication of the senior management to:
  - Provide sufficient resources
  - Ensures that all staff members receive enough ISO 35001 Awareness Training for Biorisk Management so they can better comprehend the standard.
  - Make biosafety and biosecurity policy a priority and make it known
  - Set performance goals and incorporate biorisk management across the entire organization
  - Establish the root causes of occurrences and nonconformities to stop them from happening again
  - Determine areas that could use improvement and prevention