DID WE REALLY COMMISSION THIS LABORATORY?

Diagnostic Guide
GD-002

A technical diagnostic guide to distinguishing startup, compliance testing, integrated commissioning and operational readiness

A practical guide for institutions reviewing whether a high-containment laboratory has actually demonstrated integrated performance before acceptance.

DIAGNOSTIC GUIDE

HOW TO USE THIS GUIDE

START WITH THE EVIDENCE. ASK WHAT IT ACTUALLY PROVES.

This guide was created for a common handover problem: a facility has been started, tested and documented, but the institution is still unsure whether the containment system itself has been demonstrated.

Why we created it

Commissioning is often used as a broad label for activities that are technically different. Equipment startup, TAB, calibration, HEPA testing, alarm checks and regulatory inspections may all occur without demonstrating how the complete containment system behaves when its components interact.

The purpose of this guide is to help an institution identify what evidence exists, what that evidence demonstrates, what remains untested and whether acceptance is being based on integrated performance or on a collection of successful component checks.

Who can use it

The guide is intended for owners, facility managers, biosafety personnel, designers, commissioning teams, project managers and institutional authorities preparing to accept or reassess a high-containment laboratory.

It can also be used retrospectively when an operating laboratory has persistent problems and the institution needs to determine whether those conditions were ever functionally tested at handover.

HOW TO USE IT IN PRACTICE

Work through the guide in sequence: define the intended containment functions, separate startup from verification, identify the acceptance criteria, review test coverage, examine failure and transition states, and determine whether operational readiness existed before responsibility transferred.

The objective is not to ask whether commissioning paperwork exists. It is to ask whether the evidence demonstrates the facility behavior the institution intends to accept.

01 DEFINE

02 VERIFY

03 CHALLENGE

04 ACCEPT

HOW THIS GUIDE MAY BE USED — AND WHAT IT DOES NOT AUTHORIZE

This guide is a general diagnostic guidance tool. It is designed to help structure technical questions, organize evidence and identify what requires a more specific assessment.

Acceptable use

It may be used to:

- structure preliminary technical investigations;
- prepare internal reviews and multidisciplinary discussions;
- identify missing information, measurements and documentation;
- support definition of the scope of a subsequent assessment;
- serve as educational material and an internal technical reference.

It does not constitute

This guide does not constitute a design, specification, operating procedure, commissioning protocol, acceptance criterion, certification, compliance determination, authorization to operate, or a site-specific recommendation for any particular facility.

Technical and operational decisions

No corrective action, acceptance decision, modification of criteria, intervention in critical systems, return-to-service decision, or operational decision should be based solely on this guide.

Applicable technical basis

The content should be interpreted together with the risk assessment, Basis of Design, commissioning plan, approved acceptance criteria, regulatory requirements, manufacturer instructions, institutional procedures, and other site-specific documentation.

Competent personnel

The review, execution and acceptance of containment-critical functions should be performed or reviewed by appropriately qualified personnel with access to the relevant project evidence and defined authority for the corresponding decision.

Responsibility

BioLab Solutions assumes no responsibility for decisions, modifications, interventions or actions carried out outside a site-specific assessment and without review by competent personnel.

01 What commissioning should demonstrate

Commissioning is stronger when it verifies containment functions rather than merely confirming that equipment operates.

A high-containment laboratory is an integrated system. The commissioning question is whether the installed facility collectively produces the intended containment behavior.

Examples of containment functions

- directional airflow and pressure hierarchy;
- boundary integrity where required;
- exhaust filtration integrity where applicable;
- door and interlock behavior;
- alarm and control response;
- redundancy and transition behavior;
- decontamination and transfer functions;
- failure-state visibility to operators.

The evidence question

For every critical function, ask:

- What criterion was defined?
- How was it tested?
- Under what condition?
- What result was recorded?
- Who accepted the result?
- What instruments or data sources were used, and were they suitable and current for the test?

COMMISSIONING SHOULD CONNECT DESIGN INTENT TO DEMONSTRATED SYSTEM BEHAVIOR.

02 Separate startup, testing and commissioning

These activities are related, but they do not prove the same thing.

Activity	What it can demonstrate
Equipment startup	The component energizes, runs and responds to basic controls.
TAB / airflow measurement	Measured supply and exhaust quantities under the tested condition.
Calibration	Instrument response against a reference at the time of calibration.
HEPA integrity test	Integrity of the tested filter installation under the applicable test method.
Alarm check	That a defined alarm can be triggered and communicated.
Compliance inspection	Conformity with the scope and criteria examined by the inspecting authority.
Integrated functional test	How multiple systems behave together during normal, transition or failure conditions.

> A collection of successful component tests can be necessary without being sufficient to demonstrate integrated containment performance.

03 Look for the acceptance basis

Testing is difficult to interpret when the project never defined what acceptable behavior would look like.

Acceptance criteria should exist before the final test sequence begins.

Pressure and airflow

- required relationships;
- allowed tolerances;
- directional airflow expectations;
- recovery expectations where defined.

Controls and alarms

- trigger conditions;
- response sequence;
- operator indication;
- fail-safe behavior.

Redundancy

- which function must remain available;
- transition expectations;
- degraded-state behavior;
- required operator response.

Boundaries and barriers

- applicable leak or integrity criteria;
- HEPA test requirements;
- door/interlock logic;
- transfer device conditions.

> **Diagnostic warning:** if acceptance criteria were defined only after seeing the test results, the project may be fitting the criterion to the installed condition rather than testing the installed condition against the intended requirement.

04 Confirm the facility was ready for integrated testing

Functional testing is meaningful only when the tested configuration is sufficiently complete and representative of the condition being accepted.

A test performed against a temporary, incomplete or unstable configuration may produce valid data for that moment without demonstrating the final operating system.

Installation readiness

- containment-critical construction substantially complete;
- doors, seals, penetrations and transfer devices in final condition;
- filters and housings installed in the configuration to be accepted;
- temporary openings and construction bypasses closed.

Mechanical readiness

- TAB sufficiently complete for functional testing;
- fans, dampers and VFDs operating in intended control mode;
- redundant equipment available where required;
- normal and emergency power sequences available for test.

Controls readiness

- approved sequences implemented;
- sensors calibrated or otherwise verified;
- alarms, interlocks and BMS graphics active;
- temporary overrides identified and removed unless specifically part of the test.

Test readiness

- acceptance criteria approved;
- test scripts identify prerequisites and expected results;
- instruments and data sources are suitable and traceable;
- known deficiencies that could invalidate the test are resolved or explicitly bounded.

Diagnostic question: was the system tested in a configuration that represents what the institution actually received?

05 Ask whether the complete system was tested

Containment performance lives at interfaces between systems and disciplines.

Individual systems may pass independently while their interaction remains unverified.

Examples of interfaces

- door opening versus pressure recovery;
- fan failure versus cascade stability;
- emergency power transfer versus exhaust continuity;
- interlock logic versus operational movement;
- filter loading versus available fan authority;
- alarm generation versus operator visibility;
- maintenance isolation versus adjacent zones.

Integrated evidence

The system should be challenged in combinations that reflect credible operating and failure conditions.

The purpose is not to create arbitrary stress. It is to demonstrate whether the containment function remains controlled when the facility leaves its easiest steady-state condition.

IF THE INTERFACE WAS NEVER TESTED, ITS BEHAVIOR MAY STILL BE AN ASSUMPTION.

06 Challenge failure and transition states

Redundancy has value only if the containment function survives the loss and transition it was intended to cover.

Loss of primary exhaust fan

What happens to pressure, directional airflow, alarms and operator visibility during transition to standby?

Emergency power transfer

What happens during loss, transfer, restart and restoration of normal power, and does the response remain within the project's defined acceptance criteria? A brief transient may be acceptable only where it was anticipated and bounded by the accepted design basis.

Sensor or control failure

Does the system fail predictably? Is the failure visible? Are default positions appropriate?

Door disturbance

How far does pressure move, how quickly does it recover and is airflow direction preserved?

Maintenance mode

Can equipment be isolated without unintentionally collapsing another required pressure relationship?

Degraded redundancy

What restrictions apply when backup capacity is unavailable but the primary system remains operational?

> A standby component that was never functionally tested through the transition may be redundant on paper without demonstrated continuity of containment.

COMMISSIONING EVIDENCE MATRIX

WHAT DOES THE PROJECT ACTUALLY HAVE?

Evidence available	Question to ask
Approved Basis of Design	Does it define the containment functions and assumptions that testing should demonstrate?
Commissioning plan	Was it developed before final testing, and does it cover integrated functions?
Pre-functional checklists	Do they confirm readiness for functional testing rather than substitute for it?
TAB report	Are measured flows tied to pressure relationships and final operating conditions?
HEPA integrity reports	Are the correct filters/housings identified and test conditions traceable?
Functional test scripts	Do they include normal, transition and failure states?
Deficiency log	Were failures resolved, retested and closed with evidence?
Final commissioning report	Does it state what was demonstrated, what remained open and what limitations apply?
Acceptance record	Who accepted the condition and on what evidence?

EVIDENCE QUALITY

A TEST REPORT IS ONLY AS USEFUL AS THE CONDITION IT CAN RECONSTRUCT

Commissioning evidence should allow a reviewer to understand what was tested, how it was tested, what configuration existed and whether the result met a predefined criterion.

For critical tests, look for

- date, location and system identification;
- test prerequisites and as-tested configuration;
- instrument identification and calibration status;
- setpoints, operating mode and relevant environmental conditions;
- expected result and acceptance criterion;
- measured result or raw data;
- deviations, corrective actions and retest record;
- witnesses and acceptance authority where required.

Deferred or seasonal testing

Some functions may not be testable at the preferred condition before handover. If testing is deferred, the record should state what remains unverified, why it was deferred, what interim restriction or assumption applies, and who is responsible for final completion.

Repeatability matters

A future reviewer should be able to reproduce the logic of the test and compare later performance with the accepted baseline.

> **EVIDENCE SHOULD IDENTIFY THE FUNCTION, THE CONDITION, THE CRITERION AND THE RESULT.**

WARNING SIGNS

INDICATORS THAT COMMISSIONING MAY HAVE BEEN TOO NARROW

“All equipment started successfully.”

Startup confirms component operation, not integrated containment performance.

“The TAB report is complete.”

Airflow quantities alone do not demonstrate response during door operation, fan failure or control transition.

“The BMS shows the right pressures.”

Displayed values do not independently prove calibration, airflow direction, boundary integrity or disturbance response.

“The HEPA filters passed.”

Filter integrity is one containment function, not proof of the complete exhaust or room system.

“The regulator approved the facility.”

Regulatory approval does not necessarily mean every integrated engineering function was commissioned under project-specific criteria.

“There were no alarms during testing.”

A system that was never challenged may simply never have been placed in a condition that should generate an alarm.

SUCCESSFUL TESTS ARE USEFUL ONLY WHEN THEIR SCOPE MATCHES THE FUNCTION BEING ACCEPTED.

06 Check whether deficiencies were actually closed

Commissioning is not complete because a problem was identified. Closure requires evidence of restoration.

A deficiency log should show more than issue identification and contractor response.

For each material deficiency, confirm

- the affected containment function;
- the corrective action;
- the date and responsible party;
- the retest performed;
- the acceptance criterion;
- the retest result;
- who authorized closure.

Open conditions

If a deficiency remains unresolved at handover, the institution should know:

- what uncertainty remains;
- whether operation is restricted;
- what temporary control applies;
- who accepted the temporary condition;
- what triggers final closure.

07 Operational readiness is part of acceptance

A technically verified facility is not automatically ready to operate.

The institution has to be able to interpret, maintain and respond to the condition it is accepting.

Procedures

- entry and exit;
- alarms and deviations;
- waste and material transfer;
- emergency response;
- maintenance isolation.

Training

- operators understand system behavior;
- maintenance staff understand containment implications;
- responsible personnel know escalation thresholds.

Documentation

- as-builts;
- O&M manuals;
- setpoints and alarm thresholds;
- test reports;
- accepted baseline configuration.
- control software/configuration backup where applicable.

Authority

- who can accept deviations;
- who can restrict or stop work;
- who authorizes return to service;
- who controls future changes.

> Acceptance transfers responsibility. If operating capability is incomplete, the project has transferred uncertainty rather than control.

DIAGNOSTIC SEQUENCE

DID WE ACTUALLY COMMISSION THE LAB?

01

Were containment functions and acceptance criteria defined before testing?

No → reconstruct the design/acceptance basis before treating existing test results as sufficient.
Yes → continue.

02

Does the evidence go beyond equipment startup and component checks?

No → integrated commissioning remains incomplete.
Yes → continue.

03

Were critical interfaces and transitions functionally tested?

No → untested behavior remains an assumption.
Yes → continue.

04

Were credible failure states and redundancy transitions challenged?

No → continuity under failure has not been demonstrated.
Yes → continue.

05

Were deficiencies retested and closed with traceable evidence?

No → acceptance should identify unresolved conditions and restrictions.
Yes → continue.

06

Was the institution operationally ready to receive the facility?

No → technical handover has outpaced institutional readiness.
Yes → commissioning and acceptance are substantially aligned.

WHAT TO COLLECT

COMMISSIONING REVIEW PACKAGE

Design basis

- risk assumptions
- Basis of Design
- pressure strategy
- redundancy logic
- acceptance criteria

Construction

- approved submittals
- RFIs
- field changes
- as-builts
- hidden-work records

Pre-functional

- startup reports
- calibration records
- TAB
- HEPA tests
- equipment checklists

Functional

- test scripts
- normal-state tests
- failure-state tests
- transition tests
- alarm tests

Deficiencies

- issue log
- corrective actions
- retests
- open items
- restrictions

Handover

- final report
- O&M manuals
- training records
- acceptance record
- baseline configuration

Review objective: determine whether the evidence forms a traceable chain from intended function to demonstrated behavior to institutional acceptance.

RETROSPECTIVE REVIEW

WHAT IF THE LABORATORY IS ALREADY OPERATING?

An incomplete commissioning record does not automatically mean the facility is unsafe, but it does mean some accepted conditions may not be demonstrable from the existing evidence.

Reconstruct the baseline

- identify intended containment functions;
- collect original design and test records;
- compare current configuration with as-built documentation;
- identify changes since handover;
- determine which functions were never adequately demonstrated.

Targeted verification

A retrospective review does not necessarily require repeating every original test.

It should identify the functions for which evidence is missing, unreliable or no longer representative of the current facility and define appropriate verification accordingly.

WHERE THE BASELINE IS MISSING, THE FIRST TASK IS TO REBUILD A CREDIBLE REFERENCE CONDITION.

RELATED BIOLAB RESOURCES

GO DEEPER INTO VERIFICATION AND ACCEPTANCE

NT-016
Functional versus nominal HVAC redundancy

NT-017
HVAC control hierarchies and authority logic

NT-024
Hermeticity verification: tests and limits

NT-032
Commissioning as a governance mechanism

NT-033
Functional testing versus compliance testing

NT-034
Authority and formal approval in containment systems

NT-035
Documentation as containment control

NT-036
Operations as a continuous containment activity

NT-037
Maintenance as a containment risk domain

NT-039
Lifecycle drift in containment systems

BIOLAB DIAGNOSTIC GUIDES

Short technical resources organized around real containment problems rather than individual disciplines.

Series concept: symptom → system → evidence → restoration.

CLOSING DIAGNOSTIC PRINCIPLE

COMMISSIONING IS NOT THE EXISTENCE OF TESTS. IT IS THE EVIDENCE THAT THE SYSTEM BEHAVES AS REQUIRED.

A laboratory can contain the correct equipment, successful startup records and a complete handover package while still carrying untested assumptions at the system level.

The commissioning review should therefore follow the containment function through design intent, installation, test conditions, failure behavior, deficiency closure and acceptance.

The most important question is not whether every document exists. It is whether the evidence is sufficient to explain what the facility was expected to do, what it actually demonstrated and what condition the institution accepted.

BIOLAB SOLUTIONS

Independent technical support for planning, design, commissioning, evaluation and lifecycle management of high-containment laboratories.

For a site-specific assessment, BioLab Solutions can support technical review, verification and definition of evidence criteria.

INTENT → EVIDENCE → FUNCTION → ACCEPTANCE