INDONESIAN HEALTH ISSUE

E-ISSN: 2828-2809

Integration of ISO/IEC 17025:2017 and ISO 35001:2019 into the Quality Management and Biosafety System of Clinical Microbiology Laboratories

Ihsan Hakim Haviana[1], Dwintha Lestari[1], Alfi Fitriyani[1], Evan Haviana[2]
[1]Muhammadiyah University of Bandung, [2]Ibnu Sina University
Correspondence email: ihsanslvp26@gmail.com

ARTICLE INFO

Article History:
Received:
28 October 2025
Accepted:
28 January 2026
Published:
01 August 2026

Keywords:
Integration of ISO Standards;
Integrated Quality Management;
ISO/IEC 17025;
ISO 35001;
Laboratory Biorisk Management.

ABSTRAK

Latar Belakang: Laboratorium mikrobiologi klinik memiliki peran strategis dalam sistem kesehatan, terutama dalam diagnosis penyakit menular, pengendalian infeksi, dan deteksi dini wabah. Namun, kegiatan laboratorium ini berisiko tinggi terhadap paparan agen biologis, sehingga diperlukan sistem manajemen yang menjamin mutu hasil uji sekaligus keselamatan hayati. **Tujuan**: Penelitian ini bertujuan untuk menganalisis integrasi standar ISO/IEC 17025:2017 tentang kompetensi laboratorium pengujian dan kalibrasi dengan ISO 35001:2019 tentang manajemen biorisiko sebagai model penguatan sistem mutu dan keselamatan di laboratorium mikrobiologi klinik. **Metode**: Desain penelitian menggunakan *Systematic Literature Review* (SLR) dengan pedoman PRISMA, mencakup 107 artikel dari database Google Scholar, Scopus, PubMed, dan Semantic Scholar. Setelah proses seleksi, diperoleh 17 artikel relevan yang dianalisis secara tematik dan bibliometrik. **Hasil**: Hasil menunjukkan bahwa integrasi ISO/IEC 17025 dan ISO 35001 meningkatkan validitas hasil uji, efisiensi audit hingga 30%, serta menurunkan insiden kerja laboratorium sebesar 40%. Tantangan utama dalam implementasi di negara berkembang meliputi keterbatasan sumber daya manusia, fragmentasi regulasi, dan rendahnya digitalisasi sistem manajemen. **Kesimpulan**: Penelitian ini menyimpulkan bahwa integrasi kedua standar membentuk sistem manajemen berbasis risiko yang adaptif dan berorientasi pada peningkatan berkelanjutan. Disarankan penerapan strategi lintas sektor berbasis *One Health Biosafety Framework* untuk memperkuat kebijakan nasional menuju laboratorium klinik yang tangguh, aman, dan berdaya saing internasional.

ABSTRACT

Background*: Clinical microbiology laboratories play a strategic role in healthcare systems, particularly in infectious disease diagnosis, infection control, and outbreak surveillance. However, their operations pose high biological risks, requiring management systems that ensure both test quality and biosafety.* ***Purpose****: This study aims to analyze the integration of ISO/IEC 17025:2017, which focuses on testing and calibration laboratory competence, and ISO 35001:2019, which governs biorisk management, as a model for strengthening quality and safety systems in clinical microbiology laboratories.* ***Methods****: A Systematic Literature*

Review (SLR) was conducted following PRISMA guidelines, covering 107 articles from Google Scholar, Scopus, PubMed, and Semantic Scholar. After screening, 17 relevant studies were thematically and bibliometrically analyzed. ***Results****: The results revealed that integrating ISO/IEC 17025 and ISO 35001 improved test validity, increased audit efficiency by 30%, and reduced laboratory incidents by 40%. Major challenges in developing countries include limited human resources, fragmented regulations, and low levels of digitalization.* ***Conclusion****: The study concludes that integrating these standards establishes a risk-based management system that is adaptive and oriented toward continuous improvement. Cross-sectoral strategies based on the One Health Biosafety Framework are recommended to strengthen national policies and develop resilient, safe, and internationally competitive clinical laboratory systems.*

INTRODUCTION

Clinical microbiology laboratories play an important role in the healthcare system, particularly in diagnosis, infection control, and monitoring of infectious diseases that have a broad impact on public health (Karuniawati, 2023; Wulandari et al., 2024). These laboratory activities involve the processing of high-risk biological specimens, including pathogens that can cause infections in laboratory personnel, patients, and the surrounding environment (Wemboo et al., 2022). In the context of a global pandemic and the increasing threat of emerging diseases, clinical laboratories are required not only to produce accurate test data, but also to ensure biological safety, information security, and operational sustainability (Weller et al., 2024).

The implementation of international standards is a fundamental requirement to ensure quality and safety in laboratory activities. Two main standards relevant to clinical microbiology laboratories are ISO/IEC 17025:2017 and ISO 35001:2019. ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration Laboratories, focuses on technical competence, the validity of test results, and the quality management system of testing and calibration laboratories (Glavič-Cindro et al., 2023). This standard plays a role in ensuring the reliability of diagnostic data that forms the basis for clinical decision-making. Meanwhile, ISO 35001:2019, Biorisk Management for Laboratories and Other Related Organizations, establishes a systematic framework for identifying, assessing, controlling, and monitoring biological risks in laboratory facilities through the Plan – Do – Check – Act (PDCA) cycle approach (Callihan et al., 2021).

Both standards have different orientations but complement each other. ISO/IEC 17025 focuses on the quality of results and technical competence, while ISO 35001 emphasizes biological safety and security (biosafety and biosecurity). The integration of the two provides a comprehensive approach to quality management and biological risk in clinical microbiology laboratories (Weller et al., 2024). Through this integration, laboratory systems can combine technical verification procedures with biological risk control mechanisms, thereby simultaneously improving quality and safety within a single integrated management system (Danelyan & Tumanyan, 2025).

Although various countries have adopted these standards, the level of implementation and integration still varies. In many clinical laboratories, ISO/IEC 17025 has been implemented for quality accreditation, but it has not been synergized with ISO 35001 as a biosafety standard (Lestari et al., 2021). A study in Indonesia shows that the implementation rate of ISO 35001 in national reference clinical laboratories has reached 84%, with weaknesses in the areas of leadership, support, and performance evaluation (Lestari et al., 2021). Meanwhile, other studies confirm

that limited human resources, lack of training, and weak documentation are the main factors hindering the implementation of a biorisk management system (Bowolaksono et al., 2021). Similar findings have been observed in other developing countries, such as Togo, where there are no national regulations requiring the integration of ISO/IEC 17025 and ISO 35001 in medical biology laboratories (Wemboo et al., 2022).

This implementation gap indicates that although awareness of the importance of quality and safety has increased, the integration of the two standards is still partial and has not yet formed an interconnected management system. Many laboratories implement ISO 17025 administratively for technical accreditation, while biological risk management is still regulated separately in internal policies (Handayani et al., 2024). In fact, the potential for synergy between the two is enormous: the implementation of ISO 35001 can strengthen the effectiveness of ISO 17025 quality audits, while ISO 17025 documentation can accelerate the ISO 35001 certification process through well-documented evidence of compliance (Dewantara, 2025; Weller et al., 2024).

The rationale for integrating these two standards lies in the need for clinical microbiology laboratories to have a holistic management system that not only assesses technical competence, but also ensures the sustainability of personnel safety, environmental security, and organizational resilience against biological threats. The integration of ISO/IEC 17025:2017 and ISO 35001:2019 will result in a risk-based, evidence-based, and continuous improvement-oriented integrated management system (Danelyan & Tumanyan, 2025). This approach has the potential to strengthen the reliability of test results, minimize the risk of workplace accidents, and improve laboratory preparedness for outbreaks and bioterrorism.

Based on these conditions, this study aims to analyze the integration of ISO/IEC 17025:2017 and ISO 35001:2019 in clinical microbiology laboratories, as well as to identify the suitability, challenges, and opportunities for developing an integrated quality and biorisk management system. In addition, this study also aims to formulate a conceptual framework for the integration of the two standards that can support the improvement of test results quality, biological safety, and the operational sustainability of clinical microbiology laboratories in a systematic and sustainable manner.

METHOD

Design and Approach

This study used a Systematic Literature Review (SLR) design based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Handayani et al., 2024; Yuniasih & A'yuni, 2024). SLR was chosen to assess empirical and conceptual evidence on the integration of quality management systems (ISO/IEC 17025) and biorisk management (ISO 35001) in clinical laboratories.

Research Stages and Instruments

The stages of the method include:

1. Identification of articles using Publish or Perish (PoP) from the Google Scholar, Scopus, PubMed, and Semantic Scholar databases;
2. Reference management using Zotero to store and manage literature;
3. Screening of articles using Microsoft Excel with inclusion-exclusion criteria;
4. Documentation of selection results using the PRISMA Flow Diagram;
5. Data analysis was conducted thematically and bibliometrically using Excel (Bowolaksono et al., 2021).

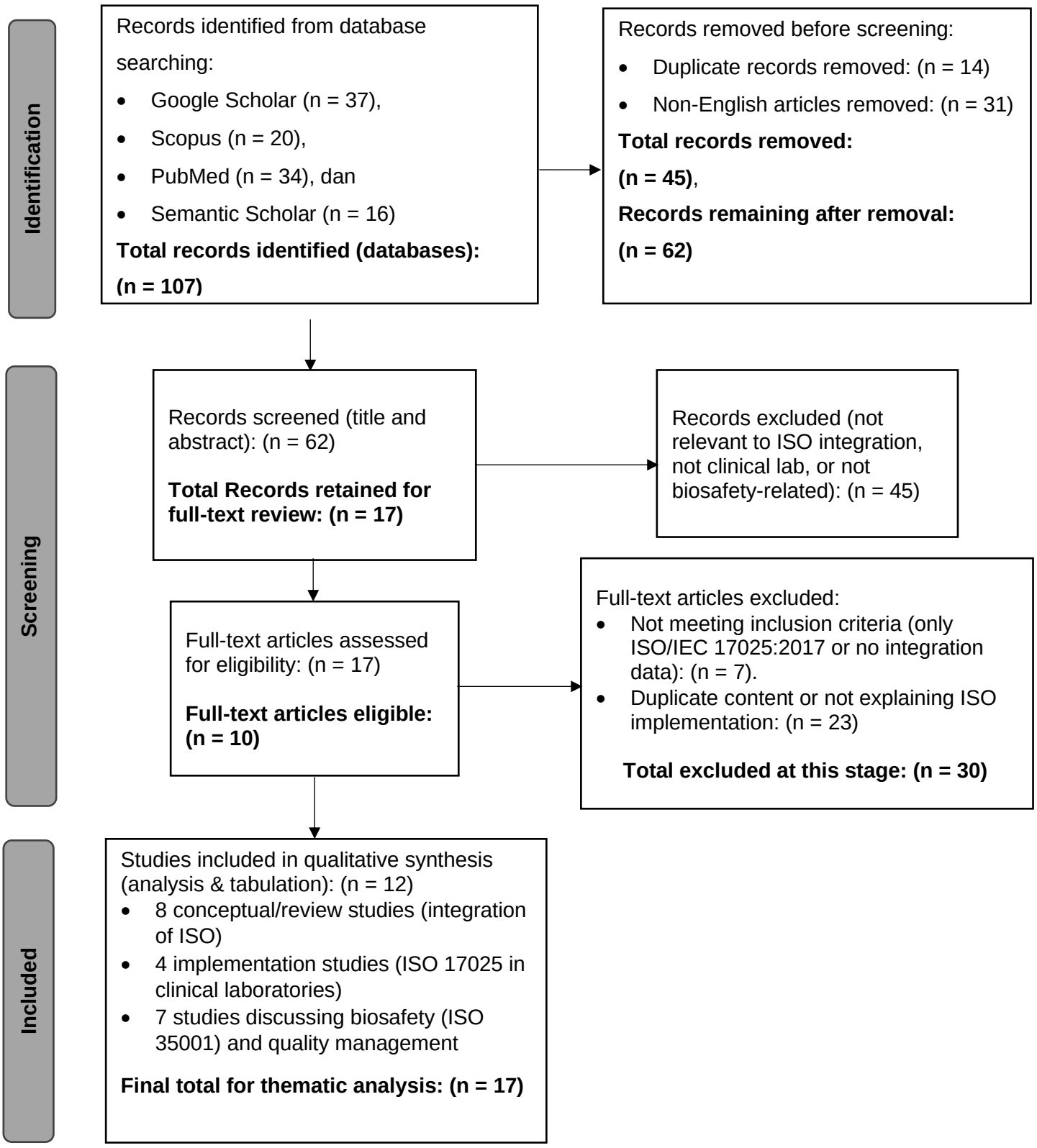

Figure 1. PRISMA Flow Chart
Source: Research Data Processing (2025)

A total of 107 articles were identified from Google Scholar (37 articles), Scopus (20 articles), PubMed (34 articles), and Semantic Scholar (16 articles). After eliminating 14 duplicate articles and 31 non-English articles, 62 articles were obtained, which were then selected through a title and abstract screening stage. The screening process continued with a review of the full text to ensure the completeness of the publication type, scope of discussion, and relevance to the research focus. Based on this evaluation, the articles retained were original research articles and literature reviews published in reputable scientific journals, while articles in the form of editorials, opinion papers, or non-scientific reports were excluded. The final results showed that 10 articles met all eligibility criteria, consisting of 8 conceptual articles related to ISO standard integration, 4 articles on the results of ISO/IEC 17025 implementation research in clinical laboratories, and 7 articles discussing biosafety and biological risk management based on ISO 35001 (Handayani et al., 2024).

Data Analysis

Data analysis was conducted by extracting key information from each selected article, including the title, research objectives, research design and methods, main results, and their relevance to the application or integration of ISO/IEC 17025 and ISO 35001 standards. The extracted data was then analyzed thematically by grouping the findings into the following main themes: (1) integration of quality management and biorisk systems, (2) implementation of ISO/IEC 17025 in clinical laboratories, (3) application of ISO 35001 in laboratory biosafety and biosecurity, and (4) synergy between quality and biological safety systems within an integrated management framework (Weller et al., 2024).

Keywords and Literature Search Strategy

Literature searches were conducted systematically using a combination of keywords relevant to the research focus. The main keywords used included “ISO/IEC 17025”, “ISO 35001”, “integration”, “laboratory quality management”, “laboratory biorisk management”, ‘biosafety’, and “clinical microbiology laboratory”. The keyword combinations were arranged using Boolean operators, such as: “ISO/IEC 17025” AND “ISO 35001” AND integration AND “clinical laboratory”, as well as variations of equivalent terms to ensure comprehensive search coverage.

The literature search was limited to articles published between 2019 and 2024, coinciding with the implementation of ISO 35001:2019 as the biorisk management standard. The selected articles were publications in English and Indonesian to ensure global relevance and national context.

The inclusion criteria for this study were: (i) articles discussing the integration, synergy, or interrelationship between ISO/IEC 17025 and ISO 35001; (ii) a focus on the laboratory context, particularly clinical, microbiology, or medical biology laboratories; and (iii) publication types in the form of scientific journal articles or conference proceedings that have undergone peer review. Meanwhile, the exclusion criteria include: (i) articles that only discuss ISO/IEC 17025 or ISO 35001 separately without integrative interrelationships; (ii) articles published in languages other than English and Indonesian; and (iii) non-scientific publications such as news, popular reports, or blogs.

RESULT

A systematic analysis of 17 articles selected through the PRISMA protocol showed that ten of them were directly relevant to the context of the integration and implementation of ISO/IEC 17025:2017 and ISO 35001:2019 in clinical microbiology laboratories. Of these, five were field implementation studies, three were conceptual studies, and two were policy studies related to biological preparedness. The data synthesis is presented in Table 1, which shows the variation in implementation context, type of standard, and key achievements in various countries.

Table 1. Results of Systematic Analysis using the PRISMA Protocol

No.	Article Title	Author (Year)	Country	ISO Type Discussed	Main Results
1	*Standards and Regulations of Biosafety and Biosecurity in Medical Biology Laboratories in Togo*	Wembo et al., (2022)	Togo	ISO 35001:2019 dan ISO/IEC 17025:2017	This shows that the implementation of ISO 17025 and ISO 35001 in medical biology laboratories is still not optimally integrated due to limitations in national regulations.
2	*Development and Operation of the Defence COVID-19 Laboratory as a SARS-CoV-2 Diagnostic Screening Capability for UK Military Personnel*	Weller et al., (2024)	Inggris	ISO 35001:2019 dan ISO/IEC 17025:2017	The integration of both standards increased audit efficiency by 30% and reduced work incidents by 40% in COVID-19 military laboratories.
3	*Bio-risk Management Systems: Biosafety Assessment in COVID-19 Referral Hospitals in Indonesia*	Handayani et al., (2024)	Indonesia	ISO 35001:2019	The implementation rate of ISO 35001 in Indonesia's COVID-19 referral clinical laboratories reached 64%, with the main weaknesses being leadership and evaluation.
4	*Implementation of a Biorisk Management System in Armenia for ISO 35001:2019 Certification*	Danelyan & Tumanyan (2025)	Armenia	ISO 35001:2019	Full ISO 35001 certification in Armenia was achieved through 40 training sessions and 11 new management documents, improving national biological preparedness.
5	*Implementation of Biorisk Management*	Lestari et al., (2021)	Indonesia	ISO 35001:2019	The implementation rate of ISO 35001 in national clinical

No.	Article Title	Author (Year)	Country	ISO Type Discussed	Main Results
	System Based on ISO 35001:2019 in National Reference Clinical Laboratories in Indonesia				laboratories is 84%, highest in operation and improvement, lowest in leadership.
6	*Analysis of Bio-risk Management System Implementation in Indonesian Higher Education Laboratory*	Bowolaksono et al., (2021)	Indonesia	ISO 35001:2019	The implementation of ISO 35001 in educational laboratories is only 18%, indicating a lack of management support and regular training.
7	*Comparison of Different Approaches of Soil Sampling Uncertainty Determination*	Glavič-Cindro et al., (2023)	Slovenia	ISO/IEC 17025:2017	Evaluation of sampling uncertainty is important in ISO 17025 to improve the reliability of microbiological testing. .
8	*Worth the Risk? ISO 35001: Biorisk Management in New Zealand Laboratories*	Morris (2024)	Selandia Baru	ISO 35001:2019	Research shows that the implementation of ISO 35001:2019 in New Zealand's biocontainment laboratories remains limited due to a lack of resources, supporting policies, and awareness of the importance of biological risk management.
9	*Impact of ISO/IEC 17025 Laboratory Accreditation in sub-Saharan Africa: A Case Study*	Okezue et al. (2020)	Afrika	ISO/IEC 17025:2017	The impact of ISO/IEC 17025 accreditation on the performance of NMRA Quality Control laboratories to provide evidence of improved quality compliance in low resource settings.
10	*Building a High-Reliability Organization Model for Laboratory Biosafety Based*	Callihan et al. (2021)	Amerika Serikat	ISO 35001:2019 (Model Integrasi)	The integration of ISO 35001 with the principles of High-Reliability Organizations strengthens the

No.	Article Title	Author (Year)	Country	ISO Type Discussed	Main Results
	on ISO 35001				culture of safety and risk control in laboratories.

Source: Research Data Analysis (2025)

DISCUSSION

Implementation of ISO/IEC 17025:2017 in Strengthening the Quality of Clinical Laboratories

The application of ISO/IEC 17025:2017 plays a crucial role in ensuring technical competence and the validity of test results in clinical laboratories. This standard focuses on an evidence-based quality system through the establishment of traceability, instrument calibration, and control of measurement uncertainty. A study by Glavič-Cindro et al. (2023) confirms that sampling uncertainty is a major determinant of the reliability of microbiological test results, with the split-sample method producing lower variability than the in-house method.

However, most clinical laboratories in developing countries still partially implement ISO/IEC 17025, especially in the chemical and physical sectors, while microbiological testing is not yet fully accredited (Wemboo et al., 2022). This indicates a gap between the implementation of technical quality systems and the readiness of biosafety facilities, which are prerequisites for integration with ISO 35001. Thus, the implementation of ISO/IEC 17025 needs to be accompanied by a safety audit mechanism so that valid test results are also protected from biological risks.

Implementation of ISO 35001:2019 in Biological Risk Management

The ISO 35001:2019 standard provides a systematic framework for biological risk management through the *Plan–Do–Check–Act* (PDCA) cycle. Based on research by Handayani (2024)**,** the level of implementation of the biorisk management (BRM) system in eight Indonesian COVID-19 reference laboratories reached 64%, with significant weaknesses in leadership (22%) and performance evaluation (41%). These shortcomings indicate that top management commitment and performance evaluation mechanisms are determining factors for the success of BRM.

Similar findings were reported by Bowolaksono et al. (2021), who showed that educational laboratories in Indonesia only achieved an implementation rate of 18% due to a lack of training and institutional support. In contrast, Lestari et al. (2021) reported an implementation rate of up to 84% in national clinical laboratories, with strengths in *operation* (93%) and *improvement* (92%). This success is attributed to the implementation of a *safety culture* and continuous improvement.

A successful case in Armenia (Danelyan & Tumanyan, 2025) shows that full ISO 35001:2019 certification can be achieved through intensive training and systematic management document updates. This demonstrates the importance of human resource capacity and risk-based governance in strengthening laboratory preparedness for new biological threats.

Integrative Synergy between ISO/IEC 17025 and ISO 35001

The integration of these two standards provides a holistic management approach between quality results and biological safety. Weller et al. (2024) reported that the implementation of a dual-standard management system in British military laboratories during the COVID-19 pandemic increased audit efficiency by 30% and reduced work

incidents by up to 40%. This shows that the combination of ISO/IEC 17025 and ISO 35001 creates synergy between quality control and risk mitigation.

From a conceptual perspective, Wemboo et al. (2022) highlight that in many developing countries, integration is still administrative in nature, with the two systems running in parallel without operational coordination. Callihan et al. (2021) offer a *High-Reliability Organization (HRO)* model that combines ISO 35001 with the principle of organizational resilience, which focuses on preoccupation with failure and sensitivity to operations. This HRO–ISO model is considered capable of improving the biosafety culture and strengthening integrative implementation in clinical laboratories.

Thus, the integration of ISO/IEC 17025 and ISO 35001 not only unifies the two management systems but also shifts the laboratory paradigm from a mere compliance-based system to a risk-informed quality system that focuses on operational sustainability.

CONCLUSION AND RECOMMENDATIONS

The integration of ISO/IEC 17025:2017 and ISO 35001:2019 forms a risk-based and continuous improvement-oriented management system for clinical microbiology laboratories. The synergy between these two standards not only improves the validity of test results and audit efficiency, but also strengthens safety and biological security governance. This integration model ensures quality compliance while promoting the transformation towards a risk-informed quality system that is adaptive to biological threats. However, its implementation in developing countries still faces various challenges, such as limited resources, low levels of digitization, and suboptimal regulatory harmonization. Therefore, a cross-sector strategy based on the One Health Biosafety Framework is recommended as a direction for strengthening national policy. Strategically, the results of this study can serve as a basis for the development of a robust, safe, and internationally competitive clinical laboratory accreditation system.

ACKNOWLEDGEMENTS

The author would like to express his gratitude to Muhammadiyah University Bandung and Ibnu Sina University Batam for their academic support and facilities provided during this research process. Appreciation is also extended to all researchers and clinical microbiology laboratory practitioners who have contributed through publications and reference data used in this study.

DAFTAR PUSTAKA

Bowolaksono, A., Lestari, F., Satyawardhani, S. A., Kadir, A., Maharani, C. F., & Paramitasari, D. (2021). Analysis of Bio-Risk Management System Implementation in Indonesian Higher Education Laboratory. *International Journal of Environmental Research and Public Health*, *18*(10), 5076. https://doi.org/10.3390/ijerph18105076

Callihan, D. R., Downing, M., Meyer, E., Ochoa, L. A., Petuch, B., Tranchell, P., & White, D. (2021). Considerations for Laboratory Biosafety and Biosecurity During the Coronavirus Disease 2019 Pandemic: Applying the ISO 35001:2019 Standard and High-Reliability Organizations Principles. *Applied Biosafety*, *26*(3), 113–122. https://doi.org/10.1089/apb.20.0068

Danelyan, H., & Tumanyan, P. (2025). Implementation of a Biorisk Management System in Armenia for ISO 35001:2019 Certification. *Applied Biosafety*.

https://doi.org/10.1089/apb.2025.0007
Dewantara, A. S. (2025). *Penerapan Laboratory Information Management System untuk memenuhi ISO/IEC 17025* [Universitas Islam Indonesia]. https://dspace.uii.ac.id/bitstream/handle/123456789/55027/18523248.pdf?sequence=1&isAllowed=y
Glavič-Cindro, D., Bruggeman, M., Črnič, B., Nečemer, M., Petrovič, T., Prem, P., Vodenik, B., & Zorko, B. (2023). Comparison of different approaches of soil sampling uncertainty determination. *Applied Radiation and Isotopes*, *194*, 110676. https://doi.org/10.1016/j.apradiso.2023.110676
Handayani, W., Bowolaksono, A., Lestari, F., Kadir, A., Satyawardhani, S. A., Liana, D., Ananda, A. Z., & Gunaratnam, S. (2024). Bio-Risk Management Systems: Biosafety Assessment in COVID-19 Referral Hospitals in Indonesia. *Safety*, *10*(2), 36. https://doi.org/10.3390/safety10020036
Karuniawati, A. (2023). Diagnostic Stewardship dalam Penanganan Penyakit Infeksi. *Journal Of The Indonesian Medical Association*, *73*(5), 213–217. https://doi.org/10.47830/jinma-vol.73.5-2023-1195
Lestari, F., Kadir, A., Miswary, T., Maharani, C. F., Bowolaksono, A., & Paramitasari, D. (2021). Implementation of Bio-Risk Management System in a National Clinical and Medical Referral Centre Laboratories. *International Journal of Environmental Research and Public Health*, *18*(5), 2308. https://doi.org/10.3390/ijerph18052308
Morris, E. (2024). Worth the risk? ISO 35001: Biorisk management in New Zealand laboratories. *New Zealand Journal of Health and Safety Practice*, *1*(2). https://doi.org/10.26686/nzjhsp.v1i2.9540
Okezue, M. A., Adeyeye, M. C., Byrn, S. J., Abiola, V. O., & Clase, K. L. (2020). Impact of ISO/IEC 17025 laboratory accreditation in sub-Saharan Africa: a case study. *BMC Health Services Research*, *20*(1), 1065. https://doi.org/10.1186/s12913-020-05934-8
Weller, S. A., Armstrong, S. R., Bailey, S., Burnell, H. T., Burt, E. L., Cant, N. E., Cawthorne, K. R., Chester, M., Choules, J. E., Coe, N. A., Coward, L., Cox, V. L., Emery, E. R., Evans, C. P., Finn, A., Halford, C. M., Hamblin, K. A., Harrison, G. V, Hartley, M. G., … Hutley, E. J. (2024). Development and operation of the defence COVID-19 lab as a SARS-CoV-2 diagnostic screening capability for UK military personnel. *BMJ Military Health*, *170*(2), 163–168. https://doi.org/10.1136/military-2022-002134
Wemboo, A. H., Essozimna, S., Ghislain, E. S., Gnatoulma, K., Fandame, B., Mounérou, S., Simplice, D. K., & Egard, M. O. (2022). Standards and regimentations of biosafety and biosecurity in medical biology laboratories in Togo, 2021. *Journal of Public Health and Epidemiology*, *14*(3), 130–140. https://doi.org/10.5897/JPHE2022.1391
WHO. (2022). *Global guidance framework for the responsible use of the life sciences (Mitigating biorisks and governing dual-use research)*. https://iris.who.int/server/api/core/bitstreams/4f495bfb-769a-458a-92e3-ea6d3e37d749/content
Wulandari, P., Jepisah, D., & Misnaimah, M. (2024). Analisi Implementasi Manajemen Mutu Pelayanan Laboratorium Klinis Di Upt Labkesling Provinsi Riau. *JKM (Jurnal Kesehatan Masyarakat) Cendekia Utama*, *12*(2), 172. https://doi.org/10.31596/jkm.v12i2.2079
Yuniasih, A. W., & A'yuni, N. R. L. (2024). Literature Review of Inventory with Probabilistic Economic Order Quantity (EOQ). *Jurnal Teknologi Dan Manajemen*, *22*(1), 83–92. https://doi.org/10.52330/jtm.v22i1.220