

DOES OUR ANNUAL VERIFICATION REALLY DEMONSTRATE CONTAINMENT?

Diagnostic Guide
GD-005

A technical diagnostic guide on periodic verification, direct measurement, and comparison with the accepted baseline

NORMAL VALUES DO NOT DEMONSTRATE THAT THE SYSTEM REMAINS THE SAME AS WHEN IT WAS ACCEPTED.

This guide was created for laboratories that conduct annual reviews but are uncertain whether those activities actually verify continued containment performance.

Why we developed it

Periodic verification is often reduced to reviewing BMS trends, reading differential pressure indicators, consulting maintenance records, or repeating a limited set of familiar tests.

These activities are useful, but they may not demonstrate that sensors remain accurate, that airflow still corresponds to the accepted condition, that HEPA systems maintain their integrity, that alarms function correctly, or that system response has not changed after years of operation and maintenance.

The purpose of this guide is to help institutions define what should be measured directly, what should be functionally tested, and what should be compared with the accepted baseline.

Who can use it

The guide is intended for facility managers, biosafety personnel, engineers, maintenance teams, commissioning specialists, and institutional authorities responsible for periodic verification of high-containment laboratories.

It can also be used to review an existing annual verification program and identify where monitoring has been confused with evidence of performance.

HOW TO USE IT IN PRACTICE

Begin with the accepted baseline and identify the containment functions that require periodic evidence. Then distinguish routine monitoring from direct verification, define the necessary tests and measurements, compare the results with the baseline, and determine which deviations require investigation or corrective action.

The objective is not to repeat commissioning every year. It is to obtain sufficient direct evidence to determine whether critical containment functions remain reliable over time.

01

BASELINE

02

MEASURE

03

CHALLENGE

04

COMPARE

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 define what requires a more specific evaluation.

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 evaluation;
- serve as educational material and an internal technical reference.

It does not constitute

This guide does not constitute a site-specific annual protocol, acceptance criterion, certification, compliance determination, authorization to operate, or a specific recommendation for a particular facility.

Technical and operational decisions

No decision concerning continued operation, restrictions, corrective action, modification of criteria, repeat testing, or return to service should be based solely on this guide.

Applicable technical basis

The content should be interpreted together with the risk assessment, accepted baseline, commissioning results, maintenance and verification programs, regulatory requirements, institutional procedures, and other site-specific documentation.

Competent personnel

Measurements and tests critical to containment should be performed or reviewed by appropriately qualified personnel using suitable instrumentation and documented methods.

Responsibility

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

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01

Begin with the accepted baseline

Verification is comparison. Without a reference condition, the current result has limited meaning.

The periodic verification program should be anchored to the condition originally accepted by the institution, not only to the setpoints displayed today.

Useful baseline records

- commissioning report;
- TAB data;
- pressure relationships;
- airflow rates;
- control sequences;
- alarm thresholds;
- HEPA integrity records;
- door/interlock behavior;
- accepted deficiencies or limitations.

Baseline question

What evidence established that the facility was acceptable at handover, and which of those conditions remain critical to current containment performance?

If the baseline cannot be reconstructed, periodic verification may first require establishing a current and technically credible reference condition.

A CURRENT VALUE IS STRONGER EVIDENCE WHEN IT CAN BE COMPARED WITH A KNOWN, ACCEPTED CONDITION.

Separate routine monitoring from periodic verification

Monitoring supports operation. Verification demonstrates performance.

Routine monitoring	What periodic verification may need to add
BMS pressure trend	Independent pressure measurement and confirmation of sensor calibration/reference.
Fan operating status	Measured airflow and confirmation of available control authority.
Filter differential pressure	Applicable HEPA integrity testing and review of system resistance.
Alarm history	Functional alarm test and confirmation of response/notification.
Door/interlock status	Direct functional testing of the interlock sequence and recovery behavior.
Maintenance completion	Evidence that the affected containment function was restored after the intervention.

A BMS can display what selected sensors report. It cannot independently demonstrate that those sensors remain accurate or that all containment functions continue to perform as intended.

03

Directly verify pressure relationships

Pressure remains useful only if the measurement and reference remain credible.

Independent measurement

Compare installed monitors and BMS values with independent readings obtained using calibrated instruments.

Reference condition

Confirm pressure tubing, reference ports, and the space against which the differential is measured.

Cascade logic

Verify the full sequence of adjacent spaces rather than reviewing isolated room values only.

Directional airflow

Where applicable, confirm the intended direction of air movement across relevant transitions.

Compare with the baseline: a room may continue to meet its nominal pressure setpoint while requiring greater exhaust, showing poorer recovery, or operating with less available control margin than during commissioning.

04

Measure airflow where it matters

Pressure alone does not indicate how much air the system is moving or how much capacity remains available.

Periodic airflow measurement can reveal drift that pressure monitoring alone may conceal.

Review

- supply airflow;
- exhaust airflow;
- room balance;
- fan speed;
- damper position;
- filter differential pressure;
- indicators of available fan/control margin.

Why comparison matters

If the same pressure differential now requires substantially greater exhaust than during commissioning, the pressure value alone may conceal envelope leakage, increased resistance, or control drift.

The verification question is whether the current operating point remains consistent with the accepted condition of the system.

STABLE PRESSURE CAN COEXIST WITH CHANGES IN AIRFLOW, GREATER FAN DEMAND, AND REDUCED RESILIENCE.

HEPA filtration

When exhaust or supply HEPA filtration forms part of the containment strategy, periodic verification should consider:

- applicable integrity testing;
- condition of the housing and seal;
- condition of test access;
- filter pressure drop;
- replacement history;
- repeat testing after maintenance.

Other terminal barriers

As applicable, review the performance and condition of:

- pass-through autoclaves;
- decontamination systems;
- effluent treatment;
- sealed transfer devices;
- critical isolation valves;
- door/interlock assemblies.

The verification scope should follow the facility's actual containment architecture. Do not add tests that do not have a defined relationship to the accepted risk-control strategy.

Challenge alarms, interlocks, and control response

Normal operation does not demonstrate that the control system will behave correctly when a limit is crossed.

WHAT HAS CHANGED SINCE THE LAST VERIFIED CONDITION?

Maintenance interventions

Filter replacement, sensor calibration, door adjustment, control changes, and ductwork can alter previously verified conditions.

Setpoint drift

Pressure targets, alarm limits, and control parameters may have changed without formal reconciliation.

Component aging

Fans, dampers, actuators, seals, and sensors may degrade while the system continues to operate.

Operational change

Higher occupancy, new equipment, more frequent door opening, or modified procedures can alter system demand.

Undocumented modifications

New penetrations, repairs, or field changes may have altered the envelope or control configuration.

Loss of margin

A system may continue to meet nominal criteria while operating closer to its capacity limits than before.

Annual verification is one of the main opportunities to detect lifecycle drift before a visible failure appears.

WHAT OFTEN PASSES FOR “ANNUAL VERIFICATION”

“The BMS values are normal.”

Displayed normal values do not independently demonstrate calibration, airflow, filtration integrity, or response to disturbances.

“Maintenance was completed.”

A closed work order does not demonstrate restoration of the containment function affected by the intervention.

“The filters have an acceptable differential pressure.”

Differential pressure indicates resistance, not integrity.

“The room is still under negative pressure.”

A single pressure value does not establish the full cascade or the system’s available margin.

“Nothing has changed.”

Aging, drift, and the accumulation of minor interventions can alter performance without a formal project modification.

“We repeat the same checklist every year.”

A fixed checklist may overlook new risks, modified equipment, different operating patterns, or functions affected by recent maintenance.

VERIFICATION SHOULD FOLLOW THE CURRENT SYSTEM AND ITS HISTORY — NOT ONLY LAST YEAR’S CHECKLIST.

Define what to do when results show drift

Periodic verification only creates control if the institution knows how to act on the evidence.

Observed result	Possible response
Within criterion and consistent with the baseline	Document continued acceptability and retain the result in the lifecycle record.
Within criterion, but materially different from the baseline	Investigate the cause and determine whether margin, system resistance, or configuration changed.
Outside criterion	Evaluate the consequence for containment, operational restrictions, corrective action, and required repeat testing.
The test cannot be completed	Record the resulting uncertainty and determine whether temporary controls or restrictions are required.
Repeated marginal result	Consider a deeper system review rather than repeatedly accepting an increasingly reduced operating margin.

A result may remain technically “passing” and still show significant degradation relative to the accepted baseline.

DOES OUR VERIFICATION PROGRAM REALLY DEMONSTRATE CONTAINMENT?

01

Is there a known, accepted baseline?

No → reconstruct the baseline or establish a credible reference condition.

Yes → continue.

02

Does the annual program include direct measurement and not only BMS review?

No → add independent verification of critical measurements.

Yes → continue.

03

Are containment-critical barriers and functions tested where applicable?

No → identify unverified functions and define appropriate tests.

Yes → continue.

04

Are alarms, interlocks, and disturbance responses functionally challenged?

No → add appropriate functional checks.

Yes → continue.

05

Are current results compared with the previously accepted condition?

No → drift may remain invisible.

Yes → continue.

06

Is authority defined for deviations, restrictions, and return to service?

No → verification generates data without a complete control mechanism.

Yes → the program supports containment control across the lifecycle.

WHAT SHOULD THE RECORD SHOW?

Reference

- accepted baseline;
- current criteria;
- approved changes since the last verification;
- known restrictions.

Measurements

- pressure;
- airflow;
- sensor calibration;
- filter DP;
- other facility-specific critical parameters.

Functional checks

- alarms;
- interlocks;
- door recovery;
- redundancy/transition where required;
- barrier integrity where applicable.

Disposition

- deviations;
- corrective actions;
- repeat testing;
- restrictions;
- acceptance / return-to-service authority.

Record objective: retain sufficient evidence to show what was verified, against what criterion, what changed, and what the institution concluded from the result.

ANNUAL DOES NOT HAVE TO MEAN IDENTICAL

Periodic verification should be structured, but its scope can respond to the facility's actual condition across its lifecycle.

Core recurring checks

Some critical functions may warrant the same direct verification at each defined interval because they are central to containment performance.

Event-driven additions

Recent maintenance, equipment changes, alarm history, control modifications, or operational changes may justify additional verification beyond the routine annual scope.

Risk-based scope

The program should reflect:

- function criticality;
- likelihood of drift;
- maintenance history;
- consequence of failure;
- available monitoring;
- applicable requirements.

THE INTERVAL MAY BE PERIODIC. THE TECHNICAL SCOPE SHOULD CONTINUE TO RESPOND TO THE ACTUAL SYSTEM.

Verify the condition under which the measurement was taken

A correct result may still be unrepresentative if the facility was tested under an unusually favorable condition.

Periodic verification should record the operating configuration in sufficient detail to determine whether the result represents the condition the laboratory actually uses.

Operating state

- occupied or unoccupied;
- normal or reduced mode;
- doors closed or representative cycles;
- primary containment equipment operating as expected;
- normal support systems available.

Mechanical state

- duty/standby equipment status;
- operating position of fans and dampers;
- filter condition;
- temporary overrides or manual commands;
- known maintenance limitations.

Control state

- active setpoints;
- alarm delays;
- control sequence review;
- BMS/PLC mode;
- disabled points or temporary logic.

Test traceability

- instrument identification and calibration status;
- date/time;
- test method;
- raw result;
- acceptance criterion;
- person performing and person reviewing the test.

Diagnostic question: would the same containment function be expected to continue meeting its criterion under a representative operating state and not only under the most favorable test condition?

THE CALENDAR IS NOT THE ONLY TRIGGER

A scheduled annual or periodic review is useful, but containment-critical verification may also be necessary after events that make previous evidence no longer representative.

Examples of event-based triggers

- intervention involving a HEPA filter or housing;
- airflow rebalancing or fan work;
- pressure sensor replacement or recalibration;
- door, seal, or envelope repair;
- control sequence or setpoint change;
- new penetration or room modification;
- significant electrical event or abnormal system excursion;
- activity change that modifies the accepted risk or operating basis.

Do not wait until the next anniversary

If an intervention changes the function that the periodic program is intended to verify, the corresponding evidence should be re-established before relying again on the previously accepted condition.

The scope may be directed to the affected function; this does not automatically require repeating all periodic tests.

PERIODIC VERIFICATION CONFIRMS CONTINUITY. EVENT-BASED VERIFICATION CONFIRMS RESTORATION AFTER CHANGE.

DOES THE PROGRAM GENERATE CURRENT EVIDENCE OF CONTAINMENT?

Use this list as a review filter. A checked item does not constitute acceptance; each element should be interpreted against the risk basis, facility configuration, and applicable criteria.

- ☐ Identify the accepted baseline and the containment functions that require periodic evidence.
- ☐ Confirm that the current facility configuration still corresponds to the baseline used for comparison.
- ☐ Use appropriate calibrated instruments and record instrument identification, method, and test condition.
- ☐ Distinguish BMS monitoring from independent measurement and functional verification.
- ☐ Verify pressure relationships and airflow rates where they remain critical to containment.
- ☐ Confirm HEPA system integrity and other barrier functions at the interval or trigger appropriate to the facility.
- ☐ Test relevant alarms, interlocks, and control responses rather than limiting the review to status displays.
- ☐ Include representative disturbances or failure-response checks where they form part of the accepted containment strategy.
- ☐ Review maintenance, modifications, and abnormal events that may require targeted reverification before the next scheduled cycle.
- ☐ Document deviations, corrective actions, repeat testing, and the authority to continue operation or return to service.

Technical-use note: This checklist is a diagnostic support tool. It does not establish site-specific acceptance criteria, replace risk assessment or professional judgment, constitute certification, or authorize operation or return to service.

If the review identifies a condition requiring site-specific evaluation, BioLab Solutions can support technical assessment, verification, and definition of the required evidence.

EXPLORE VERIFICATION, MAINTENANCE, AND LIFECYCLE DRIFT IN GREATER DEPTH

NT-010-013

Directional airflow, pressure cascades, ACH, and pressure-control failure modes

NT-019-024

HEPA integrity, envelope continuity, and leak-tightness verification

NT-037

Maintenance as a containment risk domain

NT-016-017

Redundancy and control hierarchy

NT-032-035

Commissioning, functional testing, authority, and documentation

NT-039

Lifecycle drift in containment systems

BIOLAB DIAGNOSTIC GUIDES

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

Series concept: symptom → system → evidence → restoration.

VERIFY THE FUNCTION, NOT JUST THE SCREEN.

Periodic verification should answer a simple question: does the facility continue to perform credibly relative to the condition accepted by the institution?

BMS trends, maintenance records, and routine monitoring are important parts of operational control. They become stronger evidence when supported by direct measurement, functional testing, and comparison with a known baseline.

The objective is not to recreate commissioning every year. It is to detect drift, loss of margin, failed barriers, or changes in behavior early enough for the institution to act before those conditions become normalized.

BIOLAB SOLUTIONS

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

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

BASELINE → MEASURE → CHALLENGE → COMPARE