Leveraging ISO 35001 to support global laboratory biorisk management practices

Conveners: CEPI (Standley), BRMI (Wagener) and RPHL (Sriwongsa)

Date and Time: Monday, 8 June 2026, from 2:00-4:00pm (TBC)

Venue: Kuala Lumpur Convention Centre, room TBC

Format: Presentation, panel and discussion

- Welcome and opening remarks (Standley, Sriwongsa, Wagener - 5 mins)
- Introductions (All – 5 mins)
- Presentation of results from CEPI-commissioned study (Chu – 20 mins)
- Remarks from panelists (Lim, Naidoo, Matinyi, Sriwongsa, Cornish - 10 mins each, total 50 mins)
- Questions and discussion (~30 mins)
- Concluding remarks (Standley, Sriwongsa, Wagener – 10 mins)

Background:

Since the Covid-19 pandemic, unprecedented investments have been made to expand and modernize laboratory infrastructure worldwide. However, global heterogeneity in national regulations for biosafety and biosecurity, diversity in how laboratory facilities are managed and maintained, and laboratory staff training and competencies, continue to create vulnerabilities that can undermine both global health security and One Health preparedness. The adoption of performance-based standards with a continual improvement cycle, such as ISO 35001:2019, offers a pathway to harmonize safe, secure, and responsible laboratory operations, while allowing for local adaptation. Beyond reducing biological risks—whether accidental or deliberate—ISO 35001:2019 strengthens transparency, accountability, and partner confidence, supporting evidence-based funding decisions, return-on-investment tracking, and equitable selection of research partners by clarifying operational and biorisk management expectations.

Despite its potential, ISO 35001:2019 has seen limited uptake globally. Common barriers include the perceived cost and complexity of implementation, lack of accredited certification pathways, restricted access to technical guidance, resistance to change and low visibility of the standard's added value. However, a growing number of regional and international initiatives—spanning Africa, the Asia-Pacific, and Europe—are now piloting scalable, context-adapted implementation models. These efforts are generating practical tools and lessons that can inform future WHO and WHA-aligned frameworks (e.g., WHA Resolution 77.7) and other performance-based biosafety and biosecurity standards.

Objectives:

- Showcase the diversity of initiatives across world regions, sectors, and types of laboratories that have leveraged ISO 35001, either as a framework or explicitly as a standard, to improve biorisk management
- Share practical experiences, tools and lessons learned on implementing ISO 35001 and related performance-based standards, with a focus on how successful implementation can be measured and sustained

- Explore how ISO 35001 adoption can enhance trust, transparency, and interoperability across global health security programs, particularly in surveillance, diagnostics, research and outbreaks involving dangerous pathogens.

Guiding discussion questions:

- **Barriers and enablers to adoption:**
  What have been the main challenges and enabling factors shaping ISO 35001 implementation across different regions and types of laboratory facilities?
- **Practical implementation and guidance:**
  What lessons have been learned from pilot projects and early adopters across different regions regarding the implementation of ISO 35001, and how can these experiences (and those from other management systems) potentially inform the development of new tools, training programs, or complementary technical standards?
- **Impact and evidence:**
  What emerging evidence and impact pathways exist related to measuring the potential impact of ISO 35001 on laboratory biosafety and biosecurity practices? Can its adoption enhance transparency, mutual confidence, or equitable participation in high-risk pathogen work globally?

Proposed speakers:

- **May Chu, University of Colorado**
  - Presentation of preliminary results of CEPI-commissioned study on complementarity between performance-based management system standards and technical guidance for biosafety and biosecurity
- **Hokkean Lim, Institut Pasteur Cambodge**
  - Experience of implementation of ISO 35001 at a high-containment laboratory in Cambodia
- **Kovashnee Naidoo, NICD**
  - Utility of ISO 35001 as a framework for high-containment laboratories and alignment with regional standards
- **Sandra Matinyi, Consultant**
  - ISO 35001 for enhancing performance of diagnostic and public health laboratories in Central and East Africa
- **Jintana Sriwongsa, RPHL network**
  - Twinning and mentorship models for successful implementation of ISO 35001 and related BSS capabilities
- **Ann Cornish, VIDRL**
  - Alignment of ISO 35001 with GAPIV and implementing biorisk management systems in the Australian regulatory landscape

Intended outcome:

This session will foster a global conversation on harmonizing biorisk management practices through a common, performance-based framework. Participants will have the opportunity to network and exchange with colleagues working on diverse aspects of biosafety and biosecurity implementation. They will also leave with actionable insights, examples of adaptable models, and connections to ongoing initiatives that can be replicated or scaled in their regions—advancing a shared vision of safer, more transparent, and more resilient laboratory systems.