



SERVICES

BIOLAB SOLUTIONS

SERVICES FOR HIGH-CONTAINMENT LABORATORIES

Capability, performance and governance across the facility lifecycle



Independent technical advisory for institutions creating, verifying and sustaining high-containment capability.

Services

A HIGH-CONTAINMENT FACILITY IS NEVER ONLY A BUILDING.

It begins as an institutional intention. That intention is translated into technical criteria, installed systems, operating arrangements and, eventually, routine practice.

Once the facility enters service, the conditions on which containment depends begin to change. Equipment ages. Staff turn over. Procedures evolve. New agents are introduced. Systems are modified. Maintenance is deferred or completed. Budgets tighten. Institutional priorities shift.

Containment therefore cannot be treated as a condition established once at project completion. It is a capability that must repeatedly be interpreted, demonstrated and sustained.

THE CENTRAL IDEA

High-containment capability is produced and sustained through a chain of decisions across the lifecycle.

CAPABILITY DEVELOPS – AND THEN CONTINUES TO CHANGE

01

Institutional intention

Mission · purpose · risk
tolerance

02

Technical definition

Requirements · criteria ·
interfaces

03

Project delivery

Design · construction ·
controlled change

04

Verified condition

Evidence · readiness ·
acceptance

05

Operating capability

Maintenance · surveillance ·
governance

The condition does not stop changing after handover. People, procedures, biological work, equipment, maintenance, budgets and institutional priorities continue to move.

THE FACILITY CHANGES. THE DECISIONS CHANGE WITH IT.

FACILITY LIFECYCLE

Need	Definition	Design	Delivery	Verification	Operation	Change / Renewal
Mission, institutional purpose	Risk, capability, criteria	Systems, interfaces, operability	Changes, substitutions, execution	Evidence, performance, readiness	Maintenance, staffing, response	New risks, upgrades, ageing

DECISION CYCLE RUNNING THROUGH THE LIFECYCLE

DECIDE

ESTABLISH EVIDENCE

ASSIGN AUTHORITY

ACT

REVIEW

Why this matters

The same technical condition can require very different institutional decisions depending on where the facility is in its lifecycle. A design assumption may become a construction constraint; a commissioning result may become an operating limit; a maintenance delay may become a risk-acceptance decision.

The lifecycle is not simply a sequence of project phases. It is a succession of decisions that create, test, preserve and periodically redefine capability.

THE TYPE OF DECISION CHANGES AS THE FACILITY MATURES.

PLAN

What are we trying to create?

Mission, hazards, capability, acceptable risk, institutional constraints and the consequences of choosing one containment strategy over another.

DESIGN

Can the technical solution produce the intended capability?

Interfaces, dependencies, failure modes, maintainability, equipment requirements and the relationship between individual design decisions.

DELIVER

Does each change preserve technical intent?

Substitutions, RFIs, value engineering, procurement choices, construction workarounds and undocumented assumptions.

VERIFY

Is there enough evidence to accept the facility?

Functional performance, integrated-system behaviour, alarm response, failure states, deviations and readiness for transfer to the operating institution.

OPERATE

What must be preserved – and what tells us when the condition is changing?

Maintenance, calibration, replacement, staffing, training, surveillance evidence, reference-condition integrity and response to degraded conditions.

CHANGE

Which assumptions must now be reopened?

New agents, new workflows, ageing systems, obsolescence, altered mission, accumulated deviations and changes in institutional tolerance for risk.

The decision burden does not disappear after commissioning. It changes form—and often becomes more institutional than technical.

WHERE DOES TECHNICAL CLARITY BECOME AN INSTITUTIONAL DECISION?

01

What capability do we actually need?

Before infrastructure, the institution must define the work, hazards, operating assumptions and obligations that justify a particular containment capability.

02

Can the design actually deliver it?

Whether the facility is new or existing, the challenge is whether architecture, engineering, equipment, controls and workflows can produce the required capability as one system.

03

Who protects our technical interests while it is delivered?

As decisions become distributed among project actors, somebody must remain accountable for whether changes still preserve the owner's intended capability.

04

Can we demonstrate that it works and operate it safely?

At commissioning, after modification, or whenever performance is in doubt, the institution needs evidence that critical functions and interfaces behave as required.

05

Can we sustain its performance over time?

Containment depends on maintenance, verification, replacement, specialist support and recurrent resources that persist long after capital construction ends.

06

Can we govern the conditions on which containment depends?

As risk, configuration and performance change, the institution must be able to connect containment requirements, evidence, authority, change control and response — including knowing when the reference condition itself can no longer be assumed.

These six questions are connected, but they are not sequential. Any one of them may become the institution's immediate problem at a different point in the lifecycle, and several may be active at the same time.

WHAT CAPABILITY DO WE ACTUALLY NEED?

The first question is not “Which biosafety level?” It is what the institution must be capable of doing, under what conditions, and why.

WHAT THIS QUESTION IS REALLY TESTING

A containment designation is a consequence of risk and intended activity; it should not substitute for defining them. Two institutions may both describe a need for BSL-3 capability while requiring very different combinations of throughput, equipment, operational resilience, staffing, animal work, diagnostic activity, decontamination strategy or emergency response.

The real question is therefore whether the institution has converted mission into an explicit set of technical and operational needs. That requires understanding the biological material and procedures, credible exposure or release pathways, expected operating states, workload, staffing, movement of people and materials, and the institutional consequences of interruption or failure.

WHAT UNCERTAINTY OFTEN SITS UNDERNEATH IT

Facilities are sometimes scoped around precedent: what another laboratory has, what a standard appears to require, or what a designer has previously delivered. Those references can be useful, but they do not answer whether the resulting capability is proportionate to this institution’s mission and risks.

The opposite problem also occurs in existing facilities. The original capability may once have been justified, but the work, agents, throughput, regulation or institutional mission may have changed. Continued operation does not by itself demonstrate that the original basis remains appropriate.

WHY THE ANSWER MATTERS DOWNSTREAM

Every later decision depends on this definition. If the capability is vague, design criteria become difficult to defend, commissioning lacks a clear acceptance basis, maintenance obligations appear arbitrary and governance eventually inherits controls whose original purpose cannot be reconstructed.

QUESTIONS THAT SHOULD BECOME EXPLICIT

What work must the institution be able to perform?

What biological hazards and operating scenarios drive containment?

What must remain contained, and from whom or what?

Which operating states must the facility support?

What interruption or degradation can the institution tolerate?

What capability must remain supportable over the facility lifecycle?

The decision: whether the institution has defined a containment capability that is technically justified, proportionate to risk and realistic to build, operate and sustain.

CAN THE DESIGN ACTUALLY DELIVER IT?

Compliance within individual disciplines does not necessarily produce containment when those disciplines are assembled into one facility.

WHAT THIS QUESTION IS REALLY TESTING

Containment performance emerges from interaction. Architecture establishes barriers, movement and spatial relationships. HVAC creates airflow and pressure behaviour. Controls determine how the system reacts to changing conditions. Electrical systems determine what persists during power disturbance. Equipment changes heat load, airflow, access and decontamination requirements.

The question is therefore not merely whether each discipline has satisfied its own criteria. It is whether the combined facility can preserve the required containment functions during normal operation, transition, maintenance, foreseeable disturbance and failure.

WHAT UNCERTAINTY OFTEN SITS UNDERNEATH IT

Design coordination tends to focus on clashes, dimensions and completion of documents. Containment coordination asks a different question: if one condition changes, what else changes with it?

A door moved for architectural reasons may alter pressure response and movement patterns. A diffuser substitution may affect airflow around critical work. A new freezer may increase room heat load and force the HVAC system toward a different operating point. None of these changes is necessarily wrong, but their system consequences must be understood.

WHY THE ANSWER MATTERS DOWNSTREAM

Design decisions determine what must later be constructed, commissioned, maintained and monitored. An unresolved interface can become a commissioning failure; a difficult maintenance condition can become an operating compromise; and a poorly understood control dependency can become a governance problem when the facility enters a degraded state.

QUESTIONS THAT SHOULD BECOME EXPLICIT

Which systems jointly create each critical containment function?

What happens when one of those systems changes state or fails?

Can the facility be maintained without defeating the barrier?

Do equipment and room-engineering assumptions agree?

Are alarms and control responses consistent with operational reality?

Will the eventual test programme be able to demonstrate the intended behaviour?

The decision: whether the proposed or existing configuration can be defended as an integrated containment system rather than as a set of individually acceptable design components.

WHO PROTECTS OUR TECHNICAL INTERESTS WHILE IT IS DELIVERED?

The project may have many technically competent participants and still lack one continuous owner-side view of containment.

WHAT THIS QUESTION IS REALLY TESTING

Delivery distributes technical decisions among designers, contractors, vendors, project managers and specialists. Each actor works within a legitimate scope, but the owner ultimately receives the accumulated result of all of those decisions.

The important question is whether anyone is continuously testing those decisions against the capability the institution intended to receive. A substitution, field adjustment, RFI response or value-engineering decision may be acceptable locally while changing verification requirements, maintenance access, spare-parts strategy, operating resilience or future lifecycle cost.

WHAT UNCERTAINTY OFTEN SITS UNDERNEATH IT

Project documentation can show what changed without preserving why the change was technically acceptable. As decisions accumulate, design intent may become scattered across drawings, submittals, meeting records and individual memory.

This becomes particularly important when the owner introduces an independent technical representative after the project has already begun. The immediate need may not be another design review; it may be reconstruction of the technical logic governing the current project condition.

WHY THE ANSWER MATTERS DOWNSTREAM

Commissioning can only verify the condition that has actually been delivered. If project decisions have altered technical intent without preserving traceability, commissioning inherits the uncertainty. Operations and maintenance then inherit the resulting condition after the project team has left.

QUESTIONS THAT SHOULD BECOME EXPLICIT

Which owner requirements are affected by the proposed decision?

Does a substitution preserve performance as well as specification intent?

What other systems or interfaces are affected?

Does the change alter commissioning or acceptance criteria?

Does it create a new maintenance or lifecycle dependency?

Is the rationale documented well enough to remain understandable later?

The decision: whether project changes can be accepted while preserving technical continuity from institutional requirement to installed and eventually verified condition.

CAN WE DEMONSTRATE THAT IT WORKS — AND OPERATE IT SAFELY?

Verification is not the production of test results. It is the production of evidence capable of supporting a defined technical decision.

WHAT THIS QUESTION IS REALLY TESTING

A containment system must do more than meet isolated values under ideal conditions. The institution needs to know whether critical functions behave as required when systems interact, states change, alarms occur, power transfers or components fail.

That means the verification programme must be derived from the requirements and operating conditions that matter. A pressure value, airflow measurement or alarm test has limited meaning unless it can be connected to a defined containment function and an acceptance decision.

WHAT UNCERTAINTY OFTEN SITS UNDERNEATH IT

The facility may be testable without being acceptably defined. Where design criteria or expected failure behaviour were never made explicit, testing can produce accurate measurements while leaving the institution unable to determine whether the condition is acceptable.

The same issue arises after modification or major maintenance. Returning equipment to service is not automatically equivalent to restoring the accepted containment condition. The appropriate verification scope depends on what changed and which functions could have been affected.

WHY THE ANSWER MATTERS DOWNSTREAM

Verification evidence may become part of the technical reference used during future operation. Maintenance, surveillance and governance may later depend on those records to recognize whether the containment condition has changed. Weakly defined acceptance evidence therefore creates a long-lived institutional problem.

QUESTIONS THAT SHOULD BECOME EXPLICIT

Which containment functions must be demonstrated?

What constitutes acceptable performance for each function?

Which interactions and failure states must be exercised?

What deviations remain after testing?

What evidence is sufficient for acceptance or return to service?

Will the resulting record remain usable as a future technical reference?

The decision: whether the available evidence is sufficient to justify acceptance, continued operation or return to service—and what uncertainty remains if it is not.

CAN WE SUSTAIN ITS PERFORMANCE OVER TIME?

Containment capability persists only while the functions on which it depends remain available, understood and supportable.

WHAT THIS QUESTION IS REALLY TESTING

Maintenance programmes typically organize work by equipment: service the fan, calibrate the sensor, replace the filter, inspect the damper. Containment requires another layer of understanding: which function does that asset support, how could that function degrade, and what evidence demonstrates that it remains available?

That distinction matters because not every overdue task has the same technical consequence, and completion of a work order does not automatically demonstrate restoration of containment performance. Maintenance, verification and surveillance are related, but they answer different questions.

WHAT UNCERTAINTY OFTEN SITS UNDERNEATH IT

The lifecycle burden may be distributed across facility management, vendors, biosafety personnel, procurement and capital planning. Obsolescence, specialist-support dependence and long lead times can accumulate quietly until a routine failure exposes that the original capability is no longer easily recoverable.

Temporary operating measures are particularly important. A workaround may be technically reasonable for a defined period, but if its basis, duration and verification requirements are not controlled, it can gradually become the new normal without anyone explicitly accepting the changed condition.

WHY THE ANSWER MATTERS DOWNSTREAM

Lifecycle management is where technical degradation becomes an institutional decision. A recurring alarm, obsolete controller or deferred critical intervention may eventually require re-verification, restricted operation, capital renewal or recovery rather than another maintenance action.

QUESTIONS THAT SHOULD BECOME EXPLICIT

Which functions are critical to containment or continuity?

Which assets and services support those functions?

How will degradation become visible?

What maintenance preserves the condition?

What verification demonstrates that the condition remains acceptable?

When does an operational issue require escalation beyond maintenance?

The decision: what must be preserved, verified, funded, renewed or replaced—and when routine maintenance is no longer a sufficient response.

CAN WE GOVERN THE CONDITIONS ON WHICH CONTAINMENT DEPENDS?

Governance asks whether the institution can connect containment need, technical condition, evidence, authority and response strongly enough to make defensible decisions as circumstances change.

WHAT THIS QUESTION IS REALLY TESTING

High-containment facilities generate large amounts of technical and procedural information. Governance is not the existence of that information. It is the ability to connect what must remain contained to the risks involved, the controls relied upon, the evidence used to judge performance and the authority to act when the condition changes.

A mature governance system should therefore be able to explain why a control matters, what acceptable performance looks like, how change is recognized, who owns the resulting decision and what happens when confidence is reduced.

WHAT UNCERTAINTY OFTEN SITS UNDERNEATH IT

Many apparent governance problems begin somewhere else. An institution may be unable to decide whether degraded operation is acceptable because the technical limit was never defined. It may lack confidence in surveillance data because the reference condition is uncertain. A change-control process may exist but fail to identify the containment consequences of the changes it reviews.

Governance must therefore distinguish institutional weakness from unresolved technical uncertainty. Otherwise the organization risks trying to solve an engineering problem with more procedure—or a decision-authority problem with more testing.

WHY THE ANSWER MATTERS DOWNSTREAM

When technical conditions move away from what was expected, the institution needs more than a finding. It needs a defensible path from evidence to action: continue, monitor, compensate, restrict, verify, recover, shut down or establish a new accepted condition.

QUESTIONS THAT SHOULD BECOME EXPLICIT

What containment capability is being governed?

Can risks be traced to requirements and controls?

What reference condition is used to interpret present performance?

What evidence signals normal variation, drift or degradation?

Who can accept a deviation or degraded state?

When must assumptions, limits or the reference condition be reopened?

The decision: whether the institution has a defensible basis for owning, interpreting and responding to the containment condition as it changes.

HIGH-CONTAINMENT PROBLEMS RARELY ARRIVE WITH THE RIGHT LABEL.

What appears to be an HVAC problem may actually be a design-interface problem. What appears to be a maintenance delay may actually be a governance problem.

Technical symptom

A pressure alarm recurs after maintenance.

UNDERLYING QUESTION

Was the original control logic understood, tested and preserved?

Operational symptom

A verification activity is deferred due to budget pressure.

UNDERLYING QUESTION

Who can accept the resulting uncertainty, and on what evidence?

Lifecycle symptom

Critical parts are no longer available from the original supplier.

UNDERLYING QUESTION

Was obsolescence treated as a foreseeable lifecycle obligation?

Project symptom

A contractor proposes a substitute component.

UNDERLYING QUESTION

Does the substitution preserve performance, maintainability and verification requirements?

Organizational symptom

Only one person knows why a workaround exists.

UNDERLYING QUESTION

Has institutional memory replaced traceable governance?

Risk symptom

A new procedure is introduced into an established laboratory.

UNDERLYING QUESTION

Which original assumptions now need to be reopened?

The practical value of the framework is diagnostic: it helps identify which institutional capability is missing when a decision becomes consequential.

SIX SERVICES BUILT AROUND THOSE DECISIONS

01

DEFINE

Strategy, Risk & Containment
Definition

02

INTEGRATE

Design & Technical Integration

03

PROTECT

Owner's Technical
Representation & Project
Delivery

04

VERIFY

Commissioning, Verification &
Operational Readiness

05

SUSTAIN

Lifecycle Performance &
Maintenance Planning

06

GOVERN – Containment Governance & Institutional Audit

A transversal layer connecting risk → requirements → controls → evidence → authority → change → response across the lifecycle.

The six services are not mandatory project phases. Each can be engaged independently at the point where a technical or institutional need exists, including in an established facility or after earlier work by others. Service 06 – Governance – is transversal: it can operate across any of the other five services and at any point in the facility lifecycle. Where the validity or provenance of the reference containment condition is uncertain, BioLab may also apply a separate Baseline Recovery process before historical data are relied upon for surveillance, verification or institutional decisions.

01

STRATEGY, RISK & CONTAINMENT DEFINITION

DEFINE WHAT MUST EXIST — AND WHY.

WHAT TENDS TO GO WRONG

High-containment projects often begin with a facility label, a proposed biosafety level, a room list or a preferred equipment solution before the institution has fully defined the capability it actually needs. “BSL-3” can then become shorthand for a much more complex set of unresolved questions: what work will occur, what material must remain contained, what routes of exposure or release are credible, what operating states must be supported, and what consequences the institution is trying to control.

When those decisions remain implicit, assumptions migrate into the project. They become room adjacencies, pressure relationships, filtration strategies, equipment requirements, staffing models, control sequences, emergency responses and commissioning criteria. Later, they become maintenance obligations, replacement costs and operating limits. A technical requirement can therefore persist for years even when nobody can clearly reconstruct the risk or institutional decision that originally justified it.

BioLab works in the opposite direction: from mission and biological risk toward the containment capability required to support them. For a new project, this means establishing the technical and institutional basis before architecture and engineering harden around assumptions that may be incomplete or disproportionate.

For an existing facility, the same analysis can be used when mission, agents, procedures, throughput, regulation, available resources or institutional priorities have changed enough that the original basis should no longer simply be presumed.



WHY THIS STAGE MATTERS LATER

The criteria established here become inputs to Design and Technical Integration; they determine what Commissioning must later demonstrate; they shape the maintenance and verification obligations that must be sustained; and they provide Governance with a traceable explanation of why particular controls and operating conditions matter.

If the capability cannot be defined coherently at this point, later technical precision can produce a very sophisticated answer to the wrong institutional question.

WHAT DECISION THIS SUPPORTS

Whether the proposed or existing capability is justified, proportionate and supportable, and whether its risk and containment basis remains appropriate for the work the institution needs to perform.

FROM CAPABILITY QUESTION TO DEFENSIBLE TECHNICAL BASIS.

WHAT BIOLAB EXAMINES

Mission, work and capability assumptions
Hazard and risk basis
Containment-performance criteria
Existing capabilities and constraints
Institutional readiness and sustainability
Sequence of high-impact decisions

WHAT DECISION THIS SUPPORTS

It also gives the institution a defensible basis for deciding which requirements are essential, which are negotiable, which existing constraints can be accepted and which must be changed before design or investment decisions proceed.

TYPICAL OUTPUTS

Mission/capability definition · risk basis · performance criteria · existing-capability assessment · sustainability considerations · prioritized roadmap

Result: A defensible basis for defining or redefining what capability is required and which containment obligations are technically justified.

TEST WHETHER THE FACILITY WORKS AS A SYSTEM.

WHAT TENDS TO GO WRONG

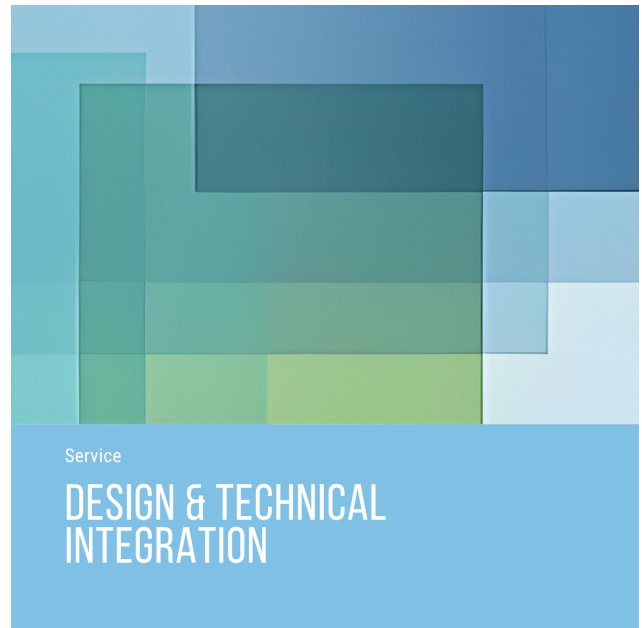
High-containment design is distributed across architecture, mechanical systems, electrical systems, controls, specialist equipment and operational planning. Each discipline can be technically competent and still produce a facility whose interfaces do not behave coherently. Containment is created in those interactions, not in the drawings of any single discipline.

A door location affects pressure relationships and movement patterns. Equipment affects heat load, airflow, service clearances and decontamination strategy. Electrical distribution determines which functions persist during loss of normal power. Controls determine how fans, dampers, alarms and pressure relationships react to failure. Maintenance access can require barriers to be breached.

A locally reasonable decision can therefore propagate through the facility and alter several other assumptions at once.

BioLab reviews these dependencies as one containment system. In a new facility, that may mean interrogating design intent before it becomes construction. In a project already designed by others, it may mean independent review of drawings, sequences, equipment interfaces and failure scenarios.

In an operating laboratory, the same approach can be applied before reconfiguration, installation of new equipment, modification of HVAC or controls, or changes in workflow that may affect the established containment condition.



WHERE SMALL CHANGES MATTER

Relocating a door can change pressure relationships and movement patterns.

Substituting a diffuser can alter airflow behaviour around critical equipment or work zones.

Moving equipment can change heat load, service clearance and contamination-control assumptions.

WHAT BIOLAB EXAMINES

Whether risk assumptions remain visible in design

Critical system dependencies and interfaces

Failure and degraded-operation scenarios

Maintainability and service access

Equipment / room / HVAC interaction

Control logic and operational coherence

Result: A new or existing configuration that can be defended as a coherent operating system, not merely as a collection of individually acceptable components.

KEEP TECHNICAL INTENT VISIBLE WHILE THE PROJECT CHANGES.

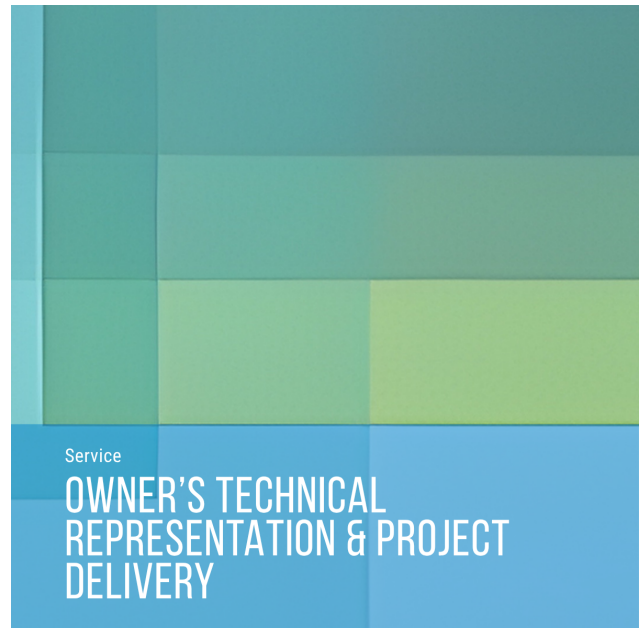
WHAT TENDS TO GO WRONG

Projects rarely lose technical intent through one obvious failure. More often, it is diluted incrementally. A substitution is accepted because the specified product is unavailable. An RFI is resolved to keep construction moving. A piece of equipment changes. A control sequence is simplified. A service route is relocated.

Each decision may be locally rational while gradually changing the condition the owner will ultimately receive.

The problem is structural. Designers protect design responsibility; contractors protect constructability and contractual delivery; vendors protect their equipment; project managers protect programme, cost and schedule.

None of those roles necessarily carries continuous responsibility for the cumulative containment consequence of every decision. The technical intent can therefore become distributed across drawings, RFIs, submittals, meeting minutes, commissioning comments and undocumented project knowledge.



BIOLAB'S ROLE

BioLab provides an independent technical line on the institution's side. We connect the requirement the owner intended to satisfy with the design that was developed, the changes proposed during delivery, the condition actually installed and the evidence that will later be required for acceptance.

A substitution is therefore not reviewed only as a product question: we consider whether it changes performance, verification, maintainability, spare-parts strategy, decontamination, resilience or future operating obligations.

PRESERVE CONTINUITY FROM INTENT TO INSTALLED CONDITION.

The role can start at project inception, but it is also valuable when BioLab enters after work is underway. In that case, the first task may be reconstructive—identifying what was intended, what changed, why it changed and which unresolved decisions still affect containment.

That reconstruction creates continuity between Design and Commissioning and prevents verification from becoming the point at which accumulated project ambiguity is finally discovered. It also preserves a more coherent technical record for later Lifecycle Performance and Governance.

WHAT BIOLAB EXAMINES

Whether changes remain consistent with owner criteria

Technical implications of substitutions and value engineering

RFIs, submittals and decisions affecting critical systems

Cross-discipline coordination during construction

Deviation accumulation and unresolved interfaces

Documentation needed for later verification

WHAT DECISION THIS SUPPORTS

Whether a proposed project decision can be accepted without undermining the capability the owner expects to receive, and whether additional analysis, verification or compensatory action is needed before that decision is allowed to propagate through the project.

TYPICAL OUTPUTS

Owner criteria matrix · milestone reviews · RFI/submittal review · deviation/change register · decision log · commissioning readiness base

Result: An independent owner-side technical line that protects continuity from institutional intent to installed condition and preserves the evidence needed to understand how that condition was reached.

04

COMMISSIONING, VERIFICATION & OPERATIONAL READINESS

MOVE FROM EXPECTED PERFORMANCE TO EVIDENCE.

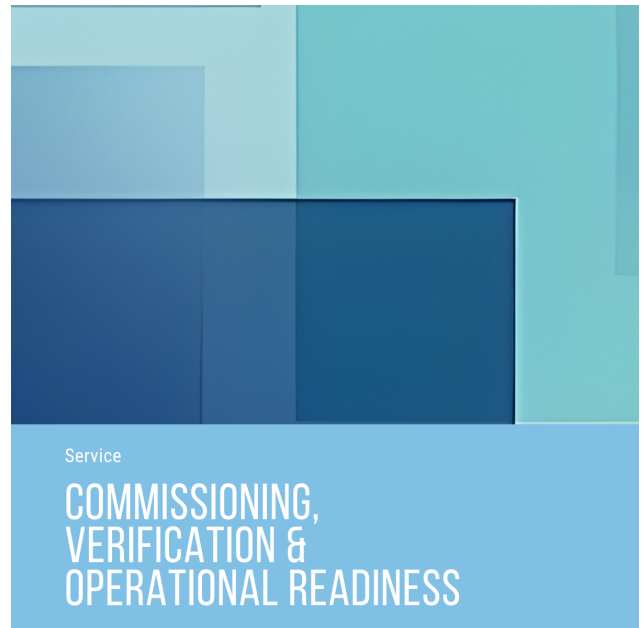
WHAT TENDS TO GO WRONG

Commissioning can become a collection of successful component tests without demonstrating that the containment system works as an integrated whole.

A fan can operate, a pressure sensor can calibrate, an alarm can activate and a room can meet a pressure criterion—yet the facility may still respond incorrectly when doors open, power transfers, equipment changes state or a component fails.

Verification also depends on the quality of the requirements that precede it. Testing cannot compensate for an undefined acceptance basis.

If the required performance, failure response or operating condition was never made explicit, a test can generate accurate data without answering the institutional question: is this condition good enough to accept and rely upon?



BIOLAB'S APPROACH

BioLab structures commissioning and verification around the decision the evidence must support. We work backward from the containment functions and acceptance criteria that matter, identify the systems and interfaces that create those functions, and examine how they perform under normal, transitional, abnormal and degraded conditions.

Deviations are not treated simply as items to close; the question is whether they alter the condition the institution is being asked to accept.

BUILD EVIDENCE THAT REMAINS USEFUL AFTER ACCEPTANCE.

In a new facility, the decision may be technical acceptance and readiness for operation. In an existing laboratory, it may be continued operation or return to service following maintenance, modification, failure or recovery.

This makes Verification a bridge between Design and operation rather than the end of the construction process.

The evidence created here can also become part of the future technical reference condition. That has consequences years later: maintenance teams may use it to understand expected performance, surveillance may use it to recognize drift, and Governance may rely upon it when determining whether a changed condition remains acceptable.

Conversely, if historical test results cannot be linked confidently to the current configuration, more testing alone may not resolve the problem. The institution may first need Baseline Recovery to determine what condition can legitimately serve as the reference for subsequent verification and surveillance.

WHAT BIOLAB EXAMINES

Whether test plans reflect critical performance criteria

Functional response of critical systems

Integrated behaviour under normal and failure conditions

Containment-system performance and alarm response

Whether deviations are understood and closed

Whether procedures and responsibilities match actual performance

TYPICAL OUTPUTS

Cx plan review · functional test records · integrated-systems testing · containment verification · re-verification scope · deviation register · readiness / return-to-service assessment

Result: Evidence sufficient to support a defined decision and, where appropriate, a defensible technical reference for subsequent operation, surveillance and change.

MAKE PERFORMANCE OBLIGATIONS VISIBLE BEFORE THEY BECOME FAILURES.

WHAT TENDS TO GO WRONG

The obligations required to sustain containment are created long before the first maintenance work order is issued. Design decisions, equipment selections, control strategies and commissioning criteria all create future dependencies.

Once the facility enters operation, those obligations often become fragmented across manuals, vendor contracts, calibration programmes, spare-parts inventories, controls specialists, budgets and institutional memory.

The result is that maintenance can become activity-based rather than containment-based. A task is considered complete because a component was serviced, not because the function on which containment depends has been shown to remain available.

Conversely, a maintenance delay may be treated as administrative backlog even when it has reduced confidence in a critical function.



A DIFFERENT WAY TO ORGANIZE THE PROBLEM

BioLab reorganizes the problem around containment dependencies. The relevant chain is not simply asset → maintenance task.

It is: containment function → supporting asset or system → credible degradation mechanism → maintenance or verification activity → evidence of continued performance → response when that evidence is no longer available or acceptable.

DISTINGUISH MAINTENANCE FROM VERIFICATION, SURVEILLANCE AND RECOVERY.

This distinction separates preventive maintenance from performance verification and surveillance. Maintenance helps preserve the condition. Verification determines whether a required function can still be demonstrated. Surveillance looks for movement away from an accepted reference condition.

When those activities identify degradation, the institution must decide whether adjustment, repair, compensatory measures, restricted operation, re-verification or recovery is required. They are connected, but they are not interchangeable.

Lifecycle work therefore feeds directly into Governance. A recurring alarm, deferred HEPA-related intervention, obsolete controls platform or unavailable spare part is not only a maintenance issue once it changes confidence in containment.

The institution needs to know what function is affected, what evidence remains, what temporary condition exists and who can authorize continued operation.

In older facilities, the analysis may also reveal that the historical reference condition itself is uncertain. At that point routine maintenance planning may need to give way to targeted verification, Baseline Recovery or capital renewal before the facility can be managed against a defensible condition.

WHAT BIOLAB EXAMINES

Which assets are critical to containment or continuity

Maintenance, calibration and verification cycles

Replacement intervals and life expectancy

Critical spares, lead times and vendor dependency

Obsolescence and specialist-support exposure

Recurring and extraordinary operating expenditure

TYPICAL OUTPUTS

Critical asset inventory · maintainability review · PM matrix · verification calendar · spare-parts strategy · replacement / renewal plan · recurring OPEX / multiyear investment model

Result: A technical and financial basis for preserving containment capability, recognizing degradation early and distinguishing routine maintenance from conditions requiring verification, recovery or renewal.

CONNECT CONTAINMENT NEED, EVIDENCE AND INSTITUTIONAL CONTROL.

WHAT TENDS TO GO WRONG

Institutions can possess competent personnel, risk assessments, procedures, commissioning records, maintenance programmes and functioning technical controls while still lacking a coherent way to govern the containment condition as those elements change.

The weakness is often not the absence of information, but the absence of a defensible chain connecting biological risk, containment need, requirements, controls, evidence and institutional authority.

These weaknesses become visible at interfaces. A new activity may be approved without reopening assumptions embedded in the facility. A maintenance result may show deterioration without defining when continued operation becomes unacceptable.

A deviation may be documented without identifying who has authority to accept it. Commissioning records may exist but no longer correspond clearly to the present configuration.



THE GOVERNANCE QUESTION

BioLab begins with the containment problem itself rather than with the organization chart or a document checklist. The first question is what must remain contained and under what conditions.

From there, the analysis considers the credible ways containment could be lost, the primary and secondary controls relied upon to interrupt those pathways, and whether those controls can be traced to requirements and evidence of performance.

Only then does the institutional layer become meaningful.

MANAGEMENT-SYSTEM REFERENCE

Where relevant, ISO 35001:2019 is used as a recognized biorisk-management reference. This work is led by BioLab personnel who have successfully completed ISO 35001:2019 Implementation & Lead Auditor training through an Exemplar Global RTP Certified Training program.

FROM CONTAINMENT CONDITION TO DEFENSIBLE DECISION.

Who owns the containment condition? Who can introduce change? Who determines whether a deviation is acceptable? What evidence distinguishes normal variation from drift, degradation or loss of confidence? What happens when performance cannot be demonstrated?

Governance is not simply whether policies exist or whether a management system contains the expected documents. The deeper question is whether the institution can use its technical and organizational information to recognize a changed containment condition and decide what should happen next.

That may mean continuing operation because the change is understood and remains within an accepted condition. It may mean increased surveillance, compensatory controls, restricted activity, re-verification, technical recovery or temporary shutdown.

The significance lies in the traceability of the decision: what changed, why it matters, what evidence was considered, who had authority and what condition was ultimately accepted.

A CRITICAL DISTINCTION

Governance cannot make an uncertain technical condition certain. Where the institution lacks a defensible reference condition, sufficient performance evidence or a technically defined operating limit, those uncertainties must be resolved through the appropriate technical process rather than normalized through procedure.

WHAT BIOLAB EXAMINES

Mandate, scope, accountability and containment ownership

Traceability from risk to requirements and controls

Authority, decision control and change management

Technical reference condition and baseline integrity

Performance evidence, degraded states and recovery

Institutional assurance, corrective action and learning

REFERENCE CONDITION AND BASELINE RECOVERY

Governance depends on the integrity of the condition against which present performance is interpreted. Historical pressure values, commissioning results, certifications or operating parameters are not automatically a valid baseline simply because they exist.

Where provenance is uncertain, the configuration has materially changed, or historical evidence cannot be connected to current containment requirements, BioLab may identify the need for a separate Baseline Recovery process.

Baseline Recovery is not governance and it is not simply another name for recommissioning. Its purpose is to determine whether an existing reference condition can legitimately be relied upon, whether targeted verification is needed, whether recommissioning is warranted, or whether a new reference condition must be established as the basis for future operation and surveillance.

NO SERVICE OPERATES IN ISOLATION.

Any of the six services can be the point of entry. Their relationships are cumulative and recursive, but they are not contractual handoffs or a required sequence. Governance is transversal and may be engaged independently or alongside any of the other services.

01 Strategy

Defines mission, risk basis and performance criteria.



02 Design

Translates those criteria into systems and interfaces.

02 Design

Establishes the intended technical basis, system dependencies and performance criteria.



03 Owner Representation

Protects that technical intent while the project changes.

03 Delivery

Determines the installed condition.



04 Verification

Tests whether that condition performs as intended.

04 Verification

Creates evidence capable of supporting an accepted reference condition.



05 Lifecycle

Identifies what must be preserved, renewed and monitored to sustain that condition.

05 Lifecycle

Reveals drift, degradation, ageing and emerging constraints.



06 Governance

Determines how evidence is interpreted, who can act and when assumptions, limits or the reference condition must be reopened.

These connections are illustrative, not sequential. Operational evidence can reopen risk definition, design assumptions, acceptance criteria or capital planning. Service 06 – Governance – operates across the framework by connecting risk, requirements, controls, evidence, authority and response. Where the reference containment condition itself is uncertain, incomplete or contradictory, a separate Baseline Recovery process may be required before historical values are used as the basis for surveillance or subsequent decisions.

THE EVIDENCE NEEDED TO MAKE A DECISION ALSO CHANGES OVER TIME.

EARLY

Evidence of need

Mission, hazard information, risk assumptions, institutional constraints and performance objectives.

DESIGN

Evidence of coherence

Design basis, calculations, interface resolution, control logic, equipment criteria, failure-state analysis and maintainability considerations.

DELIVERY

Evidence of traceability

Approved submittals, substitutions, RFIs, change records, inspection results and documented rationale for deviations from the original basis.

VERIFY

Evidence of performance and reference condition

Functional tests, integrated-system response, alarm behaviour, failure-mode results, corrective actions, operational-readiness records and the evidence used to define the accepted operating condition.

OPERATE

Evidence of continued suitability and change

Maintenance records, calibration, verification, surveillance trends, incidents, deviations, change assessments and operating-performance review interpreted against a defensible reference condition.

A technically correct decision made without durable evidence can become impossible to defend later. But the existence of historical data does not automatically create a valid baseline. Evidence becomes useful for surveillance and institutional control only when the reference condition against which it is interpreted is itself defensible.

START WITH THE QUESTION YOUR INSTITUTION IS ALREADY ASKING.

The visible question is not always the underlying problem. The purpose of the service framework is to identify where uncertainty actually sits before deciding what kind of intervention is needed.

“Do we still need this level of containment?”

This usually begins as a Strategy question, but the real issue may be whether mission, biological work or institutional risk tolerance has changed since the facility was originally defined.

If the existing technical configuration is also being questioned, the work may extend into Design. If the facility is already operating under changed assumptions, Governance may need to determine who can accept the resulting condition.

Likely start: 01 Strategy

May connect to 02 / 06

“Will this design or modification work?”

This is usually a Design and Technical Integration question. The important issue is not only whether the proposed change is technically correct in isolation, but which containment dependencies it changes.

If the modification is already being delivered, Owner Representation may be needed to control decisions. If it affects an accepted operating condition, Verification will normally be required to show what condition exists afterward.

Likely start: 02 Design

May connect to 03 / 04

“Should we accept this substitution or project change?”

This usually begins with Owner Representation, because the question is whether the project decision remains consistent with the owner’s technical intent.

The answer may require Design analysis of system consequences and may change the evidence required later during Commissioning. A decision that appears minor during delivery can also create long-term maintenance or replacement obligations.

Likely start: 03 Owner Rep

May connect to 02 / 04 / 05

THE FIRST QUESTION MAY POINT TO A DIFFERENT UNDERLYING PROBLEM.

“What evidence do we need before acceptance or return to service?”

This is usually a Verification question, but verification only works when the condition being demonstrated and the acceptance basis are sufficiently defined.

If performance requirements remain unclear, the issue may sit upstream in Strategy or Design. If historical results cannot be linked confidently to the current configuration, Baseline Recovery may be required before new verification can be meaningfully interpreted.

Likely start: 04 Verification

May connect to 01 / 02 / Baseline Recovery

“What must we maintain, monitor, fund or replace?”

This is usually a Lifecycle Performance question. The objective is not simply to build a maintenance schedule, but to identify which containment functions depend on which assets and what evidence is required to know those functions remain available.

Repeated degradation may trigger Verification. Obsolescence may require capital intervention. If the institution is operating under temporary measures or uncertain limits, Governance may become the more immediate question.

Likely start: 05 Lifecycle

May connect to 04 / 06

“Who can authorize operation under this changed or degraded condition?”

This is usually a Governance question, but the institution first needs enough technical clarity to understand what has changed and why it matters.

Where evidence is insufficient, Verification may be required. Where the reference condition itself cannot be defended, the problem is not solved through governance procedure: Baseline Recovery may need to establish what condition can legitimately be relied upon.

Likely start: 06 Governance

May connect to 04 / Baseline Recovery

A client does not need to diagnose the service correctly before contacting BioLab. The initial question is useful because it reveals where uncertainty has become visible. The technical task is then to determine where that uncertainty actually originates and which decision must ultimately be supported.

AN INDEPENDENT TECHNICAL LAYER ON THE INSTITUTION'S SIDE

Institution / Owner

Retains mission, risk and acceptance responsibility.

BioLab Solutions

Independent technical advisory focused on containment capability, reference condition, performance evidence, traceability and institutional governance.

Design Team

Architecture and engineering design responsibility.

Contractors

Construction, installation and contractual delivery.

Commissioning Providers

Testing and commissioning according to appointed scope.

Equipment Suppliers

Product, specialist equipment and vendor support.

Facility / Maintenance Team

Operation, maintenance and technical response.

Biosafety Programme

Risk-management and institutional biosafety functions.

Leadership / Committees

Authority, resources and institutional acceptance.

BioLab does not replace the designer, contractor, commissioning agent, facility operator or institutional authority. We provide an independent technical layer focused on whether the capability being created, received or sustained remains coherent with institutional needs.

CAPABILITY MUST BE CREATED, VERIFIED, SUSTAINED — AND GOVERNED.

01

Risk before infrastructure

Containment decisions should follow mission and risk, not precede them.

02

Evidence before acceptance

Installed equipment is not the same as verified capability.

03

A defensible reference before surveillance

Historical values become meaningful only when the condition they represent can legitimately be used as a baseline.

04

Governance across the lifecycle

Performance must be sustained through clear authority, traceable evidence, change control and institutional response over time.

Planning, designing, modifying, delivering, verifying, operating or recovering a high-containment facility? BioLab can enter at the point of current need and help determine where independent technical support will add the greatest value.

BIOLAB SOLUTIONS

Independent technical advisory for high-containment laboratories.

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Services

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