# CAN WE SAFETY MODIFY THIS CONTAINMENT LABORATORY?

Diagnostic Guide
GD-003

Technical diagnostic guide for change control, system dependencies, and reverification in high-containment laboratories

Practical guide for evaluating equipment additions, airflow changes, room modifications, new procedures, and other changes before they become part of the operating condition.

DIAGNOSTIC GUIDE

HOW TO USE THIS GUIDE

# A SMALL CHANGE CAN REOPEN AN IMPORTANT ASSUMPTION.

This guide was created for changes that appear local but may alter a containment function elsewhere in the system.

### Why we developed it

High-containment laboratories are routinely modified after commissioning. Equipment is replaced, workflows change, penetrations are added, pressure setpoints are adjusted, rooms are reassigned, and maintenance solutions can become permanent operating conditions.

The immediate change may be reasonable within one discipline while also altering the assumptions that support zoning, airflow, envelope integrity, redundancy, decontamination, or operational controls.

The purpose of this guide is to help distinguish which modifications can be managed locally and which require a broader containment review.

### Who can use it

It is intended for facility managers, biosafety personnel, engineers, maintenance teams, project managers, operators, and institutional authorities responsible for changes in an operating containment laboratory.

It can be used before a planned modification or retrospectively when a change has already occurred and the institution needs to determine what must be reassessed or reverified.

> PRACTICAL USE
>
> Define the proposed change, identify the containment functions it may affect, compare the new condition with the accepted baseline, determine the required level of technical review, and establish the verification needed before return to service.
>
> **The objective is not to turn every modification into a major project. It is to prevent a local change from silently altering a system assumption that no one intended to reopen.**

01 DEFINE

02 TRACE

03 REVIEW

04 VERIFY

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

This guide is a general diagnostic orientation 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 for internal technical reference.

### It does not constitute

This guide does not constitute a design, specification, operating procedure, institutional change-control process, acceptance criterion, certification, compliance determination, authorization for modification or operation, or a site-specific recommendation.

### Technical and operational decisions

No modification, intervention on critical systems, setpoint change, approval of works, continuation of operation, or return to service should be based solely on this guide.

### Applicable technical basis

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

### Competent personnel

Changes that may affect functions critical to containment should be reviewed, designed, executed, and verified by appropriately qualified personnel, with clearly defined authority to approve the new condition.

### 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.

# 01 Begin by defining the change precisely

"Replace equipment" or "adjust airflow" is not sufficient information to evaluate the consequence for containment.

A change-control review begins by describing exactly what will be different when the work is complete.

### Physical change

- new opening or penetration;
- door or wall modification;
- equipment relocation;
- new utility connection;
- change to supply or exhaust ductwork.

### Mechanical / controls change

- airflow quantity;
- setpoint or alarm threshold;
- damper or control sequence;
- fan or filter arrangement;
- redundancy logic.

### Operational change

- new procedure;
- higher throughput;
- new equipment load;
- new material-transfer route;
- change in occupancy or schedule.

### Change in the risk basis

- new agent or activity;
- different scale;
- greater aerosol potential;
- new waste stream;
- new decontamination requirement.

**Define the post-change condition:** what will exist, operate, or occur differently after the modification?

# 02 Identify the dependencies the change may affect

Containment modifications propagate through interfaces.

A change should be reviewed against the functions that depend on the altered condition.

| Change | Dependencies that may require review |
|---|---|
| **New penetration** | Envelope continuity, sealing detail, room leakage, pressure stability, and compatibility with decontamination. |
| **New equipment** | Heat load, airflow, exhaust demand, normal and emergency electrical load, utilities, drainage/condensate where applicable, space and clearances, access for maintenance and replacement, workflow, vibration, floor loading, and local containment. |
| **Airflow reduction** | Pressure cascade, directional airflow, heat load, dilution need, recovery, and control authority. |
| **Door modification** | Envelope leakage, interlock logic, pressure recovery, personnel flow, and emergency egress. |
| **Change en sistema HEPA** | Housing integrity, testability, system resistance, fan capacity, bypass risk, and exposure during maintenance. |
| **New procedure** | Risk assessment, primary containment, zoning, PPE, decontamination, waste, airflow, and operating limits. |
| **Change de setpoint** | Cascade logic, alarm limits, fan authority, adjacent rooms, and the accepted commissioning baseline. |

**THE CHANGE IS LOCAL. ITS DEPENDENCIES MAY NOT BE.**

EQUIPMENT INTEGRATION SCREEN

# NEW EQUIPMENT IS A CHANGE TO THE FACILITY, NOT JUST A PURCHASE

Adding equipment often creates secondary requirements that do not appear in the equipment specification itself.

### Space and movement

- installed footprint and service clearances;
- entry route through doors and transfer points;
- route for maintenance and replacement;
- operator circulation and emergency egress;
- floor loading and vibration where applicable.

### Environmental load

- sensible and latent heat;
- local exhaust or interaction with room air;
- air-discharge direction and turbulence;
- noise and vibration;
- operating temperature/humidity limits.

### Utilities and resilience

- normal power and need for UPS/emergency power;
- water, gases, vacuum, or compressed air;
- drainage or condensate;
- network/BMS interfaces;
- shutdown behavior upon utility loss.

### Containment and operation

- primary containment function;
- compatibility with cleaning/decontamination;
- waste and consumable routes;
- effect on pressure cascade and door cycles;
- exposure and isolation during maintenance.

> **Integration question:** can the equipment be installed, operated, maintained, decontaminated, and ultimately replaced without invalidating the accepted containment basis?

# 03 Compare the proposed condition with the accepted baseline

Change control requires a reference condition.

Before approving a modification, establish what the facility was originally designed, commissioned, and accepted to do.

### Useful baseline records

- Basis of Design;
- risk assessment;
- approved drawings;
- control sequences;
- commissioning results;
- TAB reports;
- HEPA integrity records;
- accepted setpoints and alarms;
- O&M manuals;
- as-built documentation.

### Baseline question

Does the proposed change preserve the assumptions and performance criteria against which the facility was accepted?

If not, identify exactly which assumptions are being reopened and who has authority to accept the new condition.

If no reliable baseline exists, it may be necessary to reconstruct it before confidently judging the technical consequence of the change.

# 04 Determine the required level of review

Not all changes require the same process.

| Level of change | Typical review approach |
|---|---|
| **Routine equivalent replacement** | Confirm true equivalence in performance, materials, pressure drop, control characteristics, interfaces, and maintainability, together with installation requirements and post-maintenance verification appropriate to the affected function. |
| **Like-for-like replacement with modified characteristics** | Technical review of capacity, compatibility, controls, pressure drop, materials, maintenance, and verification implications. |
| **Modification affecting containment** | Multidisciplinary review against the risk basis, envelope, HVAC, controls, operation, and commissioning criteria. |
| **Change in work or risk basis** | Risk reassessment followed by review to determine whether existing infrastructure and procedures remain appropriate. |
| **Major system reconfiguration** | Formal design development, documented approval, construction controls, and partial or full recommissioning as appropriate. |

> **Key distinction:** “same function” does not always mean “same containment consequence.” Component equivalence must be judged against the system in which it operates.

# 05 Review temporary conditions during the work

Containment may be altered before the final modification is complete.

## The intervention may create a higher-risk condition than the completed installation.

### Opening the envelope

Will the work create an open penetration, remove a housing, alter a seal, or expose a previously closed interface?

### System isolation

Will a fan, filter, damper, interlock, alarm, or pressure zone be taken out of service?

### Contamination status

Does the affected system require decontamination or a documented safe condition before intervention?

### Temporary controls

Are barriers, pressure adjustments, work restrictions, monitoring, or alternative controls required during the intervention?

**CHANGE CONTROL INCLUDES THE PATH FROM THE PREVIOUS CONDITION TO THE NEW ONE, NOT JUST THE FINAL RESULT.**

# TEMPORARY DOES NOT MEAN UNCONTROLLED

A temporary configuration can alter containment just as effectively as a permanent one. The difference is that it should have a defined duration, monitoring requirement, and exit condition.

### For a temporary change, define

- reason and technical basis;
- start date and responsible authority;
- temporary barriers, setpoints, or operating restrictions;
- monitoring and alarm expectations;
- maximum duration or review date;
- criteria for reversal or permanent approval;
- verification required when restoring the original condition or establishing the new permanent condition.

### Changes de emergencia

An urgent intervention may require action before the normal review sequence is complete. That does not eliminate change control.

Record what was changed, why immediate action was necessary, who authorized it, what temporary safeguards apply, and when the retrospective technical review must be completed.

The emergency condition should not become the mechanism by which an undocumented configuration becomes permanent.

**EVERY TEMPORARY CONDITION NEEDS AN OWNER, AN EXPIRATION OR REVIEW DATE, AND A DEFINED PATH BACK TO FULL TECHNICAL CONTROL.**

CHANGE TRIGGERS

# WHEN SHOULD THE RISK BASIS BE REOPENED?

### New biological agent or hazard

The existing strategy may have been justified for a different hazard profile.

### New procedure or scale

Aerosol generation, volumes, frequencies, or exposure routes may change even when the agent is the same.

### Change in primary containment

Replacing or removing source-control equipment may change the expected role of secondary containment.

### Change in waste or decontamination route

A new material stream may cross boundaries or require treatment not considered in the original design.

### Higher occupancy or throughput

Door cycling, equipment load, waste generation, and operational intensity may exceed the original assumptions.

### Change in room use

Reassigning a room may alter zoning, pressure relationships, equipment needs, and clean/dirty transitions.

> A change in biological risk or activity should be evaluated before deciding that the physical infrastructure may remain unchanged.

COMMON CHANGE-CONTROL FAILURES

# WHAT COMMONLY GOES WRONG

### “It is only a small penetration.”

Small penetrations also alter the envelope and may require defined sealing and subsequent verification.

### “The replacement component is equivalent.”

Equivalent capacity or dimensions do not demonstrate equivalent control behavior, resistance, access, maintainability, or testability.

### “We only changed the setpoint.”

A setpoint change may alter cascade relationships, fan operating point, alarm logic, and the accepted baseline.

### “The procedure is similar.”

Similar work may differ in scale, aerosol potential, waste, equipment, and exposure routes.

### “Maintenance already made the change.”

A change that has already been implemented still requires technical evaluation if it altered a condition critical to containment.

### “The room still shows negative pressure.”

A familiar pressure value does not demonstrate that envelope, airflow, and control assumptions remain unchanged.

**INFORMAL CHANGE BECOMES CONFIGURATION DRIFT WHEN THE NEW CONDITION IS NOT TECHNICALLY RECONCILED.**

# 06 Define verification before starting the work

The change should carry its own return-to-service logic.

The level of post-work verification should correspond to the containment function that was altered.

| Modification | Possible verification needs |
|---|---|
| **Pressure sensor replacement** | Calibration, independent comparison, and alarm/BMS confirmation. |
| **Work on door or seal** | Closure, fit/leakage review, pressure recovery, and confirmation of directional airflow. |
| **New penetration** | Seal inspection and envelope verification appropriate to the facility criteria. |
| **Airflow rebalancing** | Supply/exhaust measurement, cascade verification, alarms, and response to disturbances. |
| **Work on HEPA filter/housing** | Applicable integrity testing, airflow confirmation, and review of pressure relationships. |
| **Modification de secuencia de control** | Functional testing under normal, transitional, and relevant failure conditions. |
| **Change mayor del sistema** | Partial or full recommissioning against updated criteria. |

# 07 Control the documentation

A modification is incomplete if the accepted configuration can no longer be reconstructed.

### Update as applicable

- as-built drawings;
- control sequences;
- software/firmware or controller configuration where applicable;
- setpoints;
- alarm thresholds;
- equipment programs;
- maintenance procedures;
- O&M manuals;
- interfaces with SOPs;
- commissioning baseline;
- risk assessment.

### Preserve the decision

Record:

- what changed;
- why it changed;
- who reviewed it;
- which technical criteria applied;
- what verification was performed;
- who authorized return to service.

**IF THE NEW CONDITION IS NOT DOCUMENTED, THE NEXT CHANGE STARTS FROM AN UNRELIABLE BASELINE.**

DIAGNOSTIC SEQUENCE

# CAN THIS CHANGE BE MADE SAFELY?

01

**Is the post-change condition clearly defined?**

No → define exactly what will be different physically, mechanically, or operationally.

Yes → continue.

02

**Does the change affect a containment dependency?**

No → manage it through routine technical change control.

Yes or uncertain → continue.

03

**Does it alter the risk basis or accepted activity assumptions?**

Yes → reopen the risk assessment before approving infrastructure.

No → continue.

04

**Can it be reviewed against a reliable baseline?**

No → reconstruct the baseline or establish the current condition.

Yes → continue.

05

**Were temporary intervention conditions controlled?**

No → define isolation, decontamination, barriers, restrictions, and monitoring.

Yes → continue.

06

**Is post-work verification defined before return to service?**

No → establish verification and acceptance criteria.

Yes → proceed under the defined authority.

CHANGE REVIEW PACKAGE

# WHAT SHOULD BE AVAILABLE BEFORE APPROVAL

## Change definition

- scope;
- reason;
- affected room/system;
- drawings or sketches;
- temporary conditions.

## Risk basis

- current activity;
- proposed activity;
- hazards;
- exposure routes;
- required controls.

## Technical baseline

- BoD;
- as-builts;
- commissioning data;
- setpoints;
- control logic;
- equipment data.

## Verification plan

- required tests;
- acceptance criteria;
- responsible party;
- restrictions;
- return-to-service authority.

**Review objective:** make the technical consequence of the change visible before it becomes part of normal operation.

# WHAT IF THE CHANGE HAS ALREADY OCCURRED?

An undocumented modification does not become acceptable simply because the laboratory continued operating without an evident event.

### Reconstruct what changed

- identify the original condition;
- identify the modified condition;
- determine who made or approved the change;
- review current operating data;
- identify affected containment functions.

### Reconcile the current condition

Determine whether the modification requires:

- rerisk assessment;
- engineering correction;
- updated documentation;
- functional testing;
- partial recommissioning;
- temporary operating restrictions.

> **THE PURPOSE OF RETROSPECTIVE REVIEW IS TO RETURN AN INFORMAL CHANGE TO TECHNICAL CONTROL.**

CHANGE REVIEW CHECKLIST

# BEFORE TURNING A MODIFICATION INTO AN OPERATING CONDITION

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

□ Define exactly what changes and what the physical and operational condition will be after the modification.

□ Compare the proposed condition with the accepted baseline and the assumptions of the risk assessment.

□ Identify potentially affected containment functions: pressure, airflow, boundary, filtration, decontamination, alarms, energy, waste, or circulation.

□ Map dependencies beyond the intervention point, including shared systems and effects on adjacent spaces.

□ Classify the change by technical consequence, not solely by cost, size, or discipline.

□ Define the temporary state during the work: isolations, restrictions, monitoring, duration, and responsible party.

□ Establish before intervention which measurements and tests will demonstrate the new condition.

□ Confirm the technical and institutional authority required to approve the change and return to operation.

□ Update drawings, sequences, setpoints, O&M, SOPs, and configuration records once the change is accepted.

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

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

RELATED BIOLAB RESOURCES

# EXPLORE CHANGE, BOUNDARIES, AND LIFE-CYCLE CONTROL IN GREATER DEPTH

**NT-006**
Containment boundaries as designed objects

**NT-007–009**
Penetrations, doors, and transfer interfaces

**NT-016–017**
Redundancy and control authority

**NT-021–024**
Envelope continuity and airtightness

**NT-032–035**
Commissioning, authority, and documentation

**NT-037**
Maintenance as a containment risk domain

**NT-039**
Life-cycle drift in containment systems

**NT-040**
Risk assessment as a design input

**NT-049–051**
Decision ownership and authority interfaces

BIOLAB DIAGNOSTIC GUIDES

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

Series concept: symptom → system → evidence → restoration.

CLOSING DIAGNOSTIC PRINCIPLE

# CONTROL THE CHANGE BEFORE THE CHANGE CONTROLS THE SYSTEM.

Containment laboratories necessarily change. The control question is whether those changes remain traceable to the risk basis and the accepted condition of the system.

A modification may be technically small and still affect airflow, boundaries, controls, maintenance access, decontamination, or operating assumptions.

Effective change control makes those dependencies visible, assigns the appropriate review authority, and defines how the new condition will be demonstrated before it becomes routine.

BIOLAB SOLUTIONS

Independent technical support for planning, design, commissioning, assessment, and life-cycle management of high-containment laboratories.

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

**CHANGE → DEPENDENCIES → REVIEW → REVERIFICATION**