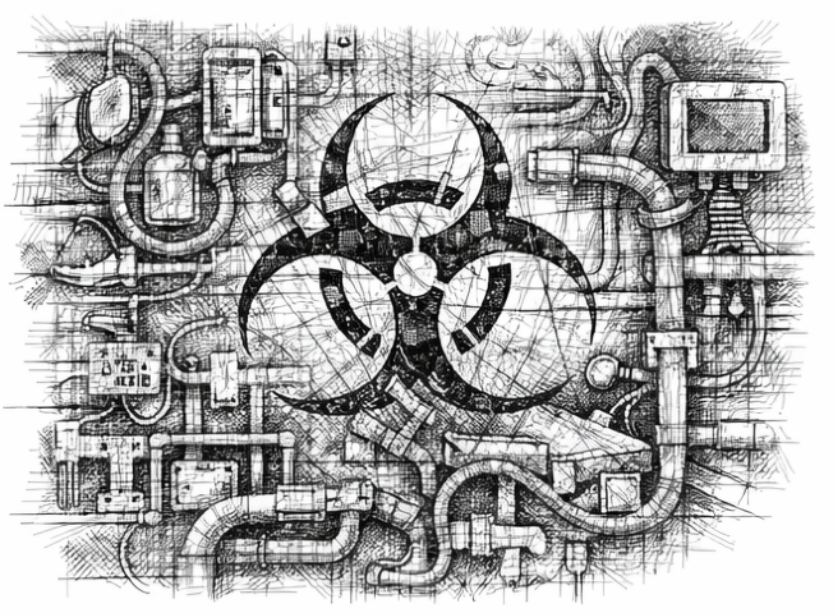

White Paper on Repositioning Biosafety From a Compliance Burden to National Strategic Infrastructure

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Conflict of interest
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Foreword

Biosafety is an integral part of the life sciences enterprise, ensuring research with biological materials can proceed safely while protecting workers, institutions, and the public. Yet its role is often misunderstood. It is frequently treated as an overly burdensome compliance requirement, rather than as a system that actively manages risk, supports scientific progress, and underpins public trust in science. This white paper draws on empirical research, including national surveys, interviews, multistakeholder workshops, and conversations among biosafety professionals, compliance staff, and researchers to examine how biosafety functions in practice and where gaps exist among policy, implementation, and perception.

Across these efforts, a consistent picture emerges. The United States has one of the most sophisticated biosafety and biosecurity policy frameworks, yet implementation is fragmented, uneven, and highly dependent on institutional resources and expertise. Biosafety professionals operate at the intersection of science, policy, and institutional priorities, translating broad and evolving guidance into real-world decisions. However, biosafety professionals are often engaged too late in the policymaking processes and positioned without the authority or structure needed to act decisively. This failure creates a system in which decisions are shaped as much by defensibility and interpretation as by actual risk.

This white paper argues that the core challenge for effective US biosafety is not a lack of expertise or commitment, but a mismatch of biosafety structure and outcome expectations. Addressing this problem requires repositioning biosafety from being seen as solely a compliance burden to a form of national strategic infrastructure embedded early in research and policy decisions. Doing so will strengthen risk management, reduce delays and inefficiencies, and better align the system with the realities of modern biological research.

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I. The Current State of Institutional Biosafety

Biosafety is the application of practices, controls, and containment infrastructure to reduce the risk of *unintentional* exposure to, contamination with, release of, or harm from pathogens, toxins, and other associated biological materials.[1] Biosafety is a critical system supporting the safe and secure conduct of modern biological science. It enables work with biological materials while protecting scientists, laboratory personnel, the public, and the environment. Biosafety also supports national preparedness and underwrites public trust in the life sciences, yet it remains largely out of view and is often misunderstood, undervalued, and structurally constrained.[2]

This white paper draws on a multisite effort of NIH-funded research (NIGMS Award #1R01GM155913), which included a national survey of biosafety professionals,[3,4] practitioner workshops,[5] political analysis and commentary,[6-8] policy discussions in Washington, DC,[9,10] and a dialogue among biosafety professionals from diverse US institutions, held at Arizona State University (ASU). Across these engagements, participants described a system that works, but not as effectively as it could. The United States maintains one of the most developed biosafety and biosecurity systems globally, with multiple layers of policy, oversight, and institutional implementation.[11] The core issue is not a lack of expertise, effort, or commitment. Instead, it is a mismatch between how biosafety functions and how it is understood, governed, and positioned.

At the center of that mismatch is a clear problem: biosafety is often treated solely as a compliance function in a system that requires it to also operate strategically. In practice, biosafety professionals are asked to interpret policies that are often unclear, sometimes contradictory, continuously changing, and inconsistently applied. Most institutions make decisions in good faith, drawing on local expertise and available guidance, but without early input from biosafety professionals, those decisions are later judged against stricter or shifting standards.

The problem lies in rules that are unstable, overly broad, and ambiguous, leaving room for wide interpretation and inconsistent application across institutions. Within this environment, behavior shifts from *managing risk* to *demonstrating compliance*. As a result, scientific work is translated into categories that align with institutional priorities or policy frameworks, even when those frameworks fail to capture

actual risks. Decision making is shaped less by conditions on the ground and more by the need to justify choices within an uncertain policy and regulatory landscape.

A shift toward compliance-driven decision making and inconsistent interpretation is reinforced by how authority is distributed. Biosafety officers, institutional biosafety committee (IBC) members, compliance staff, and local experts understand the details that matter, including the organisms, materials, techniques, facilities, and personnel involved. Yet decision-making authority increasingly sits with external actors. Federal policy officials define which activities require oversight and set expectations across institutions, while regulators enforce those expectations through compliance and oversight. Both groups operate at a distance from day-to-day research and rely on standardized reports and checklists, which often miss how protocols are carried out in practice, where workarounds occur, and what constraints laboratory personnel face. As a result, calls to improve "safety culture" remain abstract and rarely translate into concrete changes at the bench.

Some research is reviewed by federal advisory committees, designated review panels, Select Agent Programs administered by the Centers for Disease Control and Prevention (CDC) and the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA APHIS), regulatory inspectors, and oversight bodies such as the National Institutes of Health Office of Science Policy (NIH OSP) and institutional committees, including IBCs and Institutional Animal Care and Use Committees (IACUCs). These groups assess proposals, facilities, or categories of work based on submitted materials, inspections, or compliance documentation, rather than direct involvement in the research. As a result, evaluations rely on generalized information that does not fully reflect how the work is conducted in practice. This structure creates overlap across oversight processes. The same research may be reviewed under multiple frameworks, introducing delays, conflicting decisions across oversight bodies, repeated reassessments, and requirements that are not mutually compatible, without clear evidence of improved safety. Oversight operates in parallel layers in which local expertise and external authority do not consistently rely on the same understanding of the work.

Organizations prioritize research productivity, funding, and reputation, while biosafety efforts are harder to measure and reward because success is defined by the absence of accidents. In this setting,

biosafety competes with priorities that are more visible and easier to quantify, and is often treated as secondary, even when it is essential for safe and sustained research. Reputational risk further shapes decision making. Institutions manage not only scientific risk, but also the risk of public scrutiny, funding loss, and political attention. These pressures can discourage transparency, leading researchers to withhold information or delay engagement with biosafety rather than raise concerns early.

Instead of focusing on which biosafety measures fit actual conditions, decisions shift toward what can be defended under review. This shifts the standard from managing acceptable risk to an implicit expectation of zero risk, even though zero risk is not mathematically or experimentally attainable in biological research. This shift leads to more conservative or rigid approaches that do not improve safety or security and may prevent important research.

Biosafety succeeds by preventing failure. When it works, serious harm is avoided, and when problems occur, mitigation limits impact. The absence of incidents is difficult to measure because institutions cannot track what did not happen. Similarly, recorded events do not reflect actual risk. Reporting systems capture incidents and accidents but do not show whether harm occurred or how risk was managed. These systems record events, not outcomes. Near misses and changes in practice are often not captured. Effective oversight requires continuous adjustment of practices and mitigation measures as techniques, organisms, materials, and research environments change, even when those changes are not reflected in incident or accident data.

External institutions and public perception add a distinct layer of complexity. Public narratives around biosafety are dominated by risk (often not understood in a quantitative or biosafety-specific sense), secrecy or obfuscation, and failure (Table 1). Laboratories are often seen as dangerous. Information is perceived as hidden or manipulated. Problems are thought to surface only after the fact. These narratives are not baseless, but they are incomplete. They leave out the day-to-day reality of biosafety practice, which is grounded in prevention, oversight, and risk management. The biosafety community has not consistently defined its own role in this space. Communication by institutions, federal agencies, and researchers is often reactive, and engagement with external stakeholders is shaped by

political and reputational incentives rather than sustained understanding. Participants in the ASU dialogue described how narrative, power, and influence shape how biosafety is communicated and interpreted.

A related constraint is psychological safety for biosafety professionals, defined here as the ability to raise concerns, question decisions, and share uncertainty without fear of professional or reputational consequences. Biosafety participants in the ASU dialogue described environments in which these actions can carry professional risk, including damage to institutional relationships, loss of influence in decision making, or being seen as obstructive. In these settings, the underlying concern does not change, but how it is communicated does. Signals of potential risk or uncertainty may be softened, delayed, or withheld entirely. This does not reflect a lack of expertise, awareness, or ethical commitment among biosafety professionals. It reflects the conditions under which these professionals are expected to operate. When psychological safety is low, individuals are less likely to raise concerns or sound alarm bells, leaving the system unable to fully see or act on what practitioners already know. Over time, this creates a feedback loop in which concerns are raised but not addressed, trust in biosafety weakens, and both biosafety professionals and researchers disengage from reporting or escalating issues.

Participants in the ASU dialogue identified a consistent gap between policy design and real-world biosafety practice. Policies are written at a level of abstraction that does not fully capture real-world research conditions, while practice requires interpretation and adaptation. This gap is a defining feature of the system. Treating biosafety as compliance rather than as a strategic function drives many of the issues described in this report (Table 2). Participants emphasized that these challenges do not stem from individual failures but from system design that produces misalignment and confusion, even when individuals act in good faith.

II. Structure Drives Outcomes

Throughout the discussions at ASU, one theme came up repeatedly: structure is a primary constraint on how biosafety operates in practice. Culture and structure are mutually reinforcing, but participants emphasized that structure sets the conditions under which culture is expressed. Institutional reporting

lines determine whether biosafety has access to leadership and resources. Authority determines whether input can shape decisions, and resources determine whether expectations can be met.

Influence is not determined by structure alone. In some settings, biosafety professionals without formal authority are still sought out for their expertise. When biosafety is viewed as credible, practical, and aligned with institutional goals, these professionals shape decisions through relationships and trust. However, without structural alignment, this influence is uneven and difficult to sustain across an organization. Participants noted that calling for cultural change is easier than changing reporting lines, authority, and access, even though these structural factors determine outcomes.

Fragmentation of institutional oversight further constrains biosafety practice. Oversight responsibilities are distributed across agencies, institutions, and laboratories without a unifying framework that defines authority, scope, or decision rights. This produces redundancy and gaps: the same work may be reviewed multiple times under different assumptions, approved in one instance and later rejected as interpretations shift, while other activities proceed without clear ownership. Coordination mechanisms can reduce duplication but do not resolve the underlying problem. Without alignment between responsibility and authority and a shared model of risk, fragmentation produces inconsistency, inefficiency, and points of failure that become visible only after an incident or accident, including expected events that are not attributable to biosafety performance.

Much of the biosafety system is oriented around discrete moments: approval, inspections, compliance checks, and incident response. However, significant risks often emerge during ongoing work between formal checkpoints. During this period, experiments are adjusted, scaled, or repeated; personnel rotate; and materials, techniques, and equipment change within the scope of the approved protocol. These routine changes can alter how risk is experienced at the bench and diverge from the assumptions underlying the original approval. In many settings, mechanisms to verify continued alignment with approved protocols or downstream requirements, such as material handling or disposition, are limited. The period of ongoing work between formal oversight checkpoints is the least structured part of the biosafety system and exposes gaps in how oversight functions (Table 3).

The current oversight structure assumes that risk can be defined at discrete decision points, such as initial approval or periodic review. In practice, risk changes as work evolves, scales, and is modified. Oversight models based on one-time classification or episodic review do not match these conditions. A lifecycle-based approach treats oversight as ongoing, with reassessment at key transition points, so responsibility evolves alongside the work rather than ending at initial approval.

III. Biosafety as a System of Distributed Judgment

Biosafety is often framed as a technical or regulatory function, but in practice it operates as a socio-technical system shaped as much by institutions, incentives, interpretation, and professional judgment as by formal rules. These systems depend on how governance is interpreted, negotiated, and enacted in real-world settings. Biosafety is continuously constructed through interactions between practitioners, scientists, institutional leadership, regulatory frameworks and the public. The challenges identified throughout this project reflect a broader misalignment between how biosafety is formally understood and how it actually operates on the ground.[12,13]

A central feature of this system is the localization of knowledge. Biological risk is not a fixed property that can be fully specified in policy language. Instead, it is understood through specific organisms, experimental methods, facilities, and personnel as part of a risk assessment. Biosafety professionals operate within this localized space, applying judgment that integrates formal guidance with expertise and practical experience. As decisions move upward into more centralized systems, locally grounded knowledge must be translated into standardized categories for review and governance. This translation is necessary, but the process is not neutral. It simplifies complexity and can distort how risk is represented. What counts as risk depends on where evaluation occurs, who is making the assessment, and the institutional or regulatory setting in which those decisions are made. Policy operates at a high level of abstraction, while biosafety operates in applied, on-the-ground conditions.

This translation between locally grounded knowledge and centralized policy frameworks reflects what can be understood as boundary work.[14] Biosafety must constantly negotiate its position among and relationship with science, policy, and public perception. These boundaries are shaped by institutional

priorities, political pressures, evolving public narratives, and funding priorities. In practice, biosafety professionals function as regulatory intermediaries, or what Heimer (2013) describes as "regulatory wranglers," aligning scientific work with changing policy expectations while maintaining operational feasibility.[15] The challenges described in this report are most visible in settings where local expertise, policy requirements, and institutional priorities intersect.

Biosafety becomes most visible through moments of intervention, such as raising concerns; stopping, slowing, or modifying work; or introducing additional requirements. In most cases, biosafety professionals enable research by identifying how work can proceed safely. However, when risk cannot be adequately mitigated, work should not proceed. These decisions are often perceived as overbearing or obstructive, rather than as part of managing risk in practice. As a result, biosafety is most visible when incidents and accidents occur. Oversight intensifies in response to these events, while the conditions that prevent them receive less attention.

IV. Recommendations

Addressing these issues requires structural changes and better integration of biosafety into research and governance (Table 4). Biosafety should be embedded in institutional practice and aligned with institutional priorities, rather than treated as a separate or compliance-driven function.

First, biosafety professionals must be engaged earlier in policymaking and governance, including during agenda-setting, drafting, and interagency review, rather than after policies are finalized and implemented. This engagement should occur without pre-determined outcomes and with clear goals and expectations. When biosafety is involved at the design stage, it can shape research to reduce risk without slowing progress. When brought in late, biosafety is forced into a reactive role, intervening after decisions are set and contributing to delays and friction. Early engagement positions biosafety as a strategic partner in risk assessment and research design. In many settings, decisions are driven by defensibility rather than alignment with actual risk, thereby limiting the use of expert judgment in practice. This includes recognizing that while biosafety enables research, it must also be empowered to halt work when risks

cannot be responsibly managed. This shift requires evaluating decisions based on risk rather than defensibility.

Second, biosafety should be understood as a practice that supports national research infrastructure rather than simply an administrative function (Table 5).[16] Biosafety maintains continuity and reduces the risk of disruption, though many researchers experience it as restrictive in practice. Like cybersecurity or financial controls, biosafety enables high-consequence research to proceed safely and reliably. When treated as compliance, biosafety is judged by adherence to rules; when treated as infrastructure, evaluation focuses on preventing disruption, supporting research, and managing risk across the life cycle of the work.

The need to rely on local judgment within rule-based systems reflects what Gillum (2025) describes as the Compliance–Discretion Paradox (Figure 1).[2] Participants in the ASU dialogue described working within policies that are ambiguous, changing, and unevenly applied, requiring real-time judgment while remaining accountable to standards often applied retrospectively. Decisions are shaped not only by technical risk but by how those decisions will be evaluated under external review. As a result, practitioners must translate local knowledge into forms that align with policy frameworks, which can shift how risk is defined, work is categorized, and decisions are justified. As long as biosafety is structured primarily as a compliance function, this gap will persist. Addressing it requires recognizing discretion as a core feature of risk management and aligning governance structures to support its use. Without this alignment, operational friction persists.

Third, communication is central to this shift. Biosafety depends on the ability to translate complex technical work into clear, actionable information for different audiences. This includes defining a small set of core messages, grounding them in real examples, and adapting them for leadership, policymakers, and the public. This includes one-page risk summaries for leadership, pre-developed incident communication templates, short narratives that make prevention visible by showing what was avoided, and plain-language materials that explain how risks are assessed and managed for the public. Without this translation, decisions are made without the benefit of biosafety expertise, or based on mischaracterized or exaggerated risk.

Fourth, engagement with policymakers must improve. Biosafety professionals are often affected by policy but are not positioned to shape policy design, creating a persistent gap between how policies are written and how they function in practice. Bridging this gap requires structured involvement of practitioners throughout policy design, testing, and iteration. Practical approaches include pilot implementations, early-stage feedback loops, and mechanisms to evaluate policy performance during ongoing work. Without these mechanisms, policies will remain disconnected from practice.

Fifth, organizational design determines how biosafety operates. Reporting lines, decision authority, and resource allocation define whether biosafety engages early, influences decisions, and functions effectively. Biosafety professionals need clear authority to shape decisions and act on risk, with sufficient independence from competing institutional pressures. Organizations must also ensure that concerns can be raised without professional or reputational risk, allowing information to move across teams.

At the operational level, there is a need for practical, shareable outputs that translate biosafety into usable forms. ASU meeting participants emphasized the value of concise, actionable formats that can be used across institutions. Examples include:

- One-page risk summaries for leadership
- Standard templates for incident and near-miss communication
- Short, narrative case examples showing risks identified and avoided
- Scripts for engaging researchers early in project design
- Brief translation tools that connect biosafety to policy and institutional priorities
- External communications that highlight the role of biosafety in enabling cutting-edge research
- Site visits to high- and maximum-containment and other complex research laboratories (e.g., public health, animal, or containment facilities)

These outputs improve internal consistency and decision making while making biosafety clearer externally. Without them, biosafety remains abstract and poorly understood.

Gillum (2025) describes Regulatory-Implementation Friction (Figure 2) as gaps between policy design and real-world conditions that introduce delay, reinterpretation, and inefficiency without

improving safety.[2] Participants described this as repetitive reviews, shifting expectations, and the need to reframe work to meet evolving or inconsistent standards. These effects stem from fragmented authority, policy ambiguity, and reliance on discretion within a compliance-driven system. This shifts time and attention away from managing risk and toward navigating the system.

V. Conclusion

Strengthening biosafety as a field requires addressing gaps in training, professional identity, and knowledge sharing. Training is inconsistent, and much of the expertise that defines practice remains localized and informal. Expanding structured mechanisms such as case studies, peer exchange, and professional networks would improve consistency and strengthen the field. These efforts require sustained funding, support for professional development, and environments in which practitioners can raise concerns and share information without professional or reputational risk.

Participants in the ASU dialogue identified gaps between policy and implementation, limits on authority, and conditions that restrict the use of expertise. The goal is not to reduce oversight, but to make it function more effectively.

Biosafety already enables research and accounts for risks to public health and society. The problem is in how biosafety is structured: authority, responsibility, and knowledge are not aligned. Addressing this requires positioning biosafety as a core function, aligning decision-making authority with expertise, and supporting judgment in practice. For policymakers, this means funding biosafety capacity, requiring institutional structures that give biosafety authority in decision making, and aligning oversight expectations with how risk is managed in practice. Without these changes, delays, inconsistency, and workarounds will persist.

Table 1. Perception vs. Reality in Biosafety

Common Perception	Operational Reality	Consequence
Biosafety is bureaucratic	Biosafety translates policy into workable, risk-based practice	Effort is misunderstood and undervalued
Biosafety slows research	Early biosafety involvement prevents delays later	Late engagement creates the delays attributed to biosafety
Labs are inherently dangerous	Risk is actively managed through layered controls	Public perception is shaped by worst-case scenarios rather than routine practice
Regulatory oversight ensures safety and mitigates risk	Most risk emerges during ongoing work, not review points	Oversight focuses on approval and incidents rather than ongoing work
Transparency equals trust	Formal transparency mechanisms exist (e.g., IBC public members, NIH Office of Science Policy oversight), but they do not on their own build trust	Transparency alone does not address underlying trust gaps
Decisions are based on risk	Decisions are often optimized for defensibility under review	Risk management is displaced by compliance-driven decision making

Table 2. Summary of Core Findings, System Dynamics, and Implications

Theme	What's Happening	Why It Matters	System Impact
Policy Ambiguity	Rules are unclear, change over time, and are reinterpreted after decisions are made	Institutions optimize for defensibility rather than risk mitigation	Compliance replaces expertise; science is shaped to fit policy categories rather than actual risk
Science vs. Top-Down Regulation	Local experts understand risk, but decision authority is centralized	Decisions are made far from the work	Duplication, delays, and limited evidence of improved safety
Power and Incentives	Safety does not generate revenue and competes with institutional priorities	Decisions are shaped by reputation, funding, and internal incentives	Biosafety is present but not empowered; influence is inconsistent
Invisible Work	Success is defined by the absence of incidents; prevention is not measured	Value is difficult to demonstrate to leadership and funders	Biosafety is perceived as bureaucratic rather than enabling
Trust and Narrative Gaps	Public narratives emphasize danger and secrecy; communication is reactive	External actors define biosafety's role	Trust is uneven, transactional, and easily disrupted
Organizational Structure vs. Culture	Organizations emphasize culture, but structure determines outcomes	Authority, resources, and reporting lines shape behavior	Cultural initiatives fail without structural alignment
Fragmentation	Oversight is distributed across institutions, agencies, and domains without coordination	No shared framework for authority, responsibility, or learning	Redundancy, gaps, and inconsistent expectations; limited system-wide learning
Decision Distortion (Defensibility vs. Risk)	Decisions are optimized to withstand scrutiny rather than reflect actual risk	Focus shifts from risk management to defensibility	Conservative, rigid decisions that do not improve real-world safety
Outlier-Driven Policy	Rare or extreme incidents disproportionately shape policy design	Policies are built for edge cases rather than routine practice	Overcorrection, added burden, and limited improvement in everyday safety

Table 3. Where the System Breaks: From Knowledge to Decision

Stage in Workflow	What Actually Happens	Breakdown Point	Resulting Outcome
Policy Interpretation	Institutions interpret guidance using local expertise and context	Policies are ambiguous, incomplete, or change over time	The same rule is applied differently across institutions
Local Risk Assessment	Biosafety officers and IBCs assess real-world risk (organism, method, setting)	Local judgment is not trusted by external reviewers	Practical risk assessments are discounted
Upward Translation	Local decisions are translated into standardized categories for external review	Translation removes context and nuance	The meaning of "risk" changes as it moves upward
Central Review	External reviewers apply standardized or categorical criteria	Limited visibility into actual lab conditions	Decisions reflect definitions rather than practice
Communication and Reporting	Information is shared through formal reporting channels; informal discussions remain internal	Signals are diluted, buried in volume, or shaped by fear of misinterpretation	Important risks are under-communicated
Decision and Action	Requirements or mitigation steps are imposed	Actions focus on documentation rather than operational changes	Compliance changes, but lab practice does not
Post-Decision Learning	Insights emerge during ongoing work	No mechanism to feed learning back into oversight	Knowledge remains local; the system does not adapt
After Incident (if it occurs)	The system responds strongly and visibly	Learning is triggered only after serious failures; limited mechanisms exist for shared learning	Reactive correction rather than proactive prevention

Table 4. Consequences of Misalignment: What the Current System Produces

System Dynamic	What It Looks Like in Practice	Immediate Effect	Downstream Operational Impact	Long-Term System Consequence
Policy Ambiguity	Institutions interpret unclear or evolving guidance using local judgment; decisions are later reinterpreted under stricter standards	Rework, delays, and inconsistent decisions across institutions	Time diverted to justification and documentation rather than risk assessment	Erosion of trust in policy; shift toward defensibility over expertise
Decision Distortion (Defensibility vs. Risk)	Decisions are optimized to withstand audit, criticism, or external review, rather than reflect actual conditions	Overly conservative or rigid controls; reduced use of expert judgment	Slowed research timelines and unnecessary constraints on low-risk work	Reduced alignment between policy and real-world risk; diminished effectiveness of oversight
Outlier-Driven Policy	Rare or extreme incidents are used to justify broad rules applied throughout routine work	Expansion of requirements across typical research activities	Increased administrative burden without corresponding risk reduction	Systems designed around edge cases; inefficiency becomes normalized
Fragmentation	Oversight is distributed across institutions, agencies, and domains with limited coordination	Redundant reviews, gaps in responsibility, and inconsistent expectations	Biosafety professionals spend time navigating oversight, rather than managing risk	Limited system-wide learning; persistent misalignment across domains
Invisible Work	Prevention efforts (early interventions, risk mitigation, avoided incidents) are not tracked or communicated	Value of biosafety is not visible to leadership or policymakers	Under-recognition in decision making, resourcing, and prioritization	Chronic underinvestment; biosafety remains positioned as administrative rather than strategic
Low Psychological Safety	Concerns are filtered, softened, or withheld due to fear of professional or reputational consequences	Loss or delay of critical information; incomplete communication	Risks are not fully surfaced or addressed during ongoing work	Reduced ability to detect and respond to emerging issues; reactive response patterns
Translation Loss (Local to Central)	Context-rich local knowledge is translated into standardized categories for review	Loss of nuance and misinterpretation of conditions	Decisions reflect definitions rather than actual practice	Persistent disconnect between policy intent and operational reality
Reputational Risk Pressure	Decisions are shaped by concern over public perception, funding, or political attention	Risk-averse or overly cautious decisions	Prioritization of optics over operational effectiveness	Institutional behavior driven by perception management rather than safety outcomes

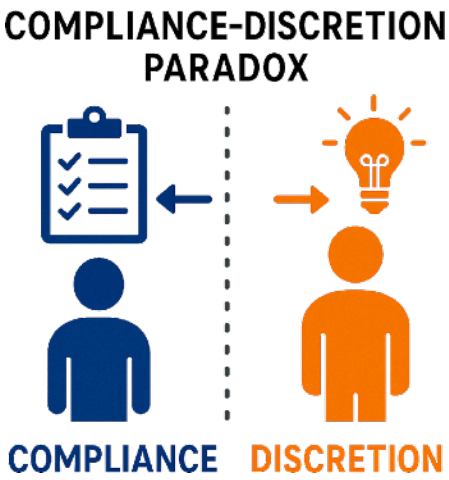
Table 5. From Current State to Strategic Shift

Current State	Desired Shift	What Changes
Compliance function	Strategic function	Biosafety shapes decisions early rather than after the fact
Cost center	Risk prevention system	Value is framed in terms of continuity, trust, and avoided disruption
Reactive communication	Proactive narrative	Biosafety defines its role, rather than responding to external pressure
Late engagement	Early integration	Risk is addressed at the design stage, reducing delays and identifying higher-risk work earlier
Advisory role	Empowered role	Authority is aligned with expertise in decision making
Fragmented system	Coordinated system	Alignment improves across institutions and policy levels

Figure 1. Compliance-Discretion Paradox*

The Compliance-Discretion Paradox is the tension between the need to follow strict requirements (compliance) and the need for expert judgment and flexibility (discretion) in real-world work.

Compliance	Discretion
Top-down rules (e.g., Dual Use Research of Concern, Pathogen with Enhanced Pandemic Potential, Federal Select Agent Program)	Practitioner judgment in complex situations
Promotes standardization and accountability	Adapts to local context, novel risks
Reduces legal liability	Relies on tacit knowledge and lived experience
Can limit innovation and overburden staff	Can appear inconsistent or under-regulated



* Adapted from David R. Gillum, *The Role of Biosafety Professionals in Biotechnology Governance: Assessing Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (PhD dissertation, Arizona State University, 2025).

Figure 2. Regulatory-Implementation Friction*

Regulatory-Implementation Friction describes how overlapping, ambiguous, and poorly coordinated policies slow implementation, complicate interpretation, and can increase risk rather than reduce it.

Dimension	Description	Observation	Implications	Potential Response
Overlapping policies	Multiple agencies issue rules without coordination	DURC, PEPP, and FSAP policies apply differently across institutions	Confusion, duplicated reporting, policy fatigue	Streamlined, centralized guidance with interagency alignment
Ambiguous Definitions	Key terms lack shared meanings	For example, "reasonably anticipated," "significant threat"	Inconsistent implementation, discretionary overload	Clearer, shared definitions with case examples
Sectoral Variability	Different institutions have different levels of capacity	Government labs vs. academia vs. industry	Unequal compliance burden: some institutions not regulated	Tiered oversight based on institutional capacity
Tacit Knowledge Gaps	Biosafety professionals rely on informal expertise, not formal support	Decisions based on experience, not policy	Risk of unsafe or uneven decisions	National training standards; preserve institutional memory
Reactive Policy Design	Rules often written in response to crises; not proactive	For example, 2014 Gain of Function (GOF) pause, COVID-19-related changes	Policy lags behind innovation; fosters distrust	Anticipatory governance with practitioner input
Implementation Blind Spots	Focus on what should be done, not how it's carried out on the ground	No empirical baseline for working-level practice	Missed gaps in real-world implementation	Funding of applied research on practitioner experience

***** Adapted from Gillum, 2025. David R. Gillum, *The Role of Biosafety Professionals in Biotechnology Governance: Assessing Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (PhD dissertation, Arizona State University, 2025).

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