Worth the risk? ISO 35001: Biorisk management in New Zealand laboratories

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Abstract

ISO 35001: 2019 – Biorisk management for laboratories and other related organisations was released five years ago to address the global need for regulation of biorisk management. This article seeks to explore the performance evaluation clause of ISO 35001 in the context of a biocontainment laboratory, with examples of implementation from overseas. The need for ISO 35001 and the barriers to certification are discussed, especially in relation to the New Zealand biocontainment laboratory. Implications for health and safety in New Zealand are also noted.

Keywords

ISO 35001; biorisk; biological risk; biorisk management; biocontainment laboratory; management system

1.0 Introduction

In 2019, the International Organization for Standardization (ISO) released the first standard to provide a management system approach to biological risk (biorisk)(Callihan et al., 2021). Despite New Zealand's unique vulnerability to biorisk(Gerard & Barratt, 2021), no New Zealand biocontainment laboratories have yet become certified to ISO 35001:2019 – Biorisk management for laboratories and other related organisations (ISO 35001).[1]

2.0 Discussion

2.1 The need for ISO 35001

Biocontainment laboratories conduct work with infectious biological agents that could have a negative impact on the environment, community health, or animals – commonly known as biological risk (biorisk)(World Health Organization, 2020). New Zealand is especially vulnerable to biorisk as it remains free of most exotic diseases and pests that are commonplace overseas, and has an economy which is heavily dependent on agricultural exports(Gerard & Barratt, 2021). The Ministry for Primary Industries (MPI) predicts that New Zealand's food and fibre sector will produce a record $58.1 billion in exports for the 2024/2025 financial year(Ministry for Primary Industries, 2024).

Biocontainment laboratories are stratified according to the level of biorisk. Biosafety Levels 1 to 4 are assigned to laboratories based on the biological agents they work with, where Biosafety Level 1 (BSL-1) represents the lowest level of biorisk and BSL-4 represents the highest(Meechan & Potts, 2020). According to data from 2023, there are four BSL-4 laboratories operating in Australia, and one BSL-3 enhanced (BSL-3+) laboratory operating in New Zealand(Lentzos et al., 2023).

New Zealand and Australian regulations use the term Physical Containment level to denote biorisk, e.g., Physical Containment 1 (PC1), as opposed to BSL(Environmental Protection Authority, 2024). New Zealand biocontainment laboratories are inspected by MPI on a regular basis, which involves a physical inspection and audit against the appropriate facility standards, for example the Facilities for Microorganisms and Cell Cultures: 2007a standard. A registered New Zealand biocontainment laboratory must abide by these standards(Environmental Protection Authority, 2024). These standards draw upon broader standards, such as AS/NZS 2243.3: 2002 – Part 3: Safety in laboratories: Microbiological aspects and containment facilities, and relevant national legislation(MAF Biosecurity New Zealand & ERMA New Zealand, 2007). Whilst the facility standards do involve safety considerations, their primary goal is to determine the facility's ability to ensure biocontainment of the organisms held within. This aligns with MPI's role of administering the Biosecurity Act 1993(Ministry for Primary Industries, 2020).

Breaches of laboratory containment, where an organism escapes from a laboratory setting, can occur due to a lapse in judgement or a failure of the systems used to contain the organism(Ritterson et al.,

[1] Wagener, S., personal communication, May 28th, 2024

2022). These breaches can have a devastating impact on the environment and/or the community. In 2007, an outbreak of the highly infectious Foot-and-Mouth Disease virus (FMD) in eight farms in southern England was traced back to broken pipes at the nearby Pirbright Institute, where scientists were experimenting with the same virus(Rhodes, 2009). The outbreak proved difficult to control, with a number of farms outside of the protection zone testing positive for FMD in a second phase, despite extensive culling and disinfection during the first phase(Lee, 2017).

Work involving biorisk can also lead to laboratory acquired infections. In 2023, two separate cases of laboratory acquired typhoid infections in New Zealand laboratories were reported in the mainstream media(Macdonald, 2023). Whilst a definitive route of infection is difficult to determine post-event, in one of the cases several contributing factors were identified, including improper use of biological safety cabinets and inconsistent use of gloves(Macdonald, 2023). Furthermore, medical providers seldom suspect occupational causes for infectious diseases unless they are given evidence to suggest otherwise and unfortunately the infection progressed to intestinal bleeding for one laboratory worker before a diagnosis of typhoid was made(Macdonald, 2023).

Global biorisk is on the rise due to a proliferation of biocontainment laboratories and an increase in high-risk biological research(Lentzos et al., 2022). The scientific community has long been calling out for regulation of biosafety and biosecurity in the life sciences. The European Committee for Standardization (CEN) Workshop Agreement (CWA) 15793 Laboratory Biorisk Management standard was originally written in 2008 by multiple international parties and served as a benchmark for best practice in biorisk management(European Committee for Standardization, 2011). ISO 35001 incorporates the key principles from CWA 15793, and supersedes this standard(Callihan et al., 2021).

2.2 Performance evaluation within ISO 35001

ISO 35001 uses the same Plan, Do, Check, Act cycle that underpins other management system standards(Joseph, 2021), but the standard emphasises “the unique aspects of biorisk management”(Lewis, 2020). The main objective of ISO 35001 is to apply a management system approach to facilitate the identification, control, and evaluation of biorisk by organisations(ISO 35001, 2019). This is quite a departure from the current approach to managing biorisk in biocontainment laboratories, which is primarily based on compliance and conformance with national regulations, not performance. It is worthwhile noting that performance-based systems inherently require compliance[1]. ISO 35001 is structured according to the Annex SL guidelines (International Organization for Standardization, 2024) and shares the same basic structure as ISO 45001:2018 – Occupational health and safety management systems.

As with all management system standards, performance evaluation and continual improvement are essential elements of ISO 35001. Clause 9 of ISO 35001 is dedicated to performance evaluation and details the expectations of internal audit, management review, and monitoring and measurement of performance of the biorisk management system (BMS)(ISO 35001, 2019). It is a requirement of the standard that regular internal audits of the BMS are conducted by the organisation. These audits shall consider not only the performance of the BMS against the requirements of ISO 35001, but also how the BMS is satisfying the requirements of the organisation(ISO 35001, 2019).

In clause 9.3, ISO 35001 states that management review of the BMS must be conducted regularly. Management reviews need to evaluate how well the BMS is achieving the objectives set by the organisation, and must also specifically consider any changes in the internal and external context for the organisation(ISO 35001, 2019). A practical example of this could involve establishing a Management Review Committee consisting of senior leadership, members of the Institutional Biosafety Committee, and operational laboratory workers(Joseph, 2021). It is important that any action points that arise from the management review process are documented and assigned to individuals for completion(Joseph, 2021).

As it is currently not possible for New Zealand biocontainment laboratories to achieve certification to ISO 35001 (see section 2.3)[1], we must look overseas for data on how effectively organisations have implemented clause 9 of ISO 35001. A study by Bowolaksono et al examined the operationalisation of ISO 35001 in university laboratories in Indonesia(Bowolaksono et al., 2021). The authors used a checklist of 202 items that were taken directly from the seven main clauses of ISO 35001 to measure how successful 11 laboratories in Indonesian universities were in embedding ISO 35001(Bowolaksono et al., 2021). Of the clauses investigated, their data showed that performance evaluation consistently scored the lowest across university laboratories. This was mainly because most laboratories had not conducted internal audits of their BMS(Bowolaksono et al., 2021).

2.3 Barriers to certification

Given the global need for better regulation of biorisk within the life sciences(Lentzos et al., 2022), why has there been such a slow uptake of ISO 35001 by biocontainment laboratories? And why is certification to the new biorisk management standard currently not an option for New Zealand biocontainment laboratories?

In their recent review of laboratory acquired infections and accidental pathogen escape from laboratory settings, Blacksell et al acknowledged the critical role that ISO 35001 plays in establishing an international benchmark for biorisk management(Blacksell et al., 2024). The authors also noted some factors that make it difficult for biocontainment laboratories to become successfully certified to ISO 35001. These include the significant investment of resources for a biocontainment laboratory to satisfy the level of infrastructure required by the standard, as well as high levels of commitment from leaders of the organisation(Blacksell et al., 2024). The requirements of other popular laboratory ISO standards, such as the management system described in ISO 17025:2017 General requirements for the competence of testing and calibration laboratories, may make it easier for laboratories to satisfy the infrastructure requirements of ISO 35001(ISO/IEC 17025, 2017). However, it is important to note that certification to other ISO standards that employ management systems does not guarantee compliance with the management system requirements of ISO 35001[1].

Whilst international biosafety organisations, such as the Association for Biosafety and Biosecurity (ABSA International), have incorporated ISO 35001 into their training programmes(Callihan et al., 2021), there is currently no coordinated international effort to implement the standard in biocontainment laboratories(Lentzos et al., 2023). Despite this, ISO 35001 lends itself well to international adoption because it does not include prescriptive measures and it is not compliance-focused, meaning it can be used harmoniously with all regulatory frameworks. This is especially relevant to the implementation of ISO 35001 in New Zealand biocontainment laboratories as New Zealand's existing legislation for biological agents, both the Biosecurity Act 1993 and the Hazardous Substances and New Organisms Act (HSNO) Act 1996, was established thirty years ago and may require updating to deal with recent developments in biorisk.

ISO 35001 certification needs to be provided by an accredited third party, such as a national accreditation board. Currently Indonesia is the only country to have ISO 35001 on its list of certifiable standards[1]. This means that biocontainment laboratories in New Zealand seeking certification to ISO 35001 would not have their certification recognised by national authorities[1]. The Global BioLabs 2023 Report acknowledges that whilst national regulators could technically provide certification to ISO 35001, this may not be appropriate for all countries and the level of credibility of certifications to the international biosecurity community may depend on the country issuing the certification(Lentzos et al., 2023). Instead, the report proposes that the International Experts Group of Biosafety and Biosecurity Regulators (IEGBBR) could assume the role of international auditor for ISO 35001(Lentzos et al., 2023). Partial implementation of ISO 35001 is an option for laboratories whose national accreditation bodies do not currently offer certification to the standard. This would involve selectively adopting clauses or functionally adopting ISO 35001, without official certification. This practice has already been observed in Australian biocontainment laboratories[1], which indicates a desire for a management system approach to biorisk.

2.4 Implications for health and safety in New Zealand

In addition to performance evaluation and continual improvement, comprehensive hazard identification and risk mitigation are central pillars of ISO 35001. This involves determining the most effective, practicable controls for the organisation, and assessing the performance of said controls(ISO 35001, 2019). Research suggests that implementation of safety management systems in an organisation does lead to improved health and safety performance(Viswanathan et al., 2024). Whilst laboratory acquired infections may be considered rare in the New Zealand workplace(Macdonald, 2023), they still represent a potential failure of a Person Conducting a Business or Undertaking (PCBU) to protect their workers from harm. A recent independent taskforce report on the state of New Zealand's health and safety performance highlighted a lack of sufficient regulations from the health and safety regulator, WorkSafe, that demonstrate best practice in New Zealand workplaces(Beaglehole et al., 2024). This is especially the case for biorisk within a biocontainment laboratory setting – for which there is no guidance from WorkSafe, nor past health and safety prosecutions that set an example of performance expectations. ISO 35001 therefore represents a meaningful contribution to laboratory safety for the New Zealand biocontainment laboratory, in lieu of official guidance from WorkSafe.

3.0 Conclusion

ISO 35001 fills the gap in biorisk management within the life sciences as an internationally recognised, management system approach to biorisk(Lewis, 2020). The section on performance evaluation includes requirements for internal audit, management review, and measuring the performance of the BMS(ISO 35001, 2019). No biocontainment laboratories operating in New Zealand, and few biocontainment laboratories operating internationally, have sought certification to ISO 35001[1]. This is troubling as New Zealand is especially susceptible to biorisk and the current legislative framework for managing biorisk in New Zealand dates from the nineteen-nineties. A lack of official guidance from WorkSafe on laboratory biological safety practices places additional emphasis on the importance of ISO 35001 for New Zealand biocontainment laboratories. There are many barriers to biocontainment laboratories becoming certified to ISO 35001. Concerted effort is required at a global level to make the official adoption of ISO 35001 more achievable.

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Conflicts of interest

None to declare.

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