SOCIEDADE BRASILEIRA DE BIOSSEGURANÇA E BIOPROTEÇÃO

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Biosecurity in Academic High-Containment Biological Environments (BSL-3[1]) Vulnerabilities, Structural Challenges, and Pathways to Strengthening Governance

1. Background

High-containment biological laboratory environments (BSL-3) are traditionally designed, evaluated, and operated from a biosafety perspective, with emphasis on measures aimed at occupational protection, physical containment of biological agents, and prevention of accidental exposures. These environments generally incorporate robust structural and operational elements, including negative pressure systems, physical barriers, biological safety cabinets, decontamination protocols, and strict use of personal protective equipment.

However, accumulated experience, both nationally and internationally, has demonstrated that the presence of adequate infrastructure alone is not sufficient to ensure system integrity. Particularly in academic settings—characterized by high personnel turnover, multiple concurrent projects, and intense interaction among different research groups—vulnerabilities emerge related to the management, control, and governance of biological materials.

In this context, it becomes essential to incorporate the concept of biosecurity, understood as the set of measures aimed at preventing unauthorized access, loss, theft, misuse, or intentional release of biological agents. In this sense, biosecurity should be understood as an integral component of biosafety, complementing it by expanding the focus from the protection of individuals and the environment to include institutional protection and responsibility in the use of biological materials. This Technical Note aims to systematically present, in a structured manner, plausible biosecurity vulnerabilities in academic BSL-3 environments, contributing to the improvement of institutional governance and to the strengthening of practices aligned with international frameworks.

It is important to emphasize that this Technical Note recognizes and values the institutional, regulatory, and scientific advances achieved in Brazil over recent decades,

[1] For practical purposes and considering its continued widespread use in technical literature and within the Brazilian institutional context, this Technical Note adopts the term BSL-3 as a general reference to environments classified as BSL-3, BSL-3A, BSL-3Ag, and equivalent designations. It should be noted, however, that such nomenclature is not recommended by the WHO Laboratory Biosafety Manual (4th edition, 2020), which advocates replacing this approach with a risk-based classification using the concepts of *high containment biological environments* and *maximum containment biological environments* for BSL-3 and BSL-4, respectively. Within this framework, the definition of containment measures should not be rigidly tied to predefined levels, but rather based on a comprehensive biological risk assessment conducted from the conceptual design phase and maintained throughout the entire lifecycle of the facility, including design, operation, maintenance, and decommissioning.

particularly in the field of biosafety applied to genetically modified organisms (GMOs), as well as the efforts undertaken by public institutions, regulatory agencies, the scientific community, and the productive sector. The analyses presented herein are not intended as criticism of specific structures or actors, nor do they refer to any particular facility, institution, or event. Rather, they are intended to provide a technical contribution to the continuous and integrated improvement of biological risk governance systems, in light of the scientific, technological, and institutional developments observed both nationally and internationally.

At the same time, it is recognized that the current context represents a valuable opportunity to promote a structured, evidence-based discussion aligned with international best practices, with the aim of consolidating a more robust, integrated, and sustainable system for the management of biological materials and the operation of high-containment environments in Brazil. In this sense, the situations described should be understood as plausible scenarios in complex environments, rather than as attributions directed at specific organizations or professionals.

Within the Brazilian context, and considering the existing regulatory framework, it is important to acknowledge that the National Technical Commission on Biosafety (CTNBio) plays a central role in regulating activities involving genetically modified organisms (GMOs), as established by Law No. 11.105/2005 and its associated regulations, including Normative Resolutions No. 18/2018 and No. 37/2022.

These regulations establish criteria for risk classification and for defining biosafety levels applicable to GMO-related activities, based on case-by-case risk assessment conducted by CTNBio, as well as requirements for the operation of containment facilities and the roles of Institutional Biosafety Committees (CIBios), including periodic inspections and project oversight.

However, it is essential to highlight that this regulatory framework is specifically focused on GMOs and their derivatives, with an emphasis on assessing risks related to release, escape, genetic stability, and potential impacts on human, animal, and environmental health.

Thus, although CTNBio regulations incorporate terminology and technical elements that are consistent with those used in laboratory biosafety, their application was not designed to directly and comprehensively regulate facilities intended for handling non-genetically modified pathogens, which require specific approaches based on biological risk assessment and internationally recognized technical frameworks.

The use of the Biosafety Quality Certificate (CQB) as evidence of compliance of facilities for activities involving non-GMO biological agents has been observed in different institutional contexts. Such interpretation, although understandable from an operational perspective, represents an extension of the scope originally intended for the CQB within the legal framework of CTNBio, highlighting a relevant conceptual gap in the country.

The CQB constitutes an institutional authorization instrument linked to the handling of GMOs, and not a certification mechanism for high-containment biological facilities for pathogens in general.

This distinction is critical to avoid undue overlap of regulatory frameworks and to ensure that biological risk assessment is conducted based on appropriate technical references, aligned with the specific characteristics of the agents, activities, and operational contexts involved.

2. Regulatory gaps applicable to high-containment biological environments

In Brazil, despite structural advances related to the implementation of high-containment biological facilities, as well as the establishment of the first institutional biosafety committees and training initiatives in this field since the second half of the 1980s, and the regulatory advances associated with genetically modified organisms (GMOs), particularly following Law No. 11.105/2005, a comprehensive and specific national regulatory framework for high-containment biological environments remains insufficiently developed.

This gap results in critical decisions related to conceptual and detailed design, definition of containment barriers, operational arrangements, access criteria, personnel training, monitoring, and validation of facilities being conducted in a heterogeneous manner, often based on local interpretations, accumulated experience, or the partial and non-harmonized adoption of international references, frequently disconnected from a structured risk-based approach.

In summary, the absence of structured national frameworks results in the country operating, in practice, without a fully defined governance system for these environments, with direct impacts on technical consistency, operational safety, institutional predictability, and decision-making consistency associated with these facilities, as well as limiting the harmonization of practices, the implementation of independent evaluations, and the induction of minimum performance standards.

3. Governance and Institutional Responsibility

One of the most relevant vulnerabilities in academic high-containment biological environments lies in the lack of clear definition of responsibilities among the different actors involved. Overlaps or gaps are frequently observed between the roles of laboratory coordinators, user researchers, institutional bodies, Institutional Biosafety Committees (CIBio), biosafety professionals, and higher levels of management.

For the purposes of this Technical Note, the term governance refers to the structured set of principles, responsibilities, processes, and institutional mechanisms that guide decision-making, oversight, and control of activities involving biological materials. This concept includes the clear definition of roles and responsibilities, the existence of formal authorization workflows, the implementation of risk identification, analysis, evaluation, treatment, communication, and monitoring processes, as well as mechanisms for monitoring, systematic review, and continuous improvement throughout the entire lifecycle of laboratory activities. This approach is aligned with international risk management and biorisk management frameworks, as established in ISO 31000 and ISO 35001, which emphasize the integration of governance, risk management, and organizational performance.

In practice, this situation manifests through the shared use of infrastructure by multiple groups without fully formalized rules, the perception that responsibility lies

predominantly with the direct user, and the lack of clarity regarding authority to authorize access, storage, internal transport, and disposal of biological materials.

This scenario compromises the decision-making chain and the integrity of the chain of custody of biological materials and makes coordinated responses to incidents more difficult. Additionally, the lack of clear definition of responsibilities compromises the integrity of the chain of custody of biological materials, hindering traceability and control throughout their entire lifecycle of use. Addressing this gap requires the formalization of a responsibility matrix, the definition of institutional custody policies, and the clear establishment of technical and administrative authority.

It is important to highlight that, in the Brazilian context, the existence of the Biosafety Quality Certificate (CQB), issued by the National Technical Commission on Biosafety (CTNBio), does not, in itself, imply recognition or operational validation of laboratory environments for work with biological agents in general. The CQB is associated with institutional authorization for the development of activities involving genetically modified organisms (GMOs), based on information submitted to CTNBio, and does not constitute a mechanism for continuous operational certification of the actual conditions of infrastructure, practices, or governance of high-containment biological laboratories, particularly with regard to the safe and secure storage and handling of higher-risk or high-consequence pathogens.

In such environments, this misinterpretation may result in the replacement of effective governance and operational evaluation mechanisms with purely documental compliance, which represents a relevant vulnerability from a biosecurity perspective.

This scenario may contribute to the consolidation of an “illusion of compliance,” in which documental regularity and adherence to formal requirements are interpreted as equivalent to the existence of effective systems of control, governance, and biosecurity, which is not always reflected in operational practice.

This lack of definition of responsibilities is further aggravated, in the Brazilian context, by the absence of sufficiently detailed and specific regulation for high-containment biological environments, reducing institutional predictability and increasing reliance on local arrangements, isolated interpretations, and solutions that are not necessarily harmonized.

In this sense, the misinterpretation of the CQB as a comprehensive certification of operational adequacy for BSL-3 environments contributes to the creation of an expanded—and not always justified—perception of operational compliance, particularly when not accompanied by robust internal mechanisms for evaluation, monitoring, and control of the activities actually performed.

It should be emphasized that such vulnerabilities are not exclusive to specific institutions, but rather reflect structural challenges observed across different organizational contexts, including in countries with more consolidated systems, reinforcing the systemic, recurring, and structural nature of this challenge in the management of complex laboratory environments.

4. Physical Access Control

Access control to BSL-3 facilities, although often structured from the perspective of physical barriers and entry restriction devices, may present significant vulnerabilities in its operational management. In academic environments, it is common to observe broad access permissions, often maintained over time without reassessment, including former students, postdoctoral researchers, collaborators, and indirect users. Additionally, access may occur in a mediated manner, through indirect relationships with students, collaborators, or partners, without systematic and formal review of granted permission. Access credentials, in this context, tend to remain active beyond what is necessary.

This condition compromises the traceability of personnel movement and increases vulnerability to unauthorized access or movement of biological materials. Mitigating these vulnerabilities requires the implementation of formal mechanisms for nominal and time-bound access control, periodic review of credentials, auditable records of entry and exit, as well as the segregation of permissions based on actual operational need, in alignment with the principle of least privilege.

Thus, it is observed that, in academic environments, access may occur through third parties, based on relationships of trust, collaboration, or operational convenience. This type of indirect access, when not formally authorized and recorded, compromises traceability and weakens institutional control mechanisms, allowing individuals to circulate in critical areas without adequate institutional oversight and without proper linkage to formal authorization processes.

Additionally, the absence of formal mechanisms for institutional accountability contributes to the dilution of responsibilities in situations of non-compliance. In complex environments, the lack of clear criteria for assigning technical and administrative responsibility may hinder the investigation of events, reduce the effectiveness of corrective actions, and compromise trust in the governance system. More than formal structures, effective governance requires not only their existence, but their continuous operationalization in daily institutional practice.

5. Inventory and Traceability of Samples

The absence of robust institutional systems for inventory and traceability of samples constitutes one of the main vulnerabilities in terms of biosecurity in high-containment biological environments. In many academic contexts, sample management is often based on decentralized controls, supported by local spreadsheets, informal records, or even individual tracking systems.

This practice results in heterogeneous identification of samples, lack of consolidated records of entry, movement, consumption, and disposal, as well as discrepancies between project records and physical inventories maintained in freezers or other storage areas.

As a consequence, a scenario of uncertainty is established regarding the existence, location, and quantity of biological material, making it difficult to verify authorized removal, detect diversion, and reconstruct events. This condition directly compromises the integrity

of the chain of custody and limits the institutional capacity for effective control and accountability[2] for the materials under its responsibility.

An appropriate response requires the adoption of integrated institutional inventory systems, with continuous recording of chain of custody and end-to-end traceability of biological materials, periodic audits, and formal processes for physical-document reconciliation. Additionally, the absence of mechanisms for early detection of inconsistencies—such as discrepancies between expected and observed inventories—may result in prolonged intervals between the occurrence of an irregularity and its identification. This time gap compromises institutional response capacity and highlights weaknesses in institutional systems for continuous monitoring.

6. Ownership and Custody of Biological Material

The definition of ownership and custody of biological material constitutes a central element of biosecurity. For the purposes of this Technical Note, ownership refers to the legal or institutional linkage of the material to a project, institution, or formal research arrangement, while custody refers to the operational responsibility for the storage, control, traceability, and appropriate use of this material throughout its lifecycle.

In academic environments, it is common to adopt informal concepts that associate possession of the material with the researcher, the project, or the laboratory, without clear institutional backing. This practice contributes to the weakening of control mechanisms and to the dilution of responsibilities.

In complex institutional environments, such as universities, the movement of biological materials between different units—even when belonging to the same institution—may occur without proper formalization and without clarity regarding the need for authorization. The perception of “institutional continuity” may lead to the undue relaxation of controls, resulting in unrecorded transfers and a breakdown in traceability.

This lack of definition is also reflected in the storage of samples in shared infrastructure without formal assignment of custody, as well as in the incorporation of materials originating from previous projects, collaborations, or personal collections without adequate institutional formalization.

As a consequence, conflicts of authority may arise, including the removal of material under claims of personal ownership and legal difficulties in characterizing irregularities. This scenario compromises the integrity of the chain of custody and the institutional capacity to exercise effective control and accountability over the materials under its responsibility.

[2] Accountability refers to the formal and traceable responsibility assigned to individuals or institutional units for the custody, use, control, and disposition of materials, processes, or decisions, accompanied by the obligation to provide justification, report on actions taken, and respond for any deviations or non-compliances. In the context of biosafety and biosecurity, accountability implies that each biological material, activity, or decision has a clearly identified responsible party, with associated records that enable the tracing of its origin, movement, use, and final disposition throughout its entire lifecycle, ensuring transparency, institutional control, and auditability.

Mitigating these vulnerabilities requires the implementation of clear institutional policies on ownership and custody, the formalization of responsibility agreements, the definition of rules for the storage, use, and transfer of biological materials, as well as alignment with formal instruments associated with research projects, including cooperation agreements, co-ownership contracts, Material Transfer Agreements (MTAs), and relationships with incubated companies or other entities linked to the activities conducted.

7. Transfer and Internal Movement of Samples

The movement of biological materials between laboratories, departments, or institutional units—including interactions with external or private structures linked to research projects—constitutes a critical point of vulnerability when carried out without formal protocols. In many academic contexts, such movements occur informally, driven by operational convenience or the dynamics of research activities.

Common examples include transportation between buildings, temporary storage in freezers belonging to other laboratories, and the sharing of materials between internal or external groups without formal records. These practices compromise traceability and may occur under inadequate conditions, undermining the containment regime originally defined for the biological material.

As a consequence, such movements weaken the chain of custody and increase the risk of unauthorized access, loss of control, or accidental exposure. Mitigating these vulnerabilities requires the implementation of formal authorization processes, detailed recording of movements, clear assignment of responsibilities, and the adoption of containment measures compatible with the risk associated with the material.

A frequently underestimated risk is the intra-institutional transport of biological materials, which, although routine, involves relevant risks of exposure, spillage, and contamination, particularly when standardized procedures or adequate training are lacking.

In this context, there has been recent mobilization toward the establishment of specific normative references in Brazil, such as ABNT NBR 17161, currently in the final stages of technical development, which aims to guide safe practices for the internal transport of biological substances. This initiative reflects the increasing maturity of the topic in Brazil and highlights the need for standardization of procedures that have historically been conducted in a heterogeneous manner across institutions.

These advances reinforce the importance of addressing biosafety and biosecurity in a systemic manner, encompassing not only facility design, but also operational workflows, movement processes, and routine practices associated with the handling of biological materials throughout their entire lifecycle.

8. Interface between Biosafety and Biosecurity

In many academic BSL-3 environments, there is a predominance of occupational biosafety over biosecurity, with focus concentrated on containment measures and individual protection, while aspects related to access control, custody, and prevention of misuse receive comparatively less attention.

In the Brazilian context, although the regulatory framework is structured in the field of genetically modified organisms (GMOs), it does not comprehensively address the full range of laboratory practices involving biological agents, particularly with regard to governance of materials, custody, and institutional use.

This asymmetry may result in systems that are effective in preventing accidents but vulnerable to diversion or unauthorized use. Additionally, there is a tendency to treat biosecurity incidents as low-criticality administrative non-conformities.

This dissociation between biosafety and biosecurity tends to be more pronounced in academic environments, where the historical emphasis on occupational protection has not been accompanied, to the same extent, by the incorporation of structured practices for the governance of biological materials.

In this context, strengthening institutional capacity requires the integration of biosafety and biosecurity within biorisk management systems, the inclusion of misuse scenarios in expanded risk assessments, and the targeted training of professionals in this field.

Furthermore, the increasing complexity of biological research—including the use of vectors, recombinant systems, and advanced platforms—heightens the relevance of systematically addressing aspects related to dual-use potential, including scenarios of unintended application or misuse, reinforcing the need for institutional mechanisms for assessment, governance, and oversight of research aligned with this reality.

8.1. Recombinant Technologies and High-Consequence Pathogens: Governance Gaps

The advancement of recombinant technologies — including genetic engineering systems, viral vectors, infectious cloning, and approaches associated with synthetic biology — has significantly expanded the possibilities for studying, modifying, and manipulating biological agents. When these technologies are applied to higher-risk or high-consequence pathogens, a field of increasing complexity emerges, situated at the intersection of biosafety, biosecurity, scientific governance, and dual-use potential of research.

In the Brazilian context, although there are consolidated regulatory instruments for activities involving genetically modified organisms (GMOs), these do not comprehensively and integratively address all dimensions associated with the use of recombinant technologies applied to high-consequence pathogens. In particular, the existing regulatory focus tends to concentrate on aspects related to genetic modification, without systematically addressing elements such as lifecycle governance of the agent, continuous operational oversight, expanded risk assessment, and potential impacts associated with misuse or unintended application of these systems.

This gap becomes more evident in activities involving the combination of higher-risk pathogens with advanced genetic manipulation techniques, where risk assessment cannot be dissociated from containment conditions, institutional context, team qualifications, material traceability, and the intended purpose of the research. In such cases, the absence of integrated national frameworks may result in heterogeneous approaches across institutions, with varying levels of rigor in the assessment and oversight of these activities.

From a governance perspective, this scenario highlights the need for more structured and coordinated mechanisms capable of integrating dimensions that are currently treated in a fragmented manner. This includes the articulation between biological risk assessment, biosafety and biosecurity analysis, consideration of dual-use aspects of research, as well as the definition of clear criteria for authorization, monitoring, and periodic review of these activities over time.

International experience indicates that effective governance of such activities does not rely on a single regulatory instrument, but rather on coordinated institutional arrangements, with clear definition of responsibilities, consistent technical criteria, and mechanisms for continuous oversight. In this context, strengthening the Brazilian biosafety and biosecurity system may benefit from the progressive incorporation of approaches that address, in an integrated manner, the inherent complexity of the use of recombinant technologies in higher-risk pathogens, in alignment with international frameworks and with the evolution of science in this field.

9. Management of Projects Involving GMOs, Vectors, and Hybrid Materials

The increasing use of genetically modified organisms (GMOs), viral vectors, and hybrid systems in academic research introduces additional challenges to governance, particularly in contexts where misalignment is observed between the regulatory status of these materials and their practical use in the laboratory.

Projects involving such systems may, in some cases, be conducted as routine experimental activities, without due attention to specific regulatory requirements, including institutional certification, mandatory notifications, appropriate classification in terms of containment level, and compliance with authorized conditions.

This gap may result in documental inconsistencies, failures in communication with regulatory bodies, and a disconnect between regulatory requirements and operational practice. Mitigating these vulnerabilities requires continuous review of project portfolios, explicit linkage between regulatory requirements and experimental execution, as well as systematic institutional oversight throughout the lifecycle of materials and activities.

This asymmetry highlights that the current regulatory framework, although robust in the field of GMOs, does not automatically translate into a comprehensive structure for biological risk governance, particularly in high-containment environments dedicated to the handling and storage of pathogens that require specific control and containment measures.

Beyond regulatory and operational aspects, the growing complexity of contemporary biological risks increases the relevance of dimensions related to the protection of sensitive knowledge associated with scientific research and technological development.

In this context, initiatives undertaken within the Brazilian State, such as the National Program for the Protection of Sensitive Knowledge (PNPC), coordinated by the Brazilian Intelligence Agency (ABIN), contribute to raising awareness and mitigating risks related to the protection of strategic assets, including those associated with scientific espionage, unauthorized access to sensitive data, and misuse of dual-use technologies.

These initiatives focus on raising awareness among research institutions and their professionals regarding the protection of critical assets—including data, biological materials, and intellectual property—promoting practices aligned with information security, cyberbiosecurity, and integrated risk management in scientific environments.

The integration of biosafety, biosecurity, and protection of sensitive knowledge reinforces the need for systemic approaches, in which security is not limited to the physical laboratory environment but extends to the digital, informational, and strategic dimensions of scientific activity, requiring institutional governance mechanisms compatible with the contemporary complexity of the life sciences.

9.1. Institutional Certification, CQB, and Biosafety Levels in the Context of GMOs

Within the specific context of activities involving genetically modified organisms (GMOs), it is necessary to clarify the relationship between institutional certification, biosafety levels, and their interpretation within the laboratory environment.

Under Law No. 11.105/2005, the National Technical Commission on Biosafety (CTNBio) establishes the requirements for institutional authorization of activities involving GMOs through the issuance of the Biosafety Quality Certificate (CQB).

The CQB is granted to institutions that meet requirements related to organizational structure, the composition and functioning of the Institutional Biosafety Committee (CIBio), personnel qualifications, and general conditions for conducting activities involving GMOs.

Within this context, CTNBio regulations—particularly Normative Resolution No. 18/2018—establish the risk classification of GMOs and define biosafety levels applicable to GMO-related activities, determined based on case-by-case risk assessment and associated with containment requirements that include aspects of infrastructure, operational practices, and control measures.

These biosafety levels, however, must be understood within the specific context of GMO handling, in which assessed risks include, among others, genetic stability, potential for recombination, environmental release, and impacts on human, animal, and ecosystem health.

Although there are conceptual overlaps with classical laboratory biosafety—particularly with regard to physical containment elements, operational flows, and effluent control—the requirements established within the CTNBio framework do not, in themselves, constitute a comprehensive certification system for high-containment biological facilities intended for non-GMO pathogens.

In particular, critical aspects for BSL-3 facilities dedicated to handling infectious biological agents—such as activity-based risk assessment, definition of primary and secondary barriers based on the agent, HVAC system performance requirements, validation, commissioning, and maintenance—are not addressed in an integrated or sufficiently detailed manner within GMO legislation.

Therefore, the use of the CQB as an indicator of compliance for BSL-3 facilities outside the GMO context should be interpreted with caution, requiring the adoption of

complementary technical references aligned with international best practices in biosafety, biosecurity, and biorisk management.

Although CTNBio regulations establish biosafety levels associated with containment requirements for GMOs, these requirements do not, in themselves, constitute a complete set of engineering and performance guidelines for high-containment biological facilities, particularly when compared to international frameworks based on risk assessment, system validation, and continuous performance verification.

10. Technical Structuring and Lifecycle of High-Containment Facilities

An aspect often overlooked in discussions on biosecurity in academic environments concerns the lifecycle of high-containment biological facilities themselves. In the Brazilian context, there is a lack of sufficiently detailed regulation to guide, in a standardized manner, the stages of conceptualization, design, implementation, commissioning, qualification, assisted operation, critical maintenance, periodic requalification, and decommissioning of such structures.

In practice, this gap manifests both in the design of new facilities and in the adaptation of structures previously intended for lower biosafety levels, as well as in the insufficient consideration of essential aspects such as preventive and corrective maintenance, structural interventions—planned or emergency—and other activities required for the safe, continuous, and sustainable operation of these facilities.

In the absence of structured frameworks, critical decisions related to conceptual design, detailed engineering design, validation for operational start-up, and the definition of institutional performance criteria are carried out in a heterogeneous manner.

This variability is also reflected in the level of technical knowledge applied to each facility, whether in engineering and architectural domains or in scientific domains, often involving highly qualified professionals in their respective fields who may not necessarily possess up-to-date knowledge of international biosafety and biosecurity practices. As a result, such decisions are frequently guided by local interpretations or by international references adopted in a partial, non-harmonized, and sometimes decontextualized manner.

In this context, the clear definition of the technical scope of the facility—often formalized in documents equivalent to a Basis of Design (BOD) — is a fundamental element to ensure alignment between intended capabilities, containment requirements, and the engineering solutions adopted. The absence of such alignment may result in incompatibilities between intended use and implemented infrastructure, with direct impacts on safety and functionality.

Biological risk assessment must constitute a mandatory and guiding structural element from the conceptual phase of the project, directing decisions related to containment barriers, operational flows, ventilation systems, equipment selection, and performance criteria. This assessment should be continuously updated throughout the entire lifecycle of the facility, reflecting the evolution of activities, handled agents, and operational conditions.

Risk assessment, in turn, must be conducted as a continuous, structured, and iterative process, involving risk identification, analysis, and evaluation, implementation of

control measures, monitoring through indicators, and periodic reassessment, in alignment with international risk management and biorisk management frameworks. However, this approach is not yet fully incorporated into Brazilian institutional practice.

10.1. Fundamental Principles for the Design of High-Containment Facilities

International experience accumulated in the design and operation of high-containment biological facilities highlights key principles that should be considered from the earliest project stages:

i. clear definition of the activities, agents, and intended capabilities of the facility;
ii. establishment of containment boundaries and operational flows consistent between clean and contaminated areas;
iii. planning of ventilation systems with validated pressure gradients, continuous monitoring, and appropriate redundancy;
iv. integration between infrastructure and critical equipment, such as biological safety cabinets, autoclaves, and storage systems;
v. provision for maintenance, technical accessibility, and safe processes for decontamination of equipment and waste;
vi. consistent adoption of a risk-based approach throughout the entire lifecycle of the facility.

Failure to observe these principles tends to result in design inconsistencies, operational limitations, and the need for late corrective interventions, with impacts on costs, timelines, and safety.

Additionally, the inadequate definition of personnel, material, and waste flows may compromise the clarity of containment zones, increase the risk of operational failures, and hinder compliance with basic biosafety requirements. Similarly, insufficient integration between critical equipment and ventilation and exhaust systems may generate operational incompatibilities, affecting the overall performance of the facility.

Failures in the design or operation of ventilation systems may also result in loss of pressure gradients or even airflow reversals under failure conditions, compromising the integrity of the containment system and increasing the risk of exposure or release of biological agents.

Furthermore, in Brazil, there is still a limited availability of independent and technically consolidated services for certification and recertification of high-containment biological facilities, which restricts the existence of structured external mechanisms for periodic performance verification. In this context, service providers with varying levels of qualification and technical recognition operate in a scenario where a broadly structured system of independent accreditation and certification for these activities has not yet been established in the country, as observed in other nations.

A similar situation can be observed in the certification of biological safety cabinets, for which there are no professionals in Brazil holding internationally recognized certifications, such as those based on the NSF/ANSI 49 standard. Nevertheless, this service is widely offered by national companies and frequently contracted by institutions that may lack

adequate information regarding the limitations and technical validity of such certifications, which may compromise the effectiveness of implemented controls.

A comparable situation is observed in commissioning and decommissioning processes, which, in more mature systems, are conducted according to structured protocols, documented criteria, and formal validation procedures. The absence of such frameworks increases the risk that facilities may begin or continue operating without sufficiently robust performance evaluation, as well as without clear parameters for deactivation, refurbishment, scope changes, or safe termination of activities.

This condition represents a significant structural gap, as high-containment biological facilities may be designed, implemented, and operated without standardized national mechanisms for independent technical validation throughout their entire lifecycle.

In the recent context of expansion of scientific infrastructure in Brazil, there has been a growing implementation of high-containment biological facility projects based on different models, including adaptations of pre-existing laboratories (BSL-2) and modular or container-based solutions, often associated with institutional funding opportunities. In part of these cases, it is observed that the design and execution process of these facilities has not been preceded by a clear and consolidated definition of the biological agents, procedures to be performed, and intended operational profiles—elements that should constitute the basis for risk assessment and infrastructure sizing.

This non-ideal sequencing of the decision-making process—where the availability of resources or the opportunity for implementation precedes the definition of technical and operational needs—may result in the creation of facilities whose complexity does not correspond to a previously characterized real demand. As a consequence, in some contexts, facilities are implemented that do not reach full operational capability or that operate at utilization levels below expectations, while still incurring high operational, maintenance, and qualification costs throughout their lifecycle.

Additionally, the design and implementation of such facilities, when conducted without the structured involvement of biosafety and biosecurity specialists, may result in significant weaknesses in critical design and operational elements. These include issues related to the integrity of physical barriers, airtightness, control and monitoring of pressure gradients, redundancy of critical systems, specification, validation, and qualification of equipment, as well as the proper implementation of components such as double-door autoclaves and their sealing systems.

The replacement of components with alternatives not validated for use in high-containment environments, the adoption of inadequate construction solutions, or the simplification of essential technical requirements may compromise facility performance and, more broadly, the reliability of the containment system. In some cases, these conditions may contribute to the consolidation of a perception of safety that is not fully supported from a technical standpoint, characterizing situations of false institutional sense of protection.

This scenario is further aggravated when the complexity of the implemented infrastructure is not matched by compatible institutional capacity for its operation, maintenance, and continuous monitoring. The management of high-containment facilities requires not only initial investment, but sustained commitment of technical, human, and

financial resources throughout the entire lifecycle of the installation, as well as a thorough understanding of biosafety and biosecurity principles by those responsible for its supervision, continuous monitoring, and periodic performance evaluation.

In this context, it is reinforced that the design of high-containment biological facilities must necessarily start from a clear definition of the activities to be conducted, the agents involved, and the associated risks, with infrastructure being the result of this process—and not its starting point. The adoption of inverse approaches, in which design is adjusted to pre-defined budget constraints or opportunistic funding availability, tends to compromise the effectiveness, safety, and technical and operational sustainability of such facilities.

11. Organizational Culture and Normalization of Deviance

Organizational culture plays a decisive role in maintaining the integrity of biosafety and biosecurity systems. In academic environments, informal practices may, over time, become incorporated as seemingly acceptable operational routines, even when not formally assessed or aligned with appropriate technical frameworks.

These practices include the removal of materials for use in other environments, non-standardized storage, informal sharing of permissions, and the adoption of operational shortcuts. The normalization of such behaviors undermines institutional control mechanisms, makes it more difficult to identify deviations, and may negatively influence the training of future professionals, particularly in academic settings.

In contexts where scientific collaboration is intense and the circulation of people and materials is dynamic, a perception may develop that certain operational procedures can be flexibly applied, especially when conducted between groups with prior interaction. This perception, even if not formally established, tends to reduce adherence to institutional protocols and contributes to the occurrence of biosecurity-related events.

In many institutional contexts, operational practices become consolidated over time without necessarily reflecting full adherence to the most robust available technical frameworks. This includes routines established through local tradition, improvised operational solutions, tacit permissions, successive procedural relaxations, and institutional tolerance of practical arrangements which, although functional in daily practice, have not been formally evaluated from a biosafety and biosecurity perspective.

This process of cultural sedimentation is particularly critical in high-containment biological environments (BSL-3), where the apparent stability of routine may mask significant weaknesses in governance, control, and biosecurity, with direct implications for institutional integrity and for both internal and external perceptions of safety.

Another relevant aspect frequently observed in high-containment environments relates to the adoption of design solutions, systems, and personal protective measures beyond what is necessary (over-design), without grounding in specific risk assessment. This practice, often associated with the perception that higher levels of containment automatically imply greater safety, may result in the implementation of excessively complex systems, such as additional physical barriers, highly demanding sealing devices, or the indiscriminate use of higher-level personal protective equipment, such as powered air-purifying respirators

(PAPRs) or full-body protective suits, regardless of the nature of the biological agent, the procedures performed, the operational context, or the risk assessment conducted.

In many cases, this complexity leads users to develop adaptive or informal practices to circumvent requirements perceived as excessive, which may compromise the effectiveness of the originally proposed measures. Thus, although such approaches may be interpreted as conservative, their decontextualized adoption may generate significant adverse effects. Excessively complex systems tend to increase the likelihood of operational failures, require higher technical capacity for operation and maintenance, increase costs, and often hinder user adherence to established procedures. Similarly, the inappropriate use of protective equipment may compromise ergonomics, reduce operational efficiency, and induce compensatory behaviors, paradoxically resulting in reduced effective safety.

This scenario is often aggravated when there is no clear definition, from the early stages of design and conception, of the biological agents to be handled, the procedures to be performed, and the operational profile of the facility. The absence of structured risk assessment throughout the entire lifecycle—from conceptual design to operation—favors the adoption of standardized or oversized solutions, often disconnected from institutional reality, local conditions, and management and maintenance capacity.

In alignment with international recommendations, safety and biosecurity in biological containment environments should be guided by a risk-based approach, rather than by the indiscriminate elevation of containment levels or technical requirements. In this sense, excessive containment measures, when not technically justified, may be as problematic as insufficient ones, representing a misalignment between actual risk and institutional response, in addition to significantly impacting operational costs and the sustainability of the facility.

In light of this context, institutional response should include clear leadership, promotion of a reporting culture, systematic review of informal practices, and structured correction of deviations based on evidence and formalized processes. These actions should be supported by qualified biosafety and biosecurity professionals with competencies in biological risk assessment and management, selection, installation, and operation of biological safety cabinets, waste management, cyberbiosecurity, and implementation of biorisk management systems such as those aligned with ISO 35001:2019.

Additionally, the recognition and formal inclusion of biosafety and biosecurity professionals with dedicated and continuous roles within institutional structures becomes essential as a structural element for consolidating an organizational culture based on risk and responsibility.

Finally, the concept of safety culture in high-containment biological facilities should be understood in an expanded manner, incorporating not only safe laboratory practices but also the protection of knowledge generated within these environments. In this context, information security, protection of scientific data, and prevention of unauthorized access become integral components of contemporary biosafety, particularly in BSL-3 environments, where highly sensitive agents and information are handled.

12. Misuse of High-Containment (BSL-3) References for Activities Involving Genetically Modified Organisms (GMOs)

Currently, in Brazil, there is a relatively frequent observation of the inappropriate adoption of references typical of high-containment biological laboratories (BSL-3) in contexts that are not justified from a risk assessment perspective, often associated with projects involving non-pathogenic genetically modified organisms (GMOs). This practice, although often supported by a perceived increase in safety, reflects a misinterpretation of the relationship between containment requirements and the regulatory framework applicable to GMOs.

In light of Law No. 11.105/2005, the National Technical Commission on Biosafety (CTNBio) is responsible for risk assessment and for defining the biosafety conditions applicable to activities involving genetically modified organisms (GMOs) . However, it is essential to recognize that this regulatory framework is not intended for the governance of high-risk or high-consequence pathogens in a broader sense. The risk classification and containment requirements applicable to GMOs result from a specific analysis that considers characteristics such as the organism, vector, genetic insert, host, environment of use, and procedures involved, and are not directly equivalent to the laboratory containment levels traditionally established for pathogens.

In this regard, the use of the GMO regulatory framework as an indirect reference to justify containment requirements applicable to pathogens may contribute to the consolidation of misinterpretations, with impacts on facility design, laboratory practices, and governance mechanisms.

Thus, the direct transposition of BSL-3 laboratory requirements—traditionally designed for work with higher-risk biological agents and those with aerosol transmission potential—to activities involving non-pathogenic GMOs constitutes an approach that may not be technically proportional to the assessed risk from a risk management perspective. This practice disregards the fact that the risk associated with GMOs is of a different nature, often related to genetic stability, dissemination potential, interaction with the environment, and possible ecological impacts, and is not necessarily associated with pathogenicity or the ability to cause disease in humans or animals.

From an infrastructure perspective, environments intended for work with GMOs should be designed based on biosafety levels defined through risk assessments conducted at the institutional level and, when applicable, validated by CTNBio. This implies that containment requirements — including physical barriers, ventilation systems, access control, operational procedures, and use of personal protective equipment — must be proportional to the identified risk and not automatically derived from models conceived for high-consequence pathogens.

The indiscriminate adoption of typical BSL-3 elements, such as complex ventilation systems with cascading negative pressure, advanced sealing doors, multi-stage anterooms, or the systematic use of higher-level personal protective equipment, may result in operational burden, significant increases in implementation and maintenance costs, and the introduction of unnecessary complexity into the system.

In many cases, such measures not only fail to add proportional safety but may also compromise usability, reduce adherence to procedures, and negatively impact the operational sustainability of facilities intended for non-pathogenic GMOs.

Additionally, this approach may create a misalignment between the implemented infrastructure and the institutional capacity for operation and maintenance, particularly in contexts where there is no continuous and sustained availability of technical and financial resources compatible with the introduced complexity. As a consequence, progressive degradation of operational conditions may occur and, paradoxically, a reduction in the effective level of safety. In academic environments, this practice may also negatively impact the training of future professionals by perpetuating inappropriate practices, routines, and conceptual references.

It is important to emphasize that the international conceptual framework, consolidated in documents such as the WHO Laboratory Biosafety Manual (4th edition, 2020), reinforces the need to adopt a risk-based approach, in which containment measures are defined based on the specific characteristics of the activities performed, rather than by automatic association with predefined laboratory levels.

In this sense, the design of laboratory facilities—whether for GMOs or pathogens—should be guided by a structured and continuous risk assessment process, conducted from the early stages of design (conceptual and basic) and continuously updated throughout the entire lifecycle of the facility. This process must consider, in an integrated manner, the agents involved, experimental procedures, operational flows, user profiles, facility location, and institutional management capacity, among other relevant factors.

In summary, the use of BSL-3 references for activities involving non-pathogenic GMOs, without support from specific risk assessment, constitutes a technically inadequate and potentially counterproductive practice. Safety in laboratory environments should not be understood as the result of the indiscriminate adoption of maximum containment levels, but rather as the proportional alignment between risk and control measures, in accordance with the applicable regulatory framework, appropriate technical references, and international best practices.

13. Personnel Management and Institutional Lifecycle

The dynamics of training, mobility, and turnover characteristics of academic environments impose additional challenges for biosecurity. Changes in institutional affiliation, transitions between research groups, and internal reorganizations, when not accompanied by formal review of access, responsibilities, and custody of materials, may generate significant vulnerabilities.

In practice, these situations manifest through overlapping roles, maintenance of access after changes in function, and conflicts related to ownership of data and biological materials. Mitigating these vulnerabilities requires the implementation of formal onboarding and offboarding processes, periodic review of access and inventories, as well as formalization of procedures for closure or transfer of responsibilities.

Personnel management in high-containment biological environments should not be limited to administrative or academic affiliations. In alignment with international recommendations, such environments require structured processes for selection, training, competency assessment, individual authorization of access, progressive supervision, and periodic review of permissions. The absence of such mechanisms favors the adoption of

informal criteria based on trust, proximity, or operational convenience, replacing objective institutional parameters.

Additionally, the existence of prior academic relationships, intergroup collaborations, and indirect links between researchers may influence, in practice, dynamic access to laboratory environments. This context reinforces the need for formal institutional criteria to prevail over interpersonal relationships in access control, use of critical infrastructure, and handling of biological materials.

In this sense, personnel management in high-containment environments must be conducted based on technical, institutional, and ethical criteria, centered on qualification, competence, and professional responsibility. Approaches based on subjective assumptions or unstructured personal evaluation criteria are not appropriate for biological risk management and may compromise institutional trust, traceability of activities, and the effectiveness of governance systems.

The integration of these dimensions with formal biorisk management systems—such as those established in ISO 35001—contributes to the consolidation of structured, risk-based approaches, with clear definition of responsibilities, formal authorization criteria, and structured mechanisms for continuous monitoring, aligned with international best practices.

14. Biosafety and Biosecurity Professionals as a Structural Function

A structural element frequently absent in the Brazilian context — and recognized as a cornerstone in more mature biosafety and biosecurity systems — is the presence of professionals dedicated exclusively to this function at the institutional level. In countries such as the United States, Canada, and several European nations, the role of biosafety officers, biosafety professionals, or equivalent positions constitutes a central component of governance in laboratory environments, particularly those of higher complexity and risk.

These professionals should not be confused with laboratory coordinators, principal investigators, or members of institutional bodies such as Institutional Biosafety Committees (CIBios). Rather, they represent a specialized, continuous technical function, independent from the direct execution of research activities, with responsibilities including, among others, biological risk assessment, issuance of technical opinions, project oversight, verification of operational compliance, support in defining containment measures, team training, incident analysis, and interface with institutional and regulatory bodies.

In the Brazilian context, this function is not yet widely institutionalized. In many cases, responsibilities related to biosafety and biosecurity are fragmented among researchers, laboratory coordinators, CIBio members, and administrative structures, without the existence of a professional with exclusive dedication and clearly defined technical authority to act continuously in biological risk management.

This gap directly contributes to several of the vulnerabilities described in this Technical Note, including the absence of structured and continuous risk assessment, inconsistency in the application of technical criteria, limitations in operational oversight, normalization of informal practices, and difficulties in coordinated incident response.

Although there are relevant experiences in the country—such as those observed in institutions like the Oswaldo Cruz Foundation (Fiocruz), the Evandro Chagas Institute (IEC), units of the Ministry of Agriculture and Livestock (MAPA), including the Federal Agricultural Defense Laboratories (LFDAs), and some EMBRAPA units—these initiatives have not yet translated into a broad and consolidated institutional policy, nor into a regulatory requirement systematically applicable to all institutions operating high-containment biological environments.

The institutionalization of this function in Brazil represents a fundamental step toward strengthening biosafety and biosecurity and should be considered both in institutional organizational structures and in the development of regulatory frameworks and public policies. The presence of qualified professionals, with specific training and continuous engagement, contributes to the consolidation of risk-based practices, standardization of processes, and strengthening of institutional safety culture.

In this context, it becomes essential to advance in defining competencies, training, and certification of these professionals, as well as their formal inclusion in institutional organizational structures, with clearly defined roles, technical autonomy, and direct interface with strategic management levels.

The consolidation of this function in Brazil should not be understood as an ancillary measure, but as an essential component for the structural strengthening of biosafety and biosecurity, with direct impact on the effectiveness of institutional practices described throughout this Technical Note.

In this regard, it is recommended that future initiatives consider, in a structured manner, the definition of professional profiles, training and certification programs, as well as their progressive incorporation into institutional policies and national regulatory frameworks, aligned with international biorisk management standards such as ISO 35001.

15. CIBio Oversight and Reporting Mechanisms

Although Institutional Biosafety Committees (CIBios) play a central role in the Brazilian biosafety system, as established by Law No. 11.105/2005, their activities in academic contexts are predominantly oriented toward fulfilling formal requirements associated with activities involving genetically modified organisms (GMOs). In many cases, their constitution and operation are directly linked to specific projects and are often composed of faculty members and researchers involved in such activities.

In this scenario, it is observed that, in institutional practice, CIBios tend to be perceived predominantly as regulatory compliance bodies, with limited routine involvement in the continuous operational oversight of laboratory environments. As a consequence, aspects related to early identification of vulnerabilities, systematic supervision of practices, and preventive action regarding broader biological risks—particularly those not directly associated with GMOs—may not be fully incorporated into day-to-day institutional operations.

As a result of this framework, in a large proportion of Brazilian institutions—with rare exceptions—Institutional Biosafety Committees (CIBios) do not consistently perform, in a structured and systematic manner, functions related to biological risk assessment in the

storage and handling of pathogens not classified as GMOs, particularly those of higher risk or consequence. This functional limitation contributes to the existence of relevant gaps in biological risk governance, particularly in high-containment environments, where activities involving GMOs and non-GMOs may coexist, often under distinct regulatory regimes.

This dissociation between a formal biosafety structure focused on GMOs and the absence of equivalent mechanisms for the systematic assessment of risks associated with pathogens reinforces the need to review and expand the institutional scope of these committees or, alternatively, to establish complementary structures with clearly defined responsibilities.

This scenario may result in underreporting incidents, delayed institutional responses, and loss of opportunities for organizational learning. Additionally, the absence of active mechanisms for continuous oversight and verification may allow operational practices that diverge from established protocols to go undetected, limiting the preventive capacity of institutional biosafety and biosecurity structures.

In this context, strengthening CIBios should go beyond strict compliance with the provisions of Law No. 11.105/2005, incorporating a broader, more integrated, and proactive role. This includes prior analysis of projects and facilities, the conduct of internal audits, continuous monitoring of operational practices, and integration with institutional structures for management, governance, and compliance.

This expansion of scope should consider a comprehensive institutional biosafety approach, not limited to GMOs, but guided by biological risk assessment in a broader sense, including activities involving pathogens, biological materials, and laboratory facilities of greater complexity.

Overcoming this structural limitation is fundamental for consolidating more robust institutional biosafety and biosecurity systems, capable of integrating different dimensions of biological risk and promoting preventive, coordinated, and evidence-based action.

16. Information Security and Cyberbiosecurity

The protection of data associated with biological materials constitutes an increasingly relevant dimension of biosecurity, especially in environments dealing with agents of interest for public health, animal health, and strategic scientific research. Information such as sample inventories, stock locations, movement records, genetic sequences, experimental protocols, and project data represent sensitive assets, whose unauthorized access, use, or disclosure may generate scientific, institutional, and, in certain contexts, regional or international security implications.

In this scenario, cyberbiosecurity emerges as an essential component of biorisk governance, integrating information security practices with biosafety and biosecurity dimensions. However, in many institutions, this dimension is still treated in a fragmented or secondary manner, often dissociated from the management of biological materials themselves.

In practice, the use of local systems for data storage, broad sharing of information through uncontrolled platforms, and the absence of clear criteria for digital access

management are frequently observed. Inventories may be maintained in individual spreadsheets, shared files without version control, or systems lacking adequate mechanisms for authentication, authorization, and traceability.

This reality compromises the integrity, confidentiality, and availability of information, in addition to making it difficult to identify unauthorized access or changes.

Furthermore, the absence of reliable audit trials limits the institutional capacity to monitor, in a timely manner, who accessed, modified, or transferred specific information over time. In environments with intense collaboration between groups, multiple users, and data exchange across units, this gap significantly increases the risk of loss of control over critical information.

Another relevant aspect concerns the integration between information systems and laboratory practices. When there is no alignment between digital records and operational reality—for example, regarding the location of samples, individuals responsible for their custody, or their usage history—a disconnect is created that compromises both traceability and the reliability of institutional data.

Mitigating these vulnerabilities requires the implementation of robust institutional cyberbiosecurity policies, aligned with best practices in information security. This includes defining access levels based on user roles and operational need (principle of least privilege), use of multi-factor authentication, implementation of audit trails, document version control, and protection of sensitive data against unauthorized access.

It is equally essential to promote integration between information technology, biosafety, and risk management teams, ensuring that the protection of data associated with biological materials is addressed in a systemic manner, with appropriate identification and classification of assets to be protected. User training regarding appropriate system use, information classification, and risks associated with improper data sharing is also a fundamental component of this process.

It should also be emphasized that cyberbiosecurity should not be understood merely as an extension of traditional information security, but as a component intrinsically associated with the governance of biological materials. Effective protection of these assets increasingly depends on the institutional ability to integrate physical and digital controls, ensuring that the lifecycle of samples is supported by reliable, secure, and auditable information systems.

In this context, weaknesses in information security and cyberbiosecurity not only increase the risk of unauthorized access or loss of control over sensitive data, but also directly impact the institutional capacity to detect, understand, and respond to incidents involving biological materials. The absence of reliable records, audit trails, and integrated information systems compromises early detection of irregularities and limits the reconstruction of events, hindering decision-making.

Thus, cyberbiosecurity should be understood as an inseparable element of incident response systems in these facilities, constituting an essential foundation for the effectiveness of institutional incident response systems described in the following section.

17. Incident Response

The absence of clear, structured, and pre-established protocols for responding to biosecurity incidents in high-containment biological laboratories significantly compromises the institutional capacity for rapid, coordinated, and risk-proportionate action. In this context, situations such as loss, unauthorized removal, unauthorized movement, or inconsistencies in biological material inventories tend, in practice, to be handled reactively and often improvisationally, without defined communication flows, decision-making processes, or activation of responsible entities.

This scenario is particularly critical in academic environments, where the multiplicity of actors, overlapping responsibilities, lack of dedicated incident management structures, and the influence of interpersonal relationships—both academic and personal—may generate uncertainty regarding who should be notified, when, and under what criteria. As a result, delays in identifying and containing events, fragmentation of institutional actions, and difficulties in coordination across units and management levels are frequently observed.

Additionally, the absence of standardized procedures for recording and documenting incidents compromises the preservation of technical and administrative evidence, hindering both internal investigations and potential inquiries conducted by external authorities. The lack of reliable audit trails—including records of access, sample movement, and changes in inventories—limits the ability to reconstruct events and identify root causes.

Another relevant aspect concerns institutional communication. In the absence of clear guidelines, there is a risk of delayed, incomplete, or misaligned communication, both internally and with regulatory and public health authorities. This situation may result in increased institutional exposure, loss of narrative control, and reputational impacts disproportionate to the nature of the event.

Mitigating these vulnerabilities requires the implementation of specific institutional biosecurity incident response plans, integrated with risk and biorisk management systems. Such plans should include structured definitions of responsibilities, escalation levels, communication flows, incident classification criteria, and procedures for immediate containment. They should also incorporate mechanisms for preserving records and evidence, ensuring the integrity of information necessary for technical analysis and decision-making.

Additionally, it is recommended that these structures be periodically tested through simulation exercises (tabletop exercises and operational simulations), in order to evaluate their effectiveness and train involved teams. The institutionalization of post-incident review processes (after-action reviews) is an essential component for organizational learning, enabling the identification of systemic weaknesses and the implementation of continuous improvements.

Finally, biosecurity incident response should not be understood merely as a reactive mechanism, but as an integral part of a broader governance system. The institutional capacity to detect, respond, learn, and adapt from adverse events — with direct support from strategic management levels — constitutes one of the fundamental pillars for strengthening biosecurity in high-containment biological facilities.

18. Role of Funding Agencies and Promotion of Good Practices

Strengthening biosecurity in high-containment biological environments depends significantly on the enabling role played by public policies and funding agencies supporting research, development, and innovation. In the Brazilian context, the systematic incorporation of criteria related to biosafety, biosecurity, institutional governance of biological materials, and the operational capacity of high-containment facilities into project evaluation, support, and monitoring processes remains limited—and in many cases absent.

In areas of greater sensitivity—particularly those involving higher-risk or high-consequence biological agents, enabling technologies, viral vectors, recombinant systems, synthetic biology, advanced containment structures, as well as activities associated with dual-use research of concern (DURC) or gain-of-function experiments—it becomes desirable for public policies in science, technology, and innovation, as well as funding agencies themselves, to more explicitly incorporate requirements related to infrastructure, governance, personnel qualification, traceability, custody, and institutional oversight.

The incorporation of these criteria represents one of the most effective mechanisms for inducing structural change, contributing to the progressive alignment of institutional practices with biosafety and biosecurity requirements, as well as to the strengthening of a culture of responsible management, operation, and use of facilities and biological materials.

Additionally, including such requirements in project evaluation and monitoring processes may promote the adoption of risk-based approaches, fostering greater consistency in institutional decision-making and in the prioritization of investments in infrastructure and capacity building.

The consolidation of a national biosecurity system in high-containment biological environments will depend, to a large extent, on the articulation between institutional actors, regulators, and funding agencies, with clear definition of roles, responsibilities, and mechanisms for promoting good practices.

In this sense, strengthening biosecurity must be conducted based on evidence, proportionality, and technical criteria, avoiding approaches that, although motivated by legitimate concerns, are not supported by structured risk management models.

19. Final Considerations

The analysis presented in this Technical Note demonstrates that, in academic high-containment biological environments (BSL-3), the main vulnerabilities are not necessarily associated with physical infrastructure, but rather with the governance of biological materials throughout their entire lifecycle.

Issues related to access, authorization, record-keeping, responsibility, custody, and control of movement constitute central elements for the integrity of these systems. In this sense, it is possible for facilities to present a high level of biosafety while simultaneously maintaining significant gaps in biosecurity.

The absence of a structured and comprehensive national regulatory framework for high-containment biological environments increases institutional vulnerability, as it transfers

to local organizations and groups technical and managerial decisions that, in more mature systems, are guided by clear regulatory parameters, validated processes, and independent verification mechanisms. In many cases, these gaps are further aggravated by overlap or confusion with the regulatory framework applicable to genetically modified organisms (GMOs), as established under Law No. 11.105/2005.

In this context, it is particularly relevant to recognize that the Brazilian regulatory model, although robust with respect to GMOs, does not automatically translate into a comprehensive system for governance of biological risks related to higher-risk or high-consequence pathogens. Thus, it is reaffirmed that the existence of a Biosafety Quality Certificate (CQB) and Institutional Biosafety Committees (CIBios), although fundamental, does not in itself guarantee continuous, integrated, and contextualized evaluation of laboratory activities involving biological agents of different natures in BSL-3 environments.

In such environments, the false equivalence between formal compliance within the GMO regulatory system and sufficiency of governance for handling pathogens may produce an undue perception of compliance, even in the absence of effective mechanisms for operational evaluation, biosecurity, and continuous oversight compatible with the complexity of these facilities.

This finding reinforces the need for evolution of the Brazilian institutional framework, with greater integration between biosafety and biosecurity, as well as the incorporation of mechanisms that systematically address the full range of laboratory activities conducted in high-containment biological environments.

Recent events reported in the literature and media involving improper movement of biological materials in academic environments provide concrete evidence of the vulnerabilities described herein, demonstrating that such weaknesses are not merely theoretical, but manifest in practice in the absence of sufficiently structured institutional systems for control, traceability, and governance.

In summary, the Brazilian challenge is not limited to the absence of specific regulations for certain agents or technologies but rather lies more broadly in the lack of a sufficiently structured national system capable of governing, in an integrated manner, the lifecycle, operation, and oversight of high- and maximum-containment biological environments.

Strengthening biosecurity in the country therefore requires a robust and structured framework based on an integrated and institutional approach aligned with international best practices, incorporating normative, operational, and cultural dimensions.

In this context, it is emphasized that the central challenge of biosecurity in academic high-containment biological environments does not lie solely in controlling the agent within the physical space, but rather in ensuring institutional control over its custody, traceability, authorized use, governance, and movement throughout its entire lifecycle.

As a structural element for addressing the vulnerabilities described, the need to institutionalize, in Brazil, the role of biosafety and biosecurity professionals with dedicated, continuous, and technically qualified functions is highlighted. International experience demonstrates that the presence of such professionals—formally integrated into institutional

organizational structures, with clearly defined responsibilities and technical autonomy—constitutes one of the most relevant pillars for the effective implementation of biological risk management systems.

The absence of this function in a systematic and widespread manner in the country contributes to fragmentation of responsibilities, discontinuity in risk assessment, and limitations in operational oversight in the daily functioning of facilities. Thus, strengthening biosafety and biosecurity in Brazil necessarily involves consolidating this professional profile, including the definition of competencies, expansion of training and certification programs, and its formal incorporation into institutional structures, particularly in high- and maximum-containment environments.

It is important to emphasize that this function does not replace, but rather complements and strengthens the role of CIBios, institutional management structures, and responsible researchers, contributing to greater robustness, consistency, and sustainability of biological material governance systems in the country.

Finally, the increasing digitalization of science and the integration of laboratory systems with information networks expand exposure to cyber threats, including ransomware attacks, data theft, and unauthorized access to sensitive information. In this context, cyberbiosecurity is consolidated as a critical dimension of biorisk management, requiring integration between biosafety, information security, and strategic intelligence. National initiatives aimed at protecting sensitive knowledge reinforce this trend, highlighting the need for integrated approaches to safeguard scientific and technological assets.

This Technical Note should be understood as a technical support instrument for decision-making, public policy formulation, and institutional strengthening, and does not constitute a mechanism for evaluation, certification, or judgment of compliance of specific facilities or institutions.

20. SB3 Recommendations for Strengthening Biosecurity in High-Containment Biological Environments

In light of the structural vulnerabilities and challenges presented throughout this Technical Note, the Brazilian Society for Biosafety and Biosecurity (SB3) presents, in a concise manner, priority recommendations for strengthening biosecurity in academic high-containment biological environments in Brazil:

i. Development of a specific national regulatory framework for high-containment biological environments, encompassing guidelines for conception, design, commissioning, qualification, operation, maintenance, requalification, and decommissioning, based on a risk-based approach.

ii. Institutionalization of the role of biosafety and biosecurity professionals, with dedicated, continuous, and technically qualified functions, formally integrated into institutional organizational structures, with clearly defined responsibilities and technical autonomy.

iii. Strengthening and expansion of the scope of CIBios to incorporate, beyond activities involving GMOs, systematic biological risk assessment associated with the storage, handling, and use of pathogens, particularly in higher-containment environments.

iv. Implementation of integrated institutional systems for inventory and traceability of biological materials, including chain-of-custody records, audit trails, periodic independent audits, and formal physical-document reconciliation processes.

v. Establishment of clear institutional policies on ownership, custody, and movement of biological materials, including formal rules for internal and external transfers, aligned with instruments such as cooperation agreements, co-ownership contracts, and Material Transfer Agreements (MTAs).

vi. Development and implementation of structured biosecurity incident response plans, including definition of responsibilities, escalation levels, communication flows, mechanisms for preservation of evidence, and periodic simulation exercises.

vii. Effective integration between biosafety and biosecurity within institutional risk assessment processes, including consideration of misuse scenarios, adoption of risk-based approaches, and incorporation of principles related to dual-use research, with particular attention to activities involving recombinant technologies applied to higher-risk or high-consequence pathogens.

viii. Incorporation of biosafety, biosecurity, and institutional governance criteria by funding agencies as mechanisms to promote good practices, including specific requirements for the evaluation of projects involving advanced technologies—such as recombinant systems, viral vectors, and other approaches with dual-use potential—particularly when associated with higher-risk biological agents.

ix. Strengthening of information security and cyberbiosecurity, including implementation of access controls based on roles and necessity, robust authentication mechanisms, audit trails, and protection of sensitive data associated with biological materials.

x. Promotion of an institutional culture based on risk, responsibility, and compliance, with emphasis on continuous training, encouragement of incident reporting, systematic review of operational practices, and consolidation of safety-oriented organizational environments.

xi. Development of coordinated national mechanisms for evaluation and oversight of activities involving recombinant technologies applied to higher-risk or high-consequence pathogens, integrating biological risk assessment, biosafety, biosecurity, dual-use considerations, and institutional governance, in alignment with international frameworks.

The Brazilian Society for Biosafety and Biosecurity (SB3) understands that the progressive implementation of these recommendations will contribute to strengthening institutional governance, reducing vulnerabilities, and aligning Brazil with international best practices in biosafety and biosecurity.

In this regard, SB3 stands ready to provide technical support for advancing this agenda in the country, supporting initiatives aimed at developing normative frameworks, qualifying institutional practices, and strengthening governance systems in biosafety and biosecurity.

Technical References and Recommended Readings

This Technical Note is aligned with internationally recognized technical and normative references, as well as national programs and institutional systems consolidated in different countries, which guide the structuring of biosafety and biosecurity systems based on risk assessment, institutional governance, and scientific responsibility.

Key references for further study include:

World Health Organization (WHO)

• WHO Laboratory Biosafety Manual (LBM), 4th edition, 2020

• WHO Global Guidance Framework for the Responsible Use of the Life Sciences, 2022

• WHO Laboratory Biosecurity Guidance, 2024

Standards and Management Systems

• ISO 35001:2019 — Biorisk Management for Laboratories and Other Related Organizations

• ISO 19011:2018 — Guidelines for Auditing Management Systems

• ISO 31000:2018 — Risk Management Guidelines

Technical and Academic Publications

• Essentials of Biological Security: A Global Perspective (Lijun et al., Wiley, 2024)

International Guidelines and Initiatives

• Tianjin Biosecurity Guidelines for Codes of Conduct for Scientists, 2021

• International Health Regulations (IHR, 2005) — World Health Organization

• Biological Weapons Convention (BWC)

These references reinforce the need to adopt risk-based approaches, integrate biosafety and biosecurity, strengthen institutional governance, and promote an organizational culture oriented toward responsibility in the life sciences.

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