

Technical guidance for surveillance of containment performance in high-containment laboratory environments.

GUIDANCE DOCUMENT

PURPOSE AND USE

WHY THIS GUIDE

High-containment laboratories are usually designed, commissioned, verified, maintained, and periodically certified through formal technical processes. Those activities are essential, but they do not by themselves provide continuous assurance that the conditions supporting containment remain unchanged between formal review points.

Facilities evolve. Workload increases, equipment is added, procedures change, personnel leave, systems are adjusted, maintenance is deferred, temporary measures persist, and building conditions shift. Many of these changes are legitimate and manageable. The difficulty is that they can accumulate gradually while the laboratory continues to appear normal.

A room may still maintain negative pressure while the exhaust system works harder to do so. A biological safety cabinet (BSC) may remain certified while the airflow environment around it changes. A temporary operating measure may persist long enough to become routine. A new institutional mandate may increase containment demands without changing the laboratory's formal designation, even when the new activities call for review of the technical, architectural, or operational conditions supporting that designation.

This guide is intended to help laboratory personnel, biosafety professionals, facility managers, engineers, and institutional decision-makers recognize those changes earlier and interpret them in context.

It does not ask whether a laboratory is simply "in compliance" at a particular moment. It asks whether the containment system is still behaving as expected, whether the conditions under which it was previously justified still apply, and whether changes are being understood and managed before they become failures.

The emphasis is therefore on surveillance: observing change, preserving evidence, recognizing patterns, and knowing when local follow-up is sufficient and when broader evaluation is warranted.

HOW TO USE THIS GUIDE

USE THE GUIDE BY SIGNAL OR BY SURVEILLANCE INTERVAL

This guide is intended to support routine surveillance of containment performance between formal verification, certification, maintenance, and risk-assessment activities.

It is not a commissioning protocol, maintenance manual, or pass/fail inspection checklist. Its purpose is to help laboratory personnel, biosafety staff, facility managers, engineers, and institutional representatives recognize when the conditions supporting containment may be changing, understand why the change may matter, and decide whether local follow-up is sufficient or broader review is needed.

The guide can be used in two ways.

The **domain sections** are useful when a particular signal has already been identified—for example, changing room pressure, recurring door problems, a new piece of equipment, loss of technical personnel, or an unresolved temporary measure.

The **surveillance-interval section** provides a practical rhythm for reviewing the facility routinely, approximately every six months, annually, and after significant change.

Throughout the guide, a **signal** should not be interpreted automatically as evidence of containment failure. Many changes have legitimate explanations. The purpose of surveillance is to preserve enough evidence to distinguish normal variation, intentional modification, deterioration, changing operational demand, and unresolved uncertainty.

The suggested surveillance frequencies do not replace:

- applicable legal or regulatory requirements;
- manufacturer instructions;
- certification or validation intervals;
- facility-specific risk assessments;
- commissioning or requalification requirements;
- institutional maintenance programs.

Where those requirements establish a more specific or more frequent activity, they take precedence.

A useful general sequence when a signal is identified is:

Confirm the observation → identify relevant recent changes → compare with the justified reference state → determine whether the issue appears local or interacting with other systems → correct where the cause is understood → verify the resulting condition → escalate where the explanation remains incomplete.

READING REFERENCE

TERMS USED IN THIS GUIDE

The following definitions clarify terms used in containment performance surveillance. They should be read alongside applicable requirements, risk assessments, and facility-specific documentation.

Reference state: the most recent operating condition that can be technically justified and demonstrated to have been accepted or verified.

Operating basis: the assumptions, criteria, activities, and relationships between systems that justify the reference state.

Escalation: referral of a condition for broader review when a local explanation is no longer sufficient.

High-containment laboratory: a facility whose activities require enhanced containment measures in response to identified risks; its designation and specific requirements depend on the applicable framework and risk assessment.

As-built drawings: documents representing the facility as actually constructed or installed, including verified modifications, rather than only the original design.

Interlock: a control function that makes the action or status of one component conditional upon a defined condition; overriding an interlock defeats that control relationship.

Personal protective equipment (PPE): equipment used by personnel as part of protective measures identified through risk assessment.

Transient excursion: an isolated or temporary departure of a variable from its expected range or behavior; it requires contextual interpretation and does not necessarily indicate failure.

Administrative closure and technical closure: the first records completion of an activity or case; the second requires sufficient evidence that the required technical function was restored or confirmed.

Standard operating procedure (SOP): a documented instruction specifying how to perform an operational activity in a defined manner.

Current operating condition: what the facility is doing now, which may or may not correspond to its justified reference state.

Signal: an observation requiring interpretation; it does not, by itself, establish a failure.

Containment: the set of measures and functions intended to prevent or reduce exposure to, and unintended release of, biological agents, according to facility risks and activities.

Enhanced control measures: measures additional to basic biosafety practices and requirements, selected through risk assessment; the term does not automatically designate a laboratory category.

Testing, adjusting, and balancing (TAB): measurement and adjustment of ventilation systems to verify and balance relevant airflows and parameters against applicable criteria.

Original equipment manufacturer (OEM): the manufacturer of the original equipment or component, whose support may be relevant to spare parts, maintenance, and verification.

Biological safety cabinet (BSC): a primary containment device intended to provide protection according to its type, configuration, installation, and conditions of use.

Containment boundary defect: a localized change in a door, joint, sealant, penetration, interface, or other physical boundary element that may affect its continuity or behavior.

Uninterruptible power supply (UPS): equipment that temporarily maintains electrical power to connected loads during a supply interruption, according to its configuration and autonomy.

Information technology (IT): data, communication, and computing systems, including those that may interact with control or recording systems.

USE AND LIMITATIONS

SCOPE AND LIMITATIONS

This guide provides general technical guidance for surveillance of containment performance in high-containment laboratory environments.

The general principles of surveillance may also help inform observation of changes in maximum-containment facilities. However, the signals, review methods, response criteria, and escalation decisions must be evaluated against those facilities' specific containment strategies, risks, and applicable requirements. This guide does not, by itself, establish a surveillance programme or acceptance criteria for maximum-containment laboratories.

It is not a substitute for:

- applicable laws, regulations, standards, codes, or institutional requirements;
- facility-specific risk assessment;
- commissioning, qualification, certification, validation, or recommissioning;
- manufacturer instructions;
- professional engineering judgment;
- biosafety or occupational-health assessment;
- emergency procedures;
- or specialist evaluation of a specific facility, system, incident, or deficiency.

The examples, surveillance intervals, and response considerations presented here are intended to support professional judgment, not to establish universal acceptance criteria.

Containment strategies differ according to facility design, agents and activities, local requirements, operating history, and institutional context. A condition described in this guide as a signal does not, by itself, demonstrate loss of containment, noncompliance, or system failure. Likewise, the absence of an identified signal does not demonstrate that a facility is safe or performing adequately.

Where an observation affects a critical containment function, cannot be explained with reasonable confidence, or falls outside the competence or authority of the personnel involved, the condition should be referred for appropriate technical or institutional evaluation.

BioLab Solutions assumes no responsibility for decisions made solely on the basis of this guide without consideration of the specific facility, applicable requirements, and competent professional review. Applying this guidance requires those conditions to be evaluated before a decision is taken.

Suggested citation and permitted use

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Surveillance summary

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SURVEILLANCE SUMMARY

This matrix is intended as a navigation aid. A check mark indicates that the condition is particularly relevant at that surveillance interval; it does not imply that the condition should be ignored at other times.

Signal or condition	Routine / monthly	~6-month review	Annual review / verification	Event-triggered	Guide section
Reference state cannot be established confidently			✓	✓	1.1
Reference data exist but are not being used for comparison		✓	✓		1.2
Current work no longer matches the conditions under which the facility was verified		✓	✓	✓	1.3
Institutional mandate or mission changes				✓	2.1
Leadership change affects containment support			✓	✓	2.2
Responsibility becomes fragmented or unclear		✓	✓	✓	2.3
Resource constraints affect maintenance, verification, or corrective work		✓	✓	✓	2.4
Critical technical competence is lost			✓	✓	2.5
Change control is being bypassed or weakened		✓	✓	✓	2.6
Corrective actions remain open or recur	✓	✓	✓		2.7
Temporary conditions become normal operation	✓	✓	✓		2.8
External technical support or procurement arrangements change		✓	✓	✓	2.9
Institutional memory is being lost		✓	✓	✓	2.10
Workload increases materially	✓	✓	✓	✓	3.1
New procedures are introduced				✓	3.2
Process scale increases				✓	3.3
New equipment is installed				✓	3.4
Equipment is relocated				✓	3.5
Room function changes gradually	✓	✓	✓		3.6
Occupancy changes	✓	✓			3.7
Working hours or shifts change		✓	✓	✓	3.8
Agents or biological materials change				✓	3.9
Waste generation or characteristics change	✓	✓	✓	✓	3.10
Personnel or material flows change	✓	✓		✓	3.11
Maintenance temporarily alters normal operating conditions				✓	3.12
Cleaning or decontamination practices change	✓			✓	3.13
PPE strategy changes		✓		✓	3.14

SURVEILLANCE SUMMARY · CONTINUED

Signal or condition	Routine / monthly	~6-month review	Annual review / verification	Event-triggered	Guide section
Workarounds become routine	✓	✓	✓		3.15
Pressure relationships shift	✓	✓	✓	✓	4.1
Pressure becomes more variable or unstable	✓	✓	✓	✓	4.2
Recovery after disturbance changes		✓	✓	✓	4.3
More control effort is required to maintain the same condition		✓	✓	✓	4.4
Control parameters are repeatedly adjusted		✓	✓	✓	4.5
Available operating margin narrows		✓	✓	✓	4.6
Redundancy exists but is not available	✓	✓	✓	✓	4.7
Seasonal or external conditions affect performance		✓	✓		4.8
Door behavior changes	✓	✓		✓	5.1
Seals, joints, finishes, or interfaces deteriorate	✓	✓	✓		5.2
New penetrations appear	✓			✓	5.3
The same boundary defect is repeatedly repaired	✓	✓	✓		5.4
A primary containment device is operating in changed surroundings	✓	✓	✓	✓	6.1
Operators report changed equipment behavior	✓			✓	6.2
Sterilization or decontamination cycles behave differently	✓	✓	✓	✓	6.3
Rarely used critical systems have not demonstrated readiness		✓	✓		6.4
Utility reliability or quality changes	✓	✓	✓	✓	7.1
Emergency-power transfer or recovery behaves differently			✓	✓	7.2
Emergency-power loading increases			✓	✓	7.3
Changes elsewhere in the building affect containment		✓		✓	8.1
Adjacent construction affects containment conditions	✓	✓		✓	8.2
Post-maintenance restoration of integrated performance is not confirmed				✓	9.1
The same system requires repeated corrective maintenance	✓	✓	✓		9.2
Measurements intended to describe the same condition disagree	✓	✓	✓	✓	10.1
Only instantaneous data are available		✓	✓		10.2

INTERPRETING AND DOCUMENTING A SIGNAL

A signal acquires meaning through context. The same observation may reflect normal variation, an intentional modification, progressive deterioration, or a condition that is not yet understood.

Surveillance is not intended to turn every change into an extensive investigation. Its purpose is to preserve enough context to decide what can be explained locally and what deserves broader review.

Four useful questions

When a signal is observed, ask:

- Is it new, or does it represent a change from known behavior?
- Is it isolated, or is it recurring, increasing, or forming a trend?
- Is more control effort required to maintain the same result?
- Does it coincide with other technical, operational, or institutional changes?

These questions do not establish severity or replace technical evaluation. They help determine what context should be preserved.

What to preserve when something changes

Before an adjustment, repair, or operational change removes the context, preserve—where reasonably practicable—the date and time, affected room or system, observed condition, operating state at the time, recent changes that may be related, whether the condition has occurred before, and any available objective data.

This does not replace an investigation. It helps prevent the evidence needed to interpret the change from disappearing before it can be reviewed.

ESCALATION TRIGGER

WHEN NOT TO WAIT FOR THE NEXT REVIEW

Some conditions justify prompt assessment rather than waiting for the next monthly, six-monthly, or annual surveillance cycle.

Immediate or expedited review is appropriate when there is:

- loss or uncertainty of required directional airflow;
- inability to maintain an intended pressure relationship;
- significant or unexplained instability affecting several rooms;
- failure of a containment-critical ventilation or control function;
- loss of required redundancy when an additional failure could compromise a necessary containment function;
- significant damage to a containment boundary;
- failure or suspected failure of a critical decontamination or sterilization process;
- major power, utility, flooding, or building event affecting containment systems;
- an incident or near miss suggesting that an assumed control did not perform as expected;
- major ventilation, controls, barrier, or equipment modification;
- a significant change in agent, procedure, scale, or facility use;
- evidence that the existing reference state can no longer be justified;
- an unresolved condition that is being compensated for through repeated adjustment or temporary measures.

The required response should remain proportionate to the condition. Not every trigger requires a full system evaluation. The point is that the change should be examined before routine operation allows it to become the new assumed normal.

A trigger for review is not a finding of failure

The surveillance approach used throughout this guide deliberately treats changes as **signals for interpretation**, not automatic findings of nonconformity.

Pressure may move because of normal variation. Increased fan speed may follow an intentional change in operating demand. A new procedure may remain fully compatible with the existing controls. Leadership change may have no adverse effect on the containment program. Even recurrence does not determine the cause by itself.

The value of surveillance lies in retaining enough information to tell those conditions apart.

A facility that notices change early can confirm whether it is real, connect it with other changes occurring at the same time, and decide whether local action is sufficient. Where the condition is expected and understood, surveillance may simply document that conclusion. Where the explanation remains incomplete, the signal stays visible rather than disappearing into a new setpoint, a closed work order, or a practice that gradually becomes normal.

That distinction is what allows surveillance to remain proportionate. It avoids treating every variation as failure while also avoiding the opposite assumption that continued operation proves that nothing important has changed.

01 Reference state and uncertainty

Containment surveillance depends on comparison. A current pressure value, airflow measurement, fan speed, alarm threshold, or equipment status can describe what the facility is doing now, but its significance often depends on knowing what condition preceded it and why that earlier condition was considered acceptable.

The reference state does not have to be the original commissioning condition. A facility may have been legitimately modified, rebalanced, recommissioned, or requalified since it first entered service. The useful reference is the most recent operating condition that can be technically justified and shown to have been accepted or verified.

Where that condition is uncertain, surveillance can still proceed, but the uncertainty itself has to be recognized. Otherwise current practice can gradually acquire the status of “normal” simply because no better historical reference remains.

1.1 No reliable reference state can be identified

SIGNAL

The laboratory is operating, but there is no sufficiently reliable record of the condition against which current performance should be compared.

Possible indicators include:

- commissioning or testing, adjusting, and balancing (TAB) records cannot be located;
- only design values remain, without evidence that those values were achieved during operation;
- only current building management system (BMS) setpoints are known;
- pressure targets, alarm thresholds, or control parameters have changed without retained justification;
- as-built information no longer reflects the installed facility;
- major modifications occurred without corresponding verification or requalification;
- staff describe present conditions as “normal” but cannot establish when or how those conditions were accepted.

WHY THIS MATTERS

The absence of a reliable reference state does not mean that the laboratory is operating incorrectly. It means that current measurements are difficult to interpret over time.

A pressure value, airflow measurement, fan speed, or alarm threshold may describe the present condition accurately while providing little evidence about how that condition arose. It may represent the intended state, a later justified modification, gradual deterioration, or a configuration that became accepted through repeated use. Those possibilities can lead to very different decisions even when the current number is identical.

The risk is therefore not only that deterioration may go unnoticed. The opposite error is also possible: a legitimate later modification may be mistaken for deterioration because someone compares the facility with an obsolete design value. Surveillance requires a reference that is technically defensible, not simply the oldest value that can be found.

WHAT TO REVIEW

Look for evidence that can help reconstruct the most recent justified operating condition. Depending on the facility, useful sources may include:

- commissioning, qualification, or recommissioning records;
- TAB and airflow verification data;
- BMS trend history;
- change-control records;
- controls modifications;
- maintenance history associated with major system changes;
- certification or validation records;
- as-built drawings and later modification drawings;
- incident and corrective-action records.

Interviews with personnel who understand earlier configurations can help establish sequence and context, but recollection should not be treated as equivalent to verified measurement.

Where records conflict, retain the discrepancy as uncertainty until it can be resolved rather than selecting whichever value appears most convenient.

RESPONSE

Establish explicitly which parts of the previous operating state can still be supported by evidence and which cannot.

Do not declare current setpoints or current practice to be the reference state solely because earlier information is missing. If sufficient evidence remains, reconstruct the reference state from the available technical history. If the earlier state cannot be recovered with reasonable confidence, establish and verify a new reference state based on the facility as it exists and operates now.

The objective is not to recreate the past at all costs. It is to create a defensible point from which future change can be interpreted.

ESCALATION

A broader technical review is warranted when:

- critical airflow, pressure, alarm, or control values cannot be justified;
- historical records materially conflict;
- major undocumented modifications have accumulated;
- current performance cannot be related to any previously verified state;
- or uncertainty about the reference state prevents the facility from determining whether an observed change is significant.

SURVEILLANCE MODE

Event-triggered review.

This should be addressed when a surveillance program is first established, after major undocumented modification, following transfer or acquisition of an existing facility, or whenever an investigation reveals that the assumed reference state cannot be substantiated.

1.2 A reference state exists, but it is no longer used to interpret current performance

SIGNAL

Commissioning, requalification, or previous verification data are available, but routine decisions rely almost entirely on current values and alarm limits.

The facility may know what the system is doing today but rarely compares that behavior with earlier verified performance.

Possible indicators include:

- pressure is reviewed, but fan speed or damper position is not;
- annual reports are archived without comparison across years;
- BMS trends exist but are used primarily during faults;
- maintenance staff respond to present setpoints without reference to earlier operating conditions;
- changes in system effort are not reviewed as long as the final controlled value remains acceptable.

WHY THIS MATTERS

Containment systems often compensate for change. The controlled result can therefore remain stable while the condition required to produce it changes.

A room may continue to maintain the same differential pressure while exhaust fan speed rises over several months. A control damper may move progressively toward the end of its travel. Filter resistance may increase while the system continues to meet its airflow requirement. None of these conditions establishes a containment failure, but they can show that the facility is using more of its available capacity to achieve the same result.

If surveillance looks only at the final controlled value, that change remains largely invisible until compensation is no longer sufficient.

The reference state is therefore useful not only for deciding whether a value has crossed a limit, but for understanding whether the relationships producing that value remain similar to those previously demonstrated.

WHAT TO REVIEW

Identify a limited number of parameters that are meaningful for comparison over time. The appropriate parameters will depend on the containment strategy, but may include:

- room-pressure behavior;
- supply and exhaust airflow;
- relevant fan operating points;
- damper or control output where available;
- filter differential pressure;
- recovery after door opening or other disturbance;
- recurring alarm history.

The purpose is not to trend every available BMS point. Data should be retained because they help interpret containment behavior, not merely because the system can collect them.

RESPONSE

Use the reference state actively during periodic review.

Where the final performance value remains stable but the effort required to maintain it is changing, identify whether the change has a known explanation. A new operating load, planned modification, or expected filter loading may explain the trend. Where no clear explanation exists, investigate before the system reaches a point at which the change becomes visible only through failure or alarm.

ESCALATION

Escalate when:

- control effort changes persist without explanation;
- available reserve appears to be declining;
- several related parameters move together;
- or current operation can no longer be reconciled with the verified reference state.

SURVEILLANCE MODE

Periodic review, supported by **continuous monitoring** where relevant data are available.

1.3 The reference state is documented, but the work has changed

SIGNAL

The facility continues to operate approximately as previously verified, but the work being performed no longer corresponds closely to the conditions under which that verification was established.

Examples may include:

- substantially higher throughput;
- larger volumes or concentrations of biological agents or materials;
- new procedures;
- additional equipment;
- increased occupancy;
- longer operating hours;
- changed waste generation;
- different agents or biological materials.

WHY THIS MATTERS

A facility can remain technically stable while the demand placed on it changes enough that the earlier reference state no longer answers the current containment question.

This is different from physical deterioration. The ventilation system may be performing exactly as intended, the intended pressure relationships may remain stable, and individual protective systems may continue to pass their required tests. The uncertainty arises because the work has moved.

A laboratory originally verified under one operating regime may later contain more equipment, more people, longer working hours, or procedures that generate different aerosol or decontamination demands. The historical reference remains useful because it describes the technical system, but it may no longer establish that the containment strategy is appropriate for current operations.

WHAT TO REVIEW

Compare current work with the assumptions that informed the existing operating basis.

Particular attention should be given to changes that affect:

- airflow or thermal load;
- use of primary containment;
- aerosol generation;
- process scale;
- occupancy;
- material movement;
- waste and decontamination demand;
- emergency response;
- maintenance burden.

The most useful question is not whether the nominal biosafety level has changed, but whether the work now places materially different demands on the controls that support containment.

RESPONSE

Review the changed activity against the current risk assessment and containment strategy.

Where the difference is minor and does not affect the assumptions supporting the facility, document the change and continue surveillance. Where the work changes those assumptions, determine whether technical verification or a revised operating basis is required.

A legitimate operational change may lead to a new reference state. The objective is not necessarily to restore the facility to the previous state, but to ensure that the new state is understood and supported by appropriate evidence.

ESCALATION

Broader review is warranted when the change in work affects:

- containment demand;
- system capacity or reserve;
- primary containment strategy;
- waste or decontamination capability;
- emergency operation;
- or other assumptions on which the previous verification depended.

Escalation is also appropriate when several individually small operational changes have accumulated and their combined effect is no longer clear.

SURVEILLANCE MODE

Event-triggered review and **periodic review**.

02 Governance change

Containment performance depends on technical systems, but the institution determines whether those systems remain understood, supported, and controllable over time. Changes in mandate, leadership, responsibility, staffing, funding, or external support may not produce an immediate technical symptom. Their significance appears when they alter the institution's ability to detect change, act on it, or preserve the conditions on which containment depends.

Governance signals therefore matter less as abstract organizational issues than as indicators that the facility's capacity to sustain its technical condition may be changing.

2.1 Institutional mandate or mission changes

SIGNAL

The laboratory or institution acquires a materially different role or scope of activity.

Possible indicators include:

- diagnostic work expands into research;
- a regional laboratory assumes national reference responsibilities;
- emergency-response or surveillance functions increase;
- animal work is introduced;
- new agents or disease programs are added;
- throughput rises substantially;
- the facility is expected to support functions not contemplated in the original operating basis.

WHY THIS MATTERS

A change in institutional mandate can alter containment demand without any physical modification to the facility.

The effect often appears indirectly. A broader program may increase throughput, require additional equipment, extend operating hours, or change the type of procedures being performed. The technical system may initially absorb those changes without difficulty, which can make the expanded mandate appear administratively rather than technically significant.

The relevant question is whether the new mission has changed the work sufficiently to alter assumptions that previously supported the containment strategy. A laboratory can retain the same biosafety-level designation while the scale, process, occupancy, or support requirements change materially.

WHAT TO REVIEW

Compare the new or expanded mandate with the operating conditions under which the facility was previously assessed.

Relevant questions include:

- Has sample or culture volume increased materially?
- Are different procedures now being performed?
- Has equipment use changed?
- Has occupancy or working time increased?
- Has waste or decontamination demand changed?
- Are emergency-response or continuity requirements different?
- Was the existing facility explicitly reviewed against the new mandate?

RESPONSE

Treat a significant mandate change as more than an administrative update.

Review the downstream operational consequences and determine whether the existing risk assessment and containment strategy still reflect the work now being performed. Where the technical implications are minor, document the change. Where they affect the operating basis, identify what additional assessment or verification is required.

ESCALATION

Escalate when the new mandate materially changes:

- the risk profile;
- workload;
- process scale;
- equipment demand;
- decontamination or waste requirements;
- emergency operation;
- or other assumptions embedded in the existing containment strategy.

SURVEILLANCE MODE

Event-triggered review.

A significant change in mandate should be reviewed when it occurs rather than waiting for the next annual cycle.

2.2 Senior leadership changes

SIGNAL

A change in senior leadership is followed by changes in priorities, funding, staffing, reporting lines, authorization, maintenance strategy, or interpretation of existing containment requirements.

WHY THIS MATTERS

Leadership turnover is not itself evidence that containment has weakened. The significance lies in what changes afterward.

A new administration may preserve the existing technical and governance arrangements without difficulty. In other cases, containment-related work may be deferred, specialist posts left vacant, verification activities reconsidered, or long-standing requirements treated as discretionary because their technical rationale is not well understood.

The effect may remain invisible for some time because the facility continues to operate. The eventual technical problem may emerge only after maintenance is postponed, system knowledge is lost, or corrective actions remain unresolved.

WHAT TO REVIEW

After significant leadership change, confirm whether there has been any change in:

- containment responsibilities;
- authority to approve corrective work;
- maintenance and verification funding;
- specialist staffing;
- risk-management expectations;
- escalation routes;
- decisions about known deficiencies.

The relevant issue is not whether leadership changed, but whether the change altered any condition required to sustain containment.

RESPONSE

Reconfirm the institutional arrangements that support the facility.

Where responsibilities, priorities, or resource commitments have changed, identify whether the new arrangements still allow the institution to detect, investigate, correct, and verify containment-related issues.

ESCALATION

Escalate when technical deficiencies remain unresolved because authority, funding, or responsibility is no longer clear, or when established containment requirements are materially changed without technical reassessment.

SURVEILLANCE MODE

Event-triggered review and **annual verification**.

2.3 Responsibility becomes fragmented or ambiguous

SIGNAL

Several groups remain responsible for different elements of containment, but no clear mechanism connects observation, decision, correction, and verification.

Typical conditions include:

- laboratory personnel observe the problem;
- biosafety evaluates risk;
- facilities manages HVAC;
- an external contractor controls the BMS;
- procurement manages service contracts;
- administration controls funding;

yet responsibility for the integrated outcome is unclear.

WHY THIS MATTERS

High-containment facilities necessarily depend on multiple disciplines. Fragmentation becomes a problem when the interfaces among them are not defined.

A technical issue can remain unresolved even when every group believes it has completed its own task. The maintenance team repairs the fan, the controls contractor restores the setpoint, biosafety records the event, and procurement closes the service order, but no one confirms that the containment condition as a whole has returned to an acceptable state.

The failure is therefore not simply one of ownership. It lies in the absence of continuity across the sequence from detection to closure.

WHAT TO REVIEW

Determine whether the institution can identify clearly:

- who receives evidence of abnormal containment behavior;
- who decides whether investigation is required;
- who has access to relevant technical data;
- who authorizes intervention;
- who releases resources;
- who decides whether operation may continue;
- who verifies that corrective action restored the intended condition;
- who updates the documented operating basis afterward.
- whether institutional responsibility for biosafety and biocontainment is explicit, and how it interfaces with responsibilities for operation, surveillance, intervention, and verification;

Some responsibilities may legitimately be shared. The issue is whether the interfaces remain explicit.

RESPONSE

Clarify the chain of responsibility around containment-related decisions and corrective actions.

The objective is not necessarily to appoint a single individual to “own” the entire system. It is to ensure that no critical step depends on an assumption that another group is responsible.

ESCALATION

Escalate when:

- corrective actions repeatedly stall between departments;
- responsibility for a deficiency is disputed;
- no one has authority to coordinate across system boundaries;
- or operation continues because responsibility for the decision to intervene remains unclear.

SURVEILLANCE MODE

Periodic review and **event-triggered review**.

2.4 Resource constraints begin affecting containment-support functions

SIGNAL

Financial, procurement, or staffing constraints begin to alter actual containment-support activities.

Possible indicators include:

- preventive maintenance is deferred;
- corrective work is repeatedly postponed;
- calibration or testing intervals are extended without technical justification;
- service contracts lapse;
- critical spares become unavailable;
- specialist personnel are not replaced;
- temporary repairs remain in service;
- annual verification scope is reduced;
- known deficiencies remain unresolved because funding has not been authorized.

WHY THIS MATTERS

Lower expenditure is not, by itself, evidence of increased risk. The relevant change occurs when resource constraints begin to affect the institution's capacity to sustain or recover the verified containment condition.

A facility may continue to perform normally for some time after maintenance or verification activities are reduced. The technical effect can therefore lag behind the budgetary decision. By the time a symptom appears, the system may already have lost redundancy, accumulated deferred work, or become dependent on temporary measures.

WHAT TO REVIEW

Identify which containment-critical functions have actually been affected.

Review whether resource constraints are changing:

- maintenance response;
- specialist support;
- calibration and testing;
- access to replacement parts;
- closure of corrective actions;
- availability of redundancy;
- verification activities.

The purpose is to connect the resource change to its operational consequence rather than assuming that any budget reduction is technically significant.

RESPONSE

Prioritize the affected activities according to their relevance to containment and the consequence of further delay.

Where work must be deferred, document the technical basis, interim controls, responsible party, and condition under which the issue must be revisited.

ESCALATION

Escalate when resource constraints result in continued operation with deficiencies that cannot be adequately justified or controlled, or when temporary measures begin to replace normal containment-support functions.

SURVEILLANCE MODE

Periodic review and **event-triggered review**.

2.5 Technical competence is lost

SIGNAL

Personnel with important facility knowledge leave, retire, are reassigned, or are replaced without equivalent transfer of knowledge.

The affected expertise may involve:

- facilities engineering;
- controls;
- biosafety;
- commissioning or verification;
- decontamination;
- specialist maintenance;
- laboratory operations.

WHY THIS MATTERS

The technical plant can remain completely unchanged while the institution's ability to operate, interpret, diagnose, intervene, or verify it deteriorates.

Loss of specialist competence may affect response to faults, interpretation of trends and alarms, maintenance decisions, control changes, and the ability to determine whether an intervention has restored the intended containment condition. The effect may not be immediately visible because equipment can continue to operate while the capability to understand and respond to abnormal behavior has weakened.

The issue is therefore not simply staffing level. It is whether the institution still retains, internally or through reliable external support, the competence required to sustain the containment system.

Competence also includes interpreting trends, alarms, and technical data in context. Familiarity with recurring deviations can reduce their recognition as relevant signals, even when personnel retain substantial operating experience.

WHAT TO REVIEW

After the loss or reassignment of key personnel, determine whether:

- the functions previously performed by the departing personnel remain covered;
- unresolved technical issues were transferred;
- current staff can interpret relevant trend and alarm data;
- current staff can make or obtain appropriate technical decisions when abnormal conditions occur;
- external specialist support is available where internal capability has been lost.

RESPONSE

Identify critical functions that depended on the departing personnel and confirm that equivalent competence remains available through trained staff, documented technical support, or qualified external resources.

Where capability has already been lost, determine whether the gap affects the facility's ability to operate, interpret, diagnose, correct, or verify containment-related conditions.

ESCALATION

Escalate when the institution can continue operating equipment but no longer has sufficient competence to interpret recurring abnormalities, make technically justified interventions, or verify that containment-related systems have been restored appropriately.

SURVEILLANCE MODE

Event-triggered review and **annual verification**.

2.6 Change control weakens or is bypassed

SIGNAL

Physical, operational, or control-system changes increasingly occur without structured review.

Possible examples include:

- equipment is relocated;
- new penetrations are added;
- alarm thresholds are modified;
- controls logic is changed;
- room functions evolve;
- exhaust connections are altered;
- new equipment is installed;
- temporary systems are introduced without formal follow-up.

WHY THIS MATTERS

Each modification may have its own consequences for containment. However, when change control weakens, the institution also progressively loses its ability to identify those consequences, evaluate interactions between modifications, and maintain a reliable reference for how the facility has evolved.

When changes occur independently, each may appear too minor to justify review. Over time, however, the cumulative condition can become difficult to reconstruct. The facility may still know what its current settings are while losing the ability to explain how they evolved or which technical assumptions remain valid.

Weak change control therefore creates two problems at once: it allows unassessed interactions to accumulate, and it erodes the reference history needed to interpret future change.

WHAT TO REVIEW

For recent modifications, determine whether the institution can establish:

- what changed;
- why it changed;
- who authorized it;
- what containment assumptions were considered;
- whether related systems were affected;
- whether post-change verification was performed where appropriate.
- whether relevant changes prompted an updated risk assessment addressing consequences for controls and system dependencies;

RESPONSE

Restore traceability before the modification history becomes more difficult to reconstruct.

Where a change has already occurred without review, assess its likely containment relevance rather than treating documentation alone as the corrective action.

ESCALATION

Escalate when multiple undocumented changes have accumulated, when the interaction among them is unclear, or when the facility can no longer establish whether its current operating state corresponds to any formally reviewed condition.

SURVEILLANCE MODE

Event-triggered review and **periodic review**.

2.7 Corrective actions remain open or recur

SIGNAL

Containment-related deficiencies are identified but repeatedly remain unresolved, return after closure, or persist under interim controls.

Possible indicators include:

- repeated extensions;
- corrective actions closed administratively without verification;
- recurring defects after nominal closure;
- responsibility repeatedly reassigned;
- temporary controls remaining in place;
- corrective work delayed by funding or procurement;
- accepted risks not being reconsidered.

WHY THIS MATTERS

A surveillance system can identify problems reliably and still fail to improve containment if the institution cannot convert observation into durable corrective action.

The important distinction is between a technically justified delay and normalization of an unresolved condition. Some corrective actions require time, specialist procurement, or planned shutdown. The problem arises when the interim state persists without active technical control or when closure reflects completion of paperwork rather than restoration of the intended condition.

WHAT TO REVIEW

For long-standing or recurring actions, determine:

- why the issue remains open;
- whether interim controls are still appropriate;
- who owns the action;
- whether the completion date remains realistic;
- what evidence will be required to close the issue technically;
- whether recurrence indicates that the previous corrective action addressed the symptom rather than the cause.

RESPONSE

Keep unresolved deficiencies visible as active conditions rather than allowing them to disappear into administrative history.

Where the same issue recurs, reconsider the mechanism rather than repeating the previous correction automatically.

ESCALATION

Escalate when:

- unresolved actions accumulate;
- interim controls become effectively permanent;
- recurrence suggests that the underlying cause remains unidentified;
- or corrective actions cannot be completed because responsibility or resources are insufficient.

SURVEILLANCE MODE

Periodic review.

2.8 Temporary conditions become part of normal operation

SIGNAL

A measure deliberately introduced or accepted as temporary continues long enough to become routine. This section concerns recognized temporary conditions; informal workarounds that emerge through routine practice are addressed in Section 3.15.

Examples include:

- manual monitoring replacing an automated function;
- an overridden interlock;
- portable cooling;
- a temporary seal;
- altered operating sequence;
- restricted operation;
- temporary PPE or staffing arrangements.

WHY THIS MATTERS

Temporary measures can be appropriate and necessary. Their significance changes when the facility stops treating them as temporary.

Over time, staff turnover and routine use can separate the measure from the event that originally justified it. A later operator may know how to perform the workaround without knowing what failure it was intended to compensate for. The temporary state can then become part of the facility's operating basis without ever having been evaluated as a permanent condition.

WHAT TO REVIEW

For temporary measures that remain active, determine:

- why the measure was introduced;
- whether the original problem still exists;
- whether a permanent corrective action remains planned;
- whether the temporary measure has altered other containment assumptions;
- whether new personnel understand its status and limitations.

RESPONSE

Make an explicit decision: restore the original condition, replace the temporary measure with a permanent solution, or formally assess and accept the revised operating condition.

Elapsed time should not make that decision implicitly.

ESCALATION

Escalate when the temporary condition:

- compensates for a critical containment control;
- has become essential to normal operation;
- persists without a credible path to resolution;
- or has consequences beyond the system in which it was introduced.

SURVEILLANCE MODE

Routine observation and **periodic review**.

2.9 External support or procurement arrangements change

SIGNAL

The institution loses or changes access to specialist services, OEM support, qualified testing providers, critical parts, specialist consumables, or external engineering support.

WHY THIS MATTERS

Containment systems depend on capabilities that may exist outside the laboratory and even outside the institution.

A change in service provider or procurement policy may appear administrative until a critical system requires intervention. If the replacement provider lacks the relevant competence, parts are incompatible, or lead times become excessive, the facility's ability to restore containment after a fault can change substantially even though normal operation remains unaffected.

WHAT TO REVIEW

Determine whether the new arrangement preserves:

- required specialist competence;
- access to appropriate replacement parts;
- acceptable response time;
- continuity of calibration or testing;
- support for critical proprietary systems.

Particular attention is warranted where support has shifted from a specialist provider to a general maintenance contractor.

RESPONSE

Identify any containment-critical dependency that is no longer adequately supported and establish an alternative before a failure makes the gap operationally significant.

ESCALATION

Escalate when the institution can no longer obtain suitable technical support, testing, or replacement components within a timeframe consistent with the risk and function of the affected system.

SURVEILLANCE MODE

Event-triggered review and **periodic review**.

2.10 Institutional memory is deteriorating

SIGNAL

Current operation increasingly depends on informal recollection rather than controlled records.

Typical signs include explanations such as:

- “That is how we have always run it.”
- “The contractor knows why it is set that way.”
- “That was changed during the renovation.”
- “Nobody currently here was involved when it was commissioned.”

WHY THIS MATTERS

Institutional memory affects the ability to interpret technical evidence.

If the reason for a damper position, alarm threshold, pressure setpoint, or temporary modification is lost, the facility may still operate perfectly well but become increasingly difficult to assess. A later change can then be interpreted only against current habit rather than against a technically understood history.

The effect is cumulative. Lost institutional memory eventually becomes reference-state uncertainty.

WHAT TO REVIEW

Identify critical aspects of the operating condition that depend primarily on individual recollection.

Determine whether the institution retains enough documentation to explain:

- significant modifications;
- unusual control settings;
- recurring technical issues;
- long-standing temporary measures;
- departures from the original design;
- the basis for important containment decisions.

RESPONSE

Convert critical tacit knowledge into controlled institutional records where possible.

Where knowledge has already been lost, document the uncertainty and determine whether it affects current technical interpretation or requires further verification.

ESCALATION

Escalate when missing institutional memory prevents the facility from justifying its current configuration, understanding previous modifications, or establishing a defensible reference state.

SURVEILLANCE MODE

Periodic review.

03 Operational change

A containment system can remain technically stable while the work performed inside it changes enough that the previous operating assumptions no longer hold. These changes may develop gradually through increased workload, altered procedures, additional equipment, different space use, or shifts in how people and materials move through the facility.

The relevant question is not whether the laboratory still carries the same designation. It is whether the work now places different demands on the controls that support containment.

3.1 Workload increases substantially

SIGNAL

The laboratory is performing materially more of the same work than before.

Possible indicators include:

- higher sample volume;
- increased culture activity;
- more frequent animal procedures;
- longer operating hours;
- additional shifts;
- more simultaneous users;
- greater waste generation;
- increased use of decontamination systems.

WHY THIS MATTERS

Increased workload can change the operating condition without altering the nominal function of the laboratory.

More work can increase occupancy, heat load, equipment duty cycle, door opening, primary containment use, waste throughput, and maintenance demand. None of these changes necessarily creates a problem on its own. The significance appears when the facility begins operating closer to the capacity of systems that previously had more reserve.

A laboratory may therefore continue to meet its immediate pressure and airflow requirements while the margin available to absorb another change becomes smaller.

WHAT TO REVIEW

Compare current workload with the conditions under which the facility was previously assessed or verified.

Review whether increased activity has changed:

- occupancy;
- equipment use;
- working hours;
- waste and decontamination demand;
- door movement;
- maintenance frequency;
- thermal load.

RESPONSE

Identify which systems are actually experiencing increased demand rather than assuming that higher workload is inherently problematic.

Where the increase is significant, determine whether the facility still has adequate technical and operational margin under the new workload.

ESCALATION

Escalate when increased workload:

- pushes systems consistently closer to capacity;
- produces recurring alarms or thermal problems;
- changes validated process loads;
- creates persistent workarounds;
- or materially exceeds the conditions under which the facility was previously verified.

SURVEILLANCE MODE

Periodic review and **event-triggered review**.

3.2 New procedures are introduced

SIGNAL

The biological material may remain unchanged, but the way it is handled changes.

Examples include:

- centrifugation;
- vortexing;
- sonication;
- homogenization;
- culture amplification;
- open transfer;
- animal inoculation;
- necropsy;
- use of sharps;
- other aerosol-generating procedures.

WHY THIS MATTERS

The risk associated with laboratory work is shaped by the procedure as much as by the agent.

A new procedure may change aerosol generation, splash potential, exposure route, release magnitude, or the point at which primary containment is required. The laboratory can therefore remain physically unchanged while the demands on its containment strategy change materially.

This is one of the clearest ways in which a historical risk assessment can remain formally present while becoming operationally outdated.

WHAT TO REVIEW

Determine whether the new procedure changes:

- aerosol generation;
- concentration or volume;
- location of open handling;
- need for primary containment;
- waste characteristics;
- decontamination requirements;
- emergency response.

RESPONSE

Review the procedure against the current risk assessment before treating it as routine.

Where the change affects containment assumptions, revise the operating basis and determine whether additional technical verification is required.

ESCALATION

Escalate when the procedure introduces exposure modes, process conditions, or containment demands that were not previously evaluated.

SURVEILLANCE MODE

Event-triggered review.

3.3 Process scale changes

SIGNAL

The same activity is performed at a materially larger scale.

Examples include:

- larger culture volumes;
- higher concentrations;
- larger batch sizes;
- more animals per procedure;
- simultaneous processing by multiple operators.

WHY THIS MATTERS

Scale and workload are related but not identical.

Higher workload means more repetitions of the same activity. Increased scale means that each individual activity carries a greater quantity of hazardous material, greater process demand, or larger consequence if containment is lost.

A process that was appropriate at one scale may require different controls when performed at another.

WHAT TO REVIEW

Compare the new process scale with:

- the existing risk assessment;
- primary containment capacity;
- equipment capacity;
- decontamination and waste handling;
- spill and emergency-response assumptions.

RESPONSE

Determine whether the existing controls remain appropriate at the larger scale.

Where the scale materially changes consequence or control demand, reassess before continuing routine operation.

ESCALATION

Escalate when increased scale affects primary containment, waste treatment, emergency response, or the consequence of release.

SURVEILLANCE MODE

Event-triggered review.

3.4 New equipment is introduced

SIGNAL

A new instrument, process device, storage system, or support equipment is installed within containment.

WHY THIS MATTERS

Equipment does not affect the facility only through its own function.

A new device can introduce additional heat, electrical demand, exhaust requirements, utility connections, airflow obstruction, maintenance access requirements, or changes in workflow. It can also affect emergency-power loading or create new decontamination and waste demands.

A piece of equipment may therefore be entirely appropriate in isolation while changing the operating condition of the room around it.

WHAT TO REVIEW

Before installation or shortly afterward, consider:

- heat output;
- electrical and emergency-power demand;
- exhaust or ventilation requirements;
- effect on supply and exhaust airflow;
- physical obstruction;
- utility penetrations;
- maintenance access;
- cleaning and decontamination;
- effect on material and personnel flow.

RESPONSE

Treat equipment installation as a change to the room, not only as procurement of an asset.

Where the equipment introduces significant new loads or changes airflow or workflow, review the impact before accepting the resulting operating condition.

ESCALATION

Escalate when the equipment:

- adds substantial heat load;
- requires exhaust;
- alters room airflow;
- creates new penetrations;
- changes emergency-power demand;
- affects decontamination capacity;
- or materially changes workflow.

SURVEILLANCE MODE

Event-triggered review.

3.5 Existing equipment is relocated

SIGNAL

An existing piece of equipment is moved within a room or transferred to another room.

The change may be modest: a BSC shifted to another wall, an incubator moved closer to a doorway, or a device placed beneath a different supply-air pattern still represents a change in operating context.

WHY THIS MATTERS

The equipment itself may remain unchanged while its relationship to the space changes.

Relocation can alter airflow around a BSC, obstruct supply or exhaust paths, change operator movement, affect clean/dirty flow, redistribute heat load, reduce emergency or maintenance access, or create new utility routing. Moving equipment nearer to a door, diffuser, exhaust point, or frequently occupied work zone can also change how the room behaves during normal use.

The containment significance therefore lies in the changed interaction between the equipment, the room, and the work—not in the device alone.

WHAT TO REVIEW

Consider whether the move changes:

- proximity to doors or diffusers;
- airflow around primary containment devices;
- operator movement;
- access to emergency equipment;
- maintenance access;
- clean/dirty separation;
- utility routing.

RESPONSE

Review the new location before treating the move as complete.

Where required, perform appropriate recertification or functional verification.

ESCALATION

Escalate when relocation affects airflow, containment, workflow, or equipment certification requirements.

SURVEILLANCE MODE

Event-triggered review.

3.6 Room function changes gradually

SIGNAL

The formal room designation remains the same, but actual use changes over time.

Examples include:

- storage becoming staging;
- an area originally used for temporary holding or staging of materials being used for sample preparation;
- sample preparation becoming culture work;
- equipment rooms becoming occupied work areas;
- anterooms accumulating storage;
- corridors becoming temporary holding areas.

WHY THIS MATTERS

Gradual repurposing can avoid the normal review that accompanies a formal renovation or project.

The change may affect occupancy, airflow assumptions, contamination zoning, movement patterns, cleanability, or emergency access even though no one event appears significant.

The room may therefore evolve into a function that would have influenced the original design had it been known at the time.

The gradual addition of ultra-low-temperature freezers or refrigerators to rooms not intended for that use can increase electrical demand and heat load, change how heat is dissipated, and alter the conditions under which the room's operation was previously verified.

WHAT TO REVIEW

Compare actual current use with:

- the intended function of the space;
- the current risk assessment;
- pressure relationships;
- airflow assumptions;
- workflow;
- emergency egress;
- cleaning and decontamination requirements.

RESPONSE

Where actual use has diverged materially from intended use, assess the current function rather than relying on the room label.

ESCALATION

Escalate when current use would have changed the original design, risk assessment, or containment strategy if it had been part of the initial program.

SURVEILLANCE MODE

Routine observation and **periodic review**.

3.7 Occupancy changes

SIGNAL

More people routinely work in a space, or staffing patterns change materially.

This may appear as a higher simultaneous headcount, greater overlap between shifts, more frequent training or visitor activity, or routine use of a room by personnel who were not part of the previous operating pattern.

WHY THIS MATTERS

Occupancy can affect the room beyond simple headcount.

More people may increase heat load, door-opening frequency, congestion, airflow disturbance, PPE consumption, communication burden, and procedural complexity. In small containment spaces, even a modest increase can change how operators move around BSCs, where materials are staged, how often doors are opened, and whether emergency access remains clear.

The relevant question is therefore not simply how many people are present, but whether the changed occupancy has altered the operating behavior of the room or the way established controls are used.

WHAT TO REVIEW

Observe whether increased occupancy changes:

- room temperature;
- door use;
- movement around BSCs;
- congestion;
- workflow;
- emergency egress;
- PPE and consumable demand.
- whether changes in occupancy or access have altered the custody, recording, or traceability of samples and materials;

RESPONSE

Where occupancy has increased, confirm that current work can still be carried out without creating persistent operational constraints or compromising established controls.

ESCALATION

Escalate when occupancy contributes to recurring airflow disturbance, congestion, altered procedures, or reduced emergency access.

SURVEILLANCE MODE

Routine observation and **periodic review**.

3.8 Working hours or shift patterns change

SIGNAL

The facility moves from daytime operation to evenings, nights, weekends, extended shifts, or continuous use.

The change may be formal, or it may develop gradually as projects, diagnostics, animal work, or staffing needs extend beyond the hours for which the facility was routinely supported.

WHY THIS MATTERS

The laboratory may operate under different technical and institutional conditions outside normal hours.

Facilities staff, engineering support, biosafety personnel, specialist contractors, security, and central-building systems may not be equally available at all times. Alarm response, maintenance access, utility support, or emergency decision-making may therefore differ even though the laboratory itself appears unchanged.

The technical plant may also operate differently if building HVAC schedules, temperature setbacks, pressure-control modes, or utility strategies change after hours. A facility verified mainly under daytime conditions should not automatically be assumed to behave identically during extended or unattended operation.

WHAT TO REVIEW

Determine whether off-hours operation has equivalent access to:

- facilities response;
- engineering support;
- biosafety support;
- emergency response;
- critical utilities;
- specialist intervention.

Also confirm that central systems do not change operating mode in ways that affect containment during extended hours.

RESPONSE

Where work extends beyond the previous operating schedule, review both technical and institutional support under the new hours.

ESCALATION

Escalate when critical support is unavailable during periods of operation or when containment behavior differs materially between normal and off-hours conditions.

SURVEILLANCE MODE

Event-triggered review and **periodic review**.

3.9 Agents or biological materials change

SIGNAL

New organisms, strains, specimens, vectors, toxins, animal species, or other biological materials are introduced, or the concentration, volume, or way existing material is handled changes materially.

WHY THIS MATTERS

The biosafety-level designation alone does not capture all of the implications of a change in biological material.

The important change may not be the identity of the agent itself. Transmission route, environmental persistence, concentration, process scale, aerosol-generating steps, animal behavior, available prophylaxis, waste characteristics, or decontamination requirements may change the actual containment demand.

The facility can therefore remain physically unchanged while the assumptions that previously justified primary containment, PPE, decontamination, emergency response, or waste handling no longer match the work.

WHAT TO REVIEW

Reassess the material in relation to:

- route of transmission;
- concentration and volume;
- procedures;
- environmental stability;
- available treatment or prophylaxis;
- decontamination;
- waste handling;
- emergency response.

RESPONSE

Update the risk assessment before routine use and determine whether existing containment controls remain appropriate.

ESCALATION

Escalate when the new material changes assumptions underlying primary containment, PPE, facility controls, decontamination, or emergency response.

SURVEILLANCE MODE

Event-triggered review.

3.10 Waste generation or waste characteristics change

SIGNAL

The quantity, composition, packaging, holding time, or route of waste changes.

Examples include higher volumes of bagged solid waste, more liquid waste, new sharps or animal waste streams, larger autoclave loads, longer temporary storage, or a change in the route used to move waste out of containment.

WHY THIS MATTERS

Waste systems often absorb operational growth quietly until capacity or workflow becomes constrained.

Increased volume can change autoclave loading frequency, validated load configuration, storage time, staging space, transfer frequency, and staff movement. A different waste type may require another decontamination method, packaging arrangement, effluent control, or external disposal route.

These pressures matter because backlog and throughput constraints can gradually drive overloading, temporary accumulation, altered routes, or other workarounds before anyone identifies waste handling as the source of the change.

WHAT TO REVIEW

Review current waste generation against:

- decontamination capacity;
- validated load configurations;
- storage arrangements;
- internal transport;
- effluent requirements;
- external disposal arrangements.
- whether arrangements, capacity, and frequency of external waste removal still correspond to current quantities and characteristics;

RESPONSE

Adjust waste management where necessary before accumulation or throughput pressure begins to drive loads not covered by the validated configuration or workarounds.

ESCALATION

Escalate when waste volume or composition exceeds validated process capacity, causes recurring backlog, or changes the decontamination assumptions of the facility.

SURVEILLANCE MODE

Routine observation, **periodic review**, and **event-triggered review**.

3.11 Personnel and material flows change

SIGNAL

People or materials move through the containment area differently from the established workflow.

Examples include:

- new entry or exit routes;
- different sample-transfer points;
- altered the sequence for donning or doffing personal protective equipment (PPE) sequence;
- temporary staging areas;
- different waste routes;
- increased movement of carts or equipment.

WHY THIS MATTERS

Containment is influenced by sequence and separation.

A workflow can change without any technical modification to the room, yet altered movement may increase door interaction, clean/dirty crossover, congestion, or transfer risk.

The significance lies in whether the new flow bypasses assumptions built into the space and procedures.

WHAT TO REVIEW

Observe actual movement rather than relying only on written SOPs.

Compare current flow with:

- room pressure relationships;
- clean/dirty zoning;
- pass-through and transfer arrangements;
- PPE sequence;
- emergency routes;
- intended separation of materials and personnel.

RESPONSE

Where actual flow has diverged from the intended sequence, determine why and whether the revised pattern remains appropriate.

ESCALATION

Escalate when the new flow defeats an intentional barrier or separation, creates recurring door conflicts, or introduces uncontrolled transfer points.

SURVEILLANCE MODE

Routine observation and **periodic review**.

3.12 Maintenance temporarily alters normal operating conditions

SIGNAL

Maintenance requires the facility to operate differently from normal.

Examples include:

- partial shutdown;
- temporary ventilation;
- opening a containment boundary;
- contractor access;
- bypass of controls;
- alarm isolation;
- removal of critical equipment;
- work on contaminated ducts or services.

WHY THIS MATTERS

Maintenance is not always performed under the same containment conditions as routine laboratory work.

During intervention, normal barriers or system relationships may be intentionally altered. If the maintenance state is not treated as a distinct operating condition, the facility may rely on assumptions that no longer apply during the work.

WHAT TO REVIEW

Before the intervention, determine:

- what normal controls will be unavailable;
- what temporary controls are required;
- whether decontamination is needed;
- who may enter;
- how the system will be returned to service;
- what post-maintenance verification is necessary.
- which internal and external teams are involved, how their work is coordinated, and who confirms restoration of affected conditions;

RESPONSE

Plan and document the maintenance state before beginning work.

After completion, confirm that the systems affected by the intervention have been restored appropriately.

ESCALATION

Escalate when maintenance affects primary containment, the facility containment boundary, or containment-critical ventilation or control functions; requires temporary control arrangements; or alters systems whose restoration cannot be confirmed through simple local checks.

SURVEILLANCE MODE

Event-triggered review.

3.13 Cleaning or decontamination practices change

SIGNAL

Cleaning chemistry, method, frequency, contact time, equipment used, sequencing, or responsible personnel change.

The change may also involve moving equipment for cleaning, closing rooms for longer or shorter periods, using a new fogging or surface-treatment method, or changing where contaminated cleaning materials enter the waste stream.

Changes in the decontaminant product, concentration, formulation, physical state, or application method can also constitute a signal, particularly when they alter conditions of use or previously verified assumptions about efficacy and compatibility.

WHY THIS MATTERS

A change in cleaning or decontamination practice can affect both biological control and the physical condition of the facility.

New chemicals may attack sealants, coatings, metals, plastics, sensors, or equipment surfaces. Reduced contact time may affect efficacy; more aggressive or more frequent treatment may accelerate deterioration. Changes in method can also alter room access, equipment position, waste generation, or the time during which normal containment conditions are interrupted.

A practice introduced for operational convenience can therefore have downstream consequences that are not visible in the cleaning procedure itself.

WHAT TO REVIEW

Consider:

- compatibility with surfaces and seals;
- required contact time;
- equipment compatibility;
- waste implications;
- frequency of use;
- whether the new method alters workflow.

RESPONSE

Confirm that the revised practice remains effective for decontamination and compatible with the materials and systems being treated.

ESCALATION

Escalate when the change contributes to recurring material degradation, affects validated decontamination processes, or creates new waste or exposure concerns.

SURVEILLANCE MODE

Event-triggered review and **routine observation**.

3.14 PPE strategy changes

SIGNAL

The PPE ensemble, respiratory-protection strategy, donning/doffing location, reuse practice, or duration of PPE use changes.

The change may be planned after risk reassessment, or it may develop operationally because staff feel that existing controls no longer provide sufficient protection.

WHY THIS MATTERS

PPE forms part of the overall risk-control strategy, but a change in PPE can mean more than a different garment or respirator.

Heavier or more complex PPE can change work duration, dexterity, visibility, communication, heat burden, movement through doors and airlocks, and the time required for donning and doffing. It may also signal that the biological risk, procedure, or confidence in another control has changed.

A PPE change may therefore be entirely appropriate, but increased PPE should not automatically be treated as equivalent to correcting an unresolved engineering or procedural deficiency.

WHAT TO REVIEW

Determine:

- why the PPE change was introduced;
- whether the biological or procedural risk changed;
- whether the change compensates for another control;
- whether donning and doffing arrangements remain appropriate;
- whether staff can use the revised PPE reliably.
- whether modified procedures retain a risk assessment consistent with current activities and the selection of PPE;

RESPONSE

Document the basis for the change and ensure that it remains integrated with the wider control strategy.

ESCALATION

Escalate when PPE is being used to compensate for unresolved engineering or procedural deficiencies without formal reassessment.

SURVEILLANCE MODE

Event-triggered review and **periodic review**.

3.15 Workarounds become routine

SIGNAL

Staff repeatedly modify the intended workflow to keep the laboratory functioning. Unlike a formally introduced temporary condition, a workaround may emerge through day-to-day practice without explicit review or acceptance.

Examples include:

- propping doors;
- suppressing alarms;
- bypassing slow transfer processes;
- storing materials in unintended spaces;
- manually replacing automated actions;
- altering procedure sequences;
- repeatedly moving equipment to make room for work.

WHY THIS MATTERS

A workaround may be a behavior problem, but it can also reveal a mismatch between the intended system and the conditions under which people are actually working.

Treating every workaround only as noncompliance risks missing the constraint that keeps producing it. At the same time, understanding the cause does not remove the need to address the risk created by the workaround itself.

Both questions therefore matter: what risk does the workaround introduce, and what problem is it solving?

WHAT TO REVIEW

Determine:

- how often the workaround occurs;
- why staff use it;
- whether it is linked to workload, equipment, space, alarms, or system performance;
- whether it has become embedded in local practice;
- whether an earlier corrective action was intended to eliminate it.

RESPONSE

Address the immediate risk created by the workaround and investigate the condition that makes it persist.

Where the workaround reflects a genuine operational need, reconsider the underlying process or facility arrangement rather than relying indefinitely on behavioral correction.

ESCALATION

Escalate when the workaround:

- affects a containment barrier;
- substitutes for a failed control;
- becomes necessary for routine work;
- recurs after repeated instruction;
- or indicates that the existing workflow can no longer be sustained as designed.

SURVEILLANCE MODE

Routine observation and **periodic review**.

04 Technical change

Technical surveillance asks whether the physical and control systems that produce containment are behaving differently, operating with less margin, or interacting differently than they did under the last justified and verified condition.

The focus is not on whether individual components have been serviced. It is on whether the system still produces the expected containment condition in the same way, with comparable stability and reserve.

4.1 Pressure relationships shift

SIGNAL

Room-to-room or room-to-corridor pressure differentials move away from their usual pattern, even though alarm limits may still be satisfied.

Possible indicators include:

- pressure values trending gradually toward a limit;
- persistent change from the historical operating range;
- one room shifting while adjacent rooms remain stable;
- several rooms shifting at the same time;
- pressure becoming more sensitive to door opening or occupancy.

WHY THIS MATTERS

A pressure value is useful, but it is only one expression of the system state.

A room may remain negative while supply and exhaust quantities have changed, a sensor has drifted, leakage has increased, or controls are compensating more aggressively. The significance lies in whether the relationship is stable and whether the current value still reflects the same operating condition as before.

The same pressure reading can therefore represent different system states depending on what is happening around it.

WHAT TO REVIEW

Compare the current condition with:

- the last justified reference state;
- historical pressure trends;
- supply and exhaust airflow data;
- recent HVAC or controls work;
- door and containment-boundary condition;
- equipment or workload changes;
- behavior in adjacent rooms.

Where several rooms change together, consider shared systems rather than assuming multiple local faults.

RESPONSE

Confirm the reading before changing setpoints or airflow.

Identify whether the pressure change has a known technical or operational explanation. If not, review the related airflow and system history before making corrective adjustments.

ESCALATION

Escalate when:

- the trend persists;
- directional airflow becomes uncertain;
- several rooms move together;
- pressure can be maintained only through increasing control effort;
- or the cause cannot be reconciled with recent changes.

SURVEILLANCE MODE

Continuous monitoring, **periodic review**, and **annual verification**.

4.2 Pressure becomes more variable or unstable

SIGNAL

The average pressure remains acceptable, but the behavior around that value changes.

Possible indicators include:

- larger fluctuations;
- more frequent excursions;
- oscillation;
- recurrent short-duration alarms;
- slower stabilization;
- increased sensitivity to door movement.

WHY THIS MATTERS

A stable average can conceal declining dynamic control.

The room may still meet its nominal criterion while the control system works harder to recover from disturbance or becomes less able to absorb normal changes in occupancy, door use, or building pressure.

Increased variability may therefore be an early signal that the operating margin is narrowing or that the control relationship is changing.

WHAT TO REVIEW

Look for correlation with:

- door activity;
- equipment operation;
- time of day;
- shift patterns;
- neighboring-room alarms;
- seasonal conditions;
- recent controls changes.

Review whether the variability is new or simply more visible because monitoring has improved.

RESPONSE

Review the trend rather than reacting only to individual excursions.

Determine whether the increased variability has a consistent trigger and whether recovery remains comparable with the established operating condition.

ESCALATION

Escalate when instability increases over time, produces directional-flow reversal, recurs without explanation, or appears across multiple rooms.

SURVEILLANCE MODE

Continuous monitoring and **periodic review**.

4.3 Recovery after disturbance changes

SIGNAL

The room or system takes longer to return to its expected condition after a disturbance.

Examples include:

- door opening;
- equipment startup or shutdown;
- power transfer;
- fan changeover;
- restart after maintenance.

WHY THIS MATTERS

Static readings do not show how the system behaves when challenged.

A room may eventually return to the same pressure while taking substantially longer to recover. That change can indicate reduced available capacity, altered leakage, weaker control response, or changed interaction with adjacent spaces.

Recovery behavior therefore provides information about resilience that a steady-state reading cannot.

WHAT TO REVIEW

Compare current recovery with:

- previous verification data;
- historical trend information;
- recent control changes;
- fan or damper performance;
- door behavior;
- changes in room use or occupancy.

RESPONSE

Confirm whether the slower recovery is repeatable and whether it occurs under specific conditions.

Avoid defining a new “normal” recovery period solely because the room eventually returns to setpoint.

ESCALATION

Escalate when recovery time increases progressively, allows sustained directional-flow reversal, becomes inconsistent, or can no longer be explained by known changes.

SURVEILLANCE MODE

Annual verification and **event-triggered review**.

4.4 Increasing control effort is required to maintain the same condition

SIGNAL

The final controlled value remains stable, but the system increasingly relies on higher effort.

Possible indicators include:

- higher fan speed;
- damper position moving closer to fully open or closed;
- increased filter differential pressure;
- increased cooling demand;
- higher controller output.

WHY THIS MATTERS

Automatic control can hide change.

The system may still maintain the required pressure, airflow, or temperature while using progressively more of its available capacity. The loss of reserve may not become visible until another disturbance occurs.

This is one of the clearest situations in which “within limits” can coexist with a materially different operating condition.

A sustained increase in control effort may indicate that the system is consuming available operating margin and approaching its adjustment limit, even while the monitored parameter remains within its intended range. The cause may require maintenance, but it may also arise from new demands or interactions with other systems.

WHAT TO REVIEW

Compare current control effort with:

- previous operating points;
- filter loading;
- recent equipment additions;
- changes in airflow demand;
- duct or damper condition;
- fan performance;
- seasonal load.

RESPONSE

Determine what is driving the increased effort.

Do not treat successful setpoint maintenance as sufficient evidence that the system is unchanged.

ESCALATION

Escalate when control devices approach their practical limits, reserve continues to decline, or no clear explanation exists for the additional effort.

SURVEILLANCE MODE

Periodic review and **annual verification**.

4.5 Control parameters are repeatedly adjusted

SIGNAL

Pressure setpoints, alarm thresholds, alarm delays, fan speeds, damper bias, or control sequences are modified repeatedly after the system has already entered routine operation.

The concern is not a documented one-time optimization, but a pattern in which further adjustment becomes the recurring response to the same or related behavior.

WHY THIS MATTERS

Adjustment can be appropriate. The concern arises when repeated tuning becomes a substitute for understanding why the system no longer holds its previous condition.

A setpoint change can restore a familiar pressure value while masking increased fan effort, altered leakage, changed system resistance, sensor error, or an effect elsewhere in the network. Alarm delays or thresholds can similarly make an unstable condition less visible without improving the underlying performance.

Over time, successive adjustments can redefine normal operation around a condition that was never fully understood or technically justified.

WHAT TO REVIEW

For each significant adjustment, determine:

- what prompted it;
- whether the underlying cause was identified;
- whether the new value was technically justified;
- whether the change affected other rooms or systems;
- whether post-adjustment performance was verified.

RESPONSE

Retain the rationale and effect of significant control changes.

Where repeated adjustment is occurring, review the broader system rather than continuing to tune the same parameter in isolation.

ESCALATION

Escalate when control changes recur without durable resolution, reduce alarm sensitivity, or shift the system progressively toward reduced reserve.

SURVEILLANCE MODE

Event-triggered review and **periodic review**.

4.6 Available operating margin narrows

SIGNAL

Systems continue to meet current demand but operate increasingly close to available capacity.

Examples include:

- exhaust fan near maximum output;
- control damper near end of travel;
- cooling capacity routinely near its limit;
- emergency-power loading approaching capacity;
- decontamination throughput leaving little recovery time.

WHY THIS MATTERS

Containment depends on more than normal steady-state operation.

The system also needs enough reserve to accommodate filter loading, peak occupancy, equipment changes, seasonal demand, disturbance, and failure. A facility can therefore remain compliant while becoming less resilient.

The concern is not simply that a component is heavily loaded, but that little capacity remains to absorb the next change.

WHAT TO REVIEW

Identify what is consuming the margin and whether the condition is:

- expected;
- temporary;
- operationally justified;
- or progressively worsening.

Where relevant to the system being examined, also review the evolution of filter pressure losses or differential pressures.

Review how the system behaves under peak demand rather than relying only on average conditions.

RESPONSE

Determine whether adequate reserve remains for credible disturbances and expected future loading.

Where the reduced margin is intentional, document the revised operating basis.

ESCALATION

Escalate when routine operation depends on system capacity close to its maximum or when expected failure modes can no longer be accommodated.

SURVEILLANCE MODE

Periodic review and **annual verification**.

4.7 Redundancy is installed but not functionally available

SIGNAL

A redundant fan, pump, UPS, control path, or other standby system exists but is not actually ready to perform its intended function.

Possible indicators include prolonged outage, failed automatic start or transfer, equipment that has not been challenged under load, dependence on manual intervention, or a nominally redundant path that shares the same upstream power, control, or utility failure point as the primary system.

WHY THIS MATTERS

Installed redundancy and available resilience are not the same.

A standby unit can be present, powered, and apparently healthy without having demonstrated that it will start, carry the required load, assume the correct control sequence, and recover the necessary containment condition when the primary path fails.

A facility may continue normal operation without difficulty while one redundant path remains unavailable. The apparent stability of the primary system can make the degraded condition feel less significant over time, even though the facility has lost part of its failure tolerance.

WHAT TO REVIEW

Confirm whether redundant systems:

- are available;
- start as intended;
- operate under load;
- recover the required containment condition;
- depend on personnel or systems that may not be available during an actual failure.
- whether effective transfer to the redundant equipment or mode has been demonstrated, including applicable transfer and recovery conditions, rather than only its physical presence or nominal availability;

RESPONSE

Restore or formally assess unavailable redundancy rather than allowing long-term single-point operation to become the assumed normal condition.

ESCALATION

Escalate when loss of redundancy materially changes the facility's failure response or leaves no adequate margin for another fault.

SURVEILLANCE MODE

Annual verification and **event-triggered review**.

4.8 Seasonal or environmental conditions change system behavior

SIGNAL

Containment performance becomes less stable under recurring environmental conditions.

Examples include:

- extreme outdoor temperature;
- high humidity;
- strong wind;
- heavy rainfall;
- seasonal utility instability;
- peak building occupancy.

WHY THIS MATTERS

Annual testing often captures the facility under only one set of environmental conditions.

A system may perform well during moderate weather while operating close to its limits during seasonal extremes. If surveillance does not preserve those differences, the facility can repeatedly pass formal verification while still experiencing predictable periods of reduced stability.

WHAT TO REVIEW

Compare system behavior across:

- seasons;
- outdoor temperature;
- building operating modes;
- peak workload;
- known utility stress periods.

Look for recurring pressure, temperature, alarm, or control-effort patterns.

RESPONSE

Identify whether the seasonal change is expected and adequately accommodated.

Where performance depends heavily on favorable external conditions, review available capacity and control strategy.

ESCALATION

Escalate when containment stability repeatedly approaches operating limits during predictable environmental conditions.

SURVEILLANCE MODE

Periodic review and **annual verification**.

05 Physical containment boundary

The containment boundary can deteriorate gradually through use, movement, cleaning, modification, or repeated local repair. Not every visible defect is significant, but recurrence, progressive change, or alteration of a critical interface can indicate that the physical condition supporting containment is changing.

5.1 Door behavior changes

SIGNAL

A containment door becomes harder or easier to open, closes more slowly, fails to latch consistently, rebounds, or develops repeated interlock problems.

WHY THIS MATTERS

Door behavior reflects both the door itself and the conditions acting across it.

A mechanical defect may be the complete explanation, but changed pressure force, frame movement, gasket deterioration, or altered sealing can produce similar symptoms. Repeated adjustment without durable resolution should therefore prompt a wider look at the conditions around the door.

WHAT TO REVIEW

Check:

- closer and hardware;
- hinges and alignment;
- seals and gaskets;
- frame condition;
- room pressure behavior;
- recent HVAC or balance changes.

RESPONSE

Start with the door as a local mechanical issue, but expand the review if the defect recurs or cannot be explained mechanically.

ESCALATION

Escalate when door performance affects reliable closure, interlocks, pressure control, or directional airflow.

SURVEILLANCE MODE

Routine observation and **event-triggered review**.

5.2 Sealants, joints, finishes, or interfaces deteriorate

SIGNAL

Visible cracking, separation, shrinkage, corrosion, delamination, damaged coving, staining, loss of adhesion, or deterioration around joints, finishes, doors, panels, and penetrations.

WHY THIS MATTERS

Appearance alone does not determine containment significance. Some surface defects are cosmetic; others affect cleanability, moisture resistance, decontamination compatibility, pest exclusion, or the integrity of the containment boundary.

The location and mechanism matter. A small recurring gap at a wall-panel interface may be more significant than a larger superficial finish defect elsewhere. Repeated failure is particularly important because it can indicate movement, vibration, moisture, chemical attack, substrate failure, or unsuitable material rather than an isolated maintenance issue.

WHAT TO REVIEW

Consider:

- location and extent;
- whether the defect has recurred;
- nearby penetrations or joints;
- cleaning chemistry;
- evidence of moisture;
- vibration or building movement.

RESPONSE

Repair isolated defects appropriately, but retain the history of recurring locations.

Where recurrence persists, investigate the mechanism rather than repeatedly restoring appearance.

ESCALATION

Escalate when deterioration affects critical boundaries, compromises decontaminability, or repeatedly returns after repair.

SURVEILLANCE MODE

Routine observation and **periodic review**.

5.3 New penetrations appear

SIGNAL

A new cable, pipe, conduit, sensor, hose, fixing, bracket, or other service penetrates a containment boundary, including small additions made during maintenance, IT work, equipment installation, or renovation.

WHY THIS MATTERS

The penetration may be entirely acceptable, but it is a physical modification to a previously defined boundary.

An undocumented or poorly controlled penetration can introduce a leakage path, bypass an intended seal, compromise fire or pressure sealing, create surfaces that are difficult to clean or decontaminate, or simply create uncertainty about whether the current boundary still corresponds to the condition that was previously verified.

The issue is therefore not that every penetration is hazardous; it is whether the modification was reviewed, sealed, documented, and verified in proportion to its effect.

WHAT TO REVIEW

Determine:

- when and why it was installed;
- who reviewed it;
- how it was sealed;
- whether it affects cleaning or decontamination;
- whether post-work verification was required.

RESPONSE

Confirm that the penetration has been incorporated into the documented facility condition rather than treated as an informal addition.

ESCALATION

Escalate when the installation cannot be technically justified, when sealing is uncertain, or when multiple undocumented penetrations have accumulated.

SURVEILLANCE MODE

Event-triggered review and **routine observation**.

5.4 The same boundary defect is repaired repeatedly

SIGNAL

The same joint, penetration, door frame, panel interface, seal, or finish repeatedly requires repair, or several repairs occur in the same local area over time.

WHY THIS MATTERS

Repeated repair changes the significance of the defect.

The damaged material may be the visible endpoint of another condition: structural or thermal movement, vibration, moisture, pressure loading, door misalignment, repeated impact, chemical incompatibility, or failure of the underlying substrate. Restoring the surface can temporarily remove the symptom without removing the driver.

Repair history therefore becomes evidence about causation, not merely a record of maintenance frequency.

When a repair recurs, it is also worth examining whether the materials used are compatible with the substrate, movement of the boundary, and cleaning or decontamination methods. Substituting a product without understanding the mechanism behind recurrence may leave the cause unchanged.

WHAT TO REVIEW

Compare:

- repair history;
- location;
- timing;
- adjacent system changes;
- environmental conditions;
- cleaning practices.

RESPONSE

Treat recurrence as evidence of an unresolved mechanism and investigate beyond the immediate defect.

ESCALATION

Escalate when repeated repair affects containment integrity or when the underlying cause cannot be established.

SURVEILLANCE MODE

Periodic review and **routine observation**.

06 Protective systems and local containment

Primary containment devices, sterilization systems, decontamination equipment, and other protective systems are often verified individually. Those tests remain essential, but they do not always show whether the device is operating under the same surrounding conditions or whether its use has changed enough to affect the role it plays in the wider containment strategy.

6.1 A primary containment device is operating in a changed environment

SIGNAL

A BSC remains within its current certification status, or another primary containment device continues to meet its applicable verification requirements, but conditions around it have changed.

Possible examples include:

- nearby equipment has been added or moved;
- supply airflow has been altered;
- door traffic has increased;
- room occupancy has changed;
- the cabinet has been relocated;
- the room pressure relationship has changed.

WHY THIS MATTERS

Device certification or verification, or equipment qualification where applicable, demonstrates an important part of performance, but it does not necessarily show that the interaction between the device and its operating environment is unchanged.

A cabinet can meet its certification criteria while the airflow around it has become more turbulent, door activity has increased, or nearby equipment has changed how people work around the opening. None of those changes automatically compromises containment, but they introduce conditions that the device-level test may not fully represent.

The issue is therefore not only whether the applicable device-level certification, qualification, or verification remains current, but whether the environment in which the device operates has changed enough that the interaction deserves review.

WHAT TO REVIEW

Consider:

- changes in room airflow;
- relocation of supply diffusers or exhaust grilles;
- increased door movement;
- new equipment near the cabinet;
- changes in operator position or workflow;
- relocation of the device;
- changes in room pressure.

RESPONSE

Maintain the applicable certification or verification requirements, but review significant changes in the operating environment separately.

Where the device has been moved or the surrounding airflow altered, determine whether additional verification is needed.

ESCALATION

Escalate when environmental or workflow changes may interfere materially with primary containment performance, or when repeated operational problems occur despite satisfactory device-level certification or verification.

SURVEILLANCE MODE

Routine observation and **event-triggered review**.

6.2 Operators report that equipment behavior has changed

SIGNAL

Experienced users notice that a protective device or critical piece of equipment behaves differently.

Examples may include:

- increased noise;
- unusual vibration;
- different airflow sensation;
- recurrent sash or airflow alarms;
- slower response;
- unusual temperature;
- changed behavior when nearby doors open.

WHY THIS MATTERS

Operator perception is not a substitute for measurement, but it can be an early indicator that operating conditions have changed.

Personnel who use the same equipment every day often recognize small differences before the cause becomes obvious. Dismissing such observations because the equipment has not failed can remove useful evidence. Treating them as proof of failure would be equally inappropriate.

Their value lies in prompting confirmation.

WHAT TO REVIEW

Check:

- recent maintenance, certification, qualification, or verification, as applicable;
- room airflow changes;
- alarm history;
- equipment relocation;
- neighboring equipment changes;
- whether several users report the same condition.

RESPONSE

Confirm whether the observation corresponds to a measurable or repeatable change.

If the change is local to the device, address it accordingly. If the device appears normal, consider whether the surrounding room conditions have changed.

ESCALATION

Escalate when the change recurs, affects safe use, coincides with room-level changes, or cannot be explained through normal equipment checks.

SURVEILLANCE MODE

Routine observation and **event-triggered review**.

6.3 Sterilization or decontamination process behavior changes

SIGNAL

A validated process continues to complete successfully but begins behaving differently.

Possible indicators include:

- longer cycle duration;
- altered temperature or pressure profile;
- slower heat-up or evacuation;
- more aborted cycles;
- recurrent indicator failures;
- increasing adjustment of load configuration;
- growing dependence on operator intervention.

WHY THIS MATTERS

A completed cycle does not always mean the process is operating under the same conditions as before.

Changes in utilities, loading, equipment condition, or operational demand can gradually move the process away from the state under which it was validated. The process may continue to produce acceptable outcomes while becoming less reproducible or more dependent on operator adjustment.

That shift matters because validated performance depends not only on the final outcome but also on maintaining the conditions that support it.

WHAT TO REVIEW

Compare current performance with:

- validated cycle parameters;
- typical load configurations;
- utility conditions;
- maintenance history;
- abort or failure history;
- changes in waste type or volume.
- whether supplies, their specifications, or their quality have changed and whether such changes could affect previously verified process conditions;

RESPONSE

Investigate recurring changes in cycle behavior before compensating through repeated load modification or procedural adjustment.

Where operational demand has changed, determine whether the validation basis still reflects actual use.

ESCALATION

Escalate when the process can no longer reproduce validated conditions consistently, relies increasingly on operator adaptation, or receives loads materially different from those previously evaluated.

SURVEILLANCE MODE

Periodic review.

6.4 Rarely used critical systems may no longer have demonstrated readiness

SIGNAL

A safety-critical or standby system remains unused for long periods.

Examples include:

- redundant fans;
- emergency ventilation modes;
- backup controls;
- whole-room decontamination systems;
- emergency transfer systems;
- rarely used pass-through or isolation devices.

WHY THIS MATTERS

Low use can conceal deterioration that normal operation would otherwise reveal.

A standby system may still exist physically while seals degrade, actuators seize, consumables expire, or operator familiarity is lost. The absence of demand therefore does not demonstrate readiness.

The more important question is whether the system could perform its intended function when needed.

WHAT TO REVIEW

Confirm:

- recent functional testing;
- consumable status;
- mechanical condition;
- availability of trained personnel;
- current procedures;
- availability of external support where required.

RESPONSE

Establish an appropriate readiness check based on the consequence of failure and the role of the system.

Do not rely on installation status alone.

Where appropriate, link periodic demonstration of readiness to the existing maintenance or testing programme, without confusing the scheduling of an activity with evidence of satisfactory performance.

ESCALATION

Escalate when a critical standby function cannot be demonstrated, required consumables or support are unavailable, or personnel are no longer able to operate the system reliably.

SURVEILLANCE MODE

Periodic review and **annual verification**.

07 Utilities and resilience

Containment depends on supporting services that may sit outside the immediate laboratory. Electrical power, chilled water, controls networks, steam, compressed air, or other utilities may be taken for granted while they remain stable, but changes in quality or availability can alter how the containment system behaves.

7.1 Utility quality or reliability changes

SIGNAL

The facility experiences a change in the quality or reliability of a supporting utility.

Possible examples include:

- more frequent power interruptions;
- unstable voltage;
- reduced chilled-water performance;
- steam interruptions;
- pressure variation in compressed air or vacuum;
- unreliable BMS communications;
- recurring water-supply problems.

WHY THIS MATTERS

A containment system may depend on utilities that are not visible from within the room.

The laboratory can therefore experience technical instability even when its own equipment is functioning correctly. A change in chilled water may appear as a thermal problem. A controls-network interruption may affect monitoring or recovery. Repeated short power disturbances may expose restart behavior that routine operation never reveals.

Continuity of supply does not, by itself, demonstrate that utility quality remains adequate for the systems that depend on it. A change in quality can alter process behavior without causing a visible interruption of service.

WHAT TO REVIEW

Identify which containment-critical systems depend on the affected utility and whether the observed change influences:

- ventilation;
- controls;
- monitoring;
- decontamination;
- emergency systems;
- critical equipment.

RESPONSE

Treat recurring utility problems as part of the containment context rather than as unrelated building-service events.

Where the effect is measurable, compare system behavior before, during, and after the utility disturbance.

ESCALATION

Escalate when utility instability prevents reliable normal operation, alters failure response, or creates repeated containment-related disturbances.

SURVEILLANCE MODE

Routine observation, **periodic review**, and **event-triggered review**.

7.2 Emergency-power transfer behaves differently

SIGNAL

Backup power becomes available, but the containment system no longer responds as expected during transfer or recovery.

Possible indicators include:

- longer loss of pressure;
- unexpected restart sequence;
- manual reset required;
- controls fail to reconnect automatically;
- alarms behave differently;
- some critical systems do not return to service.

WHY THIS MATTERS

A successful generator start does not demonstrate that the containment system itself recovered correctly.

The important condition is what happens between loss of normal power and restoration of stable containment. If controls, fans, monitoring, or other critical systems restart differently, the facility may have a failure mode that is not visible during normal operation.

WHAT TO REVIEW

Review:

- transfer and restart sequence;
- duration of any pressure loss;
- automatic versus manual recovery;
- controls and communications;
- equipment that did not restart;
- differences from previous tests or events.

RESPONSE

Document actual system behavior during the event and compare it with the intended failure response.

Where the sequence differs, determine whether the change is acceptable or requires correction.

ESCALATION

Escalate when containment recovery is delayed, depends on unexpected manual intervention, or differs materially from the verified emergency condition.

SURVEILLANCE MODE

Event-triggered review and **annual verification**.

7.3 Emergency-power loading increases

SIGNAL

Additional equipment or functions are added to generator, UPS, or emergency circuits, or new containment-critical equipment is introduced without equivalent backup support.

The increase may be obvious after a major expansion, or cumulative through smaller additions that individually appear insignificant.

WHY THIS MATTERS

Emergency capacity is often assessed at a particular point in the facility lifecycle. Later additions can gradually consume the electrical, UPS, fuel-duration, and sequencing margin that was originally available.

The relevant question is not only whether the generator or UPS has sufficient nameplate capacity. Motor starting, transfer sequence, inrush current, control-power dependencies, battery duration, load priorities, and the order in which ventilation and other containment-critical functions recover can determine whether the emergency state actually works as intended.

The normal electrical system may continue to operate without any indication that this resilience has changed. The difference may become visible only when the backup system is needed.

WHAT TO REVIEW

Compare current emergency loads with:

- available generator and UPS capacity;
- original load assumptions and subsequent additions;
- priority and sequencing of connected equipment;
- motor starting and other transient demands;
- control-power and UPS dependencies;
- new containment-critical equipment;
- expected operating duration and fuel or battery autonomy.

RESPONSE

Reassess emergency loading after significant additions rather than assuming that available capacity remains unchanged.

ESCALATION

Escalate when backup systems approach capacity, critical loads cannot be supported, or load priorities no longer correspond to current containment needs.

SURVEILLANCE MODE

Event-triggered review and **annual verification**.

08 External dependencies and system boundaries

The functional boundary of a containment system often extends beyond the walls of the laboratory. Shared ventilation, central utilities, roof exhaust, controls, drainage, and neighboring spaces can affect containment even when no work occurs inside the suite itself.

8.1 Changes elsewhere in the building affect containment

SIGNAL

A modification outside the containment suite coincides with changed behavior inside it.

Examples include:

- central HVAC work;
- roof exhaust modification;
- changes in building pressure;
- chilled-water work;
- electrical-system changes;
- drainage modification;
- changes in neighboring room use.

WHY THIS MATTERS

The laboratory wall does not necessarily define the technical boundary of the containment system.

Shared infrastructure can create dependencies that are easy to overlook during local troubleshooting. A change in central ventilation may alter room pressure. A roof modification may affect exhaust performance. A change in neighboring occupancy may alter building air balance.

If the investigation remains confined to the laboratory, the initiating mechanism may never be found.

WHAT TO REVIEW

When unexplained change appears, determine whether any recent work occurred in:

- central plant;
- mechanical rooms;
- roof systems;
- adjacent spaces;
- shared controls;
- utility infrastructure.

RESPONSE

Expand the investigation boundary when local evidence does not explain the change.

Look for timing and shared dependencies before repeatedly adjusting the containment system itself.

ESCALATION

Escalate when external modifications affect multiple rooms, shared systems, or conditions that cannot be isolated through local adjustment.

SURVEILLANCE MODE

Event-triggered review and **periodic review**.

8.2 Adjacent construction or renovation coincides with changed behavior

SIGNAL

Containment performance changes during or after nearby construction, renovation, roof work, utility work, controls modification, or other building intervention—even when the work does not occur inside the laboratory itself.

Possible indicators include pressure instability, unusual vibration, dust or odor, water ingress, airflow changes, utility interruptions, or controls anomalies.

WHY THIS MATTERS

Construction can alter the conditions around a containment facility without directly entering the containment area.

Temporary ventilation, blocked or relocated intakes and exhausts, duct disturbance, roof work, open shafts, structural vibration, changed building pressure, utility isolation, control-system changes, or temporary penetrations elsewhere in the building can all propagate effects into the laboratory.

The symptom may therefore appear local even when the cause lies outside the containment boundary or in shared infrastructure.

WHAT TO REVIEW

Compare the timing of the change with:

- construction and demolition activities;
- utility shutdowns or temporary connections;
- temporary ventilation or pressure-control arrangements;
- roof, intake, exhaust, shaft, or duct work;
- structural work and sources of vibration;
- controls or building-automation changes;
- temporary openings, barriers, or penetrations elsewhere in the building.

RESPONSE

Coordinate with the project or facilities team before treating the issue solely as a laboratory fault.

Where construction could plausibly affect containment, establish appropriate monitoring and post-work verification.

ESCALATION

Escalate when construction changes shared infrastructure, produces repeated instability, or leaves uncertainty about restoration of the previous containment condition.

SURVEILLANCE MODE

Event-triggered review.

09 Maintenance and technical intervention as sources of change

Maintenance is necessary to preserve containment, but intervention can itself change the operating condition. The relevant question is not whether the repaired component works, but whether the containment relationships affected by the intervention have also been restored.

9.1 Post-maintenance restoration of integrated performance is not confirmed

SIGNAL

A technical intervention is completed successfully at the component level, but no proportionate check confirms the resulting integrated containment condition.

Examples include fan, damper, sensor, HEPA-filter, controls, door, duct, or power-system work where the repaired or replaced component functions correctly but the relationships around it have not been rechecked.

WHY THIS MATTERS

Component restoration and system restoration are not always equivalent.

A replacement fan may deliver a different airflow. A new sensor may alter the control response. A filter replacement may change system resistance. A door replacement may change leakage. Controls work may alter sequencing, interlocks, alarm behavior, or how adjacent rooms respond.

The intervention can therefore be technically successful at the component level while the integrated containment condition has shifted. The question after maintenance is not only “does the repaired item work?” but “did the system return to an acceptable and understood operating condition?”

WHAT TO REVIEW

Determine:

- what system relationships the intervention could affect;
- whether operating values changed afterward;
- whether controls required retuning;
- whether pressure or airflow returned to the justified reference state;
- whether post-work verification was defined in advance.

RESPONSE

Match the post-intervention check to the consequence of the work.

A minor equivalent replacement may require only local confirmation. A change affecting airflow, controls, or containment boundaries may require broader functional verification.

ESCALATION

Escalate when the intervention affects several containment dependencies, produces unexplained changes, or the previous operating condition cannot be restored or justified.

SURVEILLANCE MODE

Event-triggered review.

9.2 Corrective maintenance repeatedly affects the same system

SIGNAL

The same fan, damper, sensor, door, control loop, autoclave, or utility repeatedly generates corrective work.

WHY THIS MATTERS

Repeated maintenance can look like a series of independent failures because each work order is opened and closed separately.

The recurrence may instead indicate an unresolved root cause, unsuitable operating duty, environmental stress, poor repair quality, or a problem elsewhere in the system that repeatedly appears through the same component.

The history therefore becomes more informative than the latest fault.

WHAT TO REVIEW

Compare:

- frequency of recurrence;
- previous corrective actions;
- whether the same symptom returns;
- operating conditions at the time of failure;
- related changes elsewhere in the system.
- whether installed replacement parts retain the necessary specifications and functional equivalence, and whether their substitution coincides with the appearance or recurrence of the problem;

RESPONSE

When recurrence develops, review the sequence as one problem rather than continuing to treat each event independently.

ESCALATION

Escalate when repeated intervention fails to produce durable resolution, containment reliability is affected, or temporary repair becomes routine.

SURVEILLANCE MODE

Periodic review.

10 Data quality and interpretability

Containment surveillance depends on evidence. Where the data themselves are unreliable, incomplete, or too fragmented to compare over time, the facility may either miss meaningful change or investigate variation that is not real.

The absence of evidence can also be a relevant signal. Missing trend history, alarm records, post-maintenance evidence, redundancy-readiness testing, justification for parameter changes, or technical closure of corrective actions reduces the facility's ability to explain its current condition. Missing data do not demonstrate deterioration, but they increase uncertainty that should be recognized.

10.1 Instruments intended to describe the same condition disagree

SIGNAL

Different measurements of the same parameter produce materially different results.

Examples include:

- BMS pressure versus independent manometer;
- local gauge versus central monitoring;
- measured airflow versus control-system indication;
- disagreement between redundant sensors.

WHY THIS MATTERS

Before interpreting a trend as system change, the facility has to establish that the measurement is trustworthy.

A drifting sensor, damaged pressure tubing, changed sensor location, or calibration problem can create apparent containment change where none exists. The reverse is also possible: a poorly performing instrument can conceal a real change.

Agreement between instruments does not by itself demonstrate that the measurement is correct. Two values can agree and still be misleading if they share an error in reference, configuration, scaling, location, calibration, or data acquisition. A plausible number should still be traceable to a reliable measurement chain.

WHAT TO REVIEW

Check:

- calibration status;
- sensor location;
- pressure tubing or impulse lines;
- measurement method;
- units;
- recent replacement or controls work.

RESPONSE

Resolve significant measurement disagreement before using the affected value to make system-level conclusions.

Where necessary, confirm the condition independently.

ESCALATION

Escalate when critical containment decisions depend on measurements whose accuracy cannot be established.

SURVEILLANCE MODE

Routine observation, **periodic review**, and **event-triggered review**.

10.2 Only instantaneous values are available

SIGNAL

The facility can see current conditions but cannot retrieve enough history to determine how they have changed.

WHY THIS MATTERS

Many meaningful changes do not appear as sudden failures.

Pressure may become gradually more variable. Fan speed may rise over months. Alarm frequency may increase slowly. Seasonal instability may recur at the same time each year. None of these patterns is easy to recognize from a display showing only the current value.

Without historical continuity, the facility can confirm what is happening now but may have little evidence of how it arrived there.

WHAT TO REVIEW

Determine which parameters are important enough to retain longitudinally.

Depending on the facility, this may include:

- pressure trends;
- fan speed or control effort;
- alarm history;
- filter resistance;
- selected environmental conditions.
- airflow and pressure drop where these variables are relevant to interpreting performance, without substituting isolated measurements for trend records;

Avoid collecting large volumes of data that no one reviews. The objective is interpretability, not data accumulation.

RESPONSE

Retain enough history to support comparison and periodic review of the containment condition.

Where historical data do not exist, begin establishing a usable trend rather than attempting to infer past behavior from current values.

ESCALATION

Escalate when lack of data materially prevents interpretation of recurring or unexplained containment behavior.

SURVEILLANCE MODE

Continuous monitoring and **periodic review**.

10.3 Data are retained but cease to be used to interpret performance

SIGNAL

The system records trends, alarms, or technical histories, but these are consulted mainly after an incident or are not reviewed in a way that allows gradual changes or recurring patterns to be recognized.

Continuous records may exist without comparison against the reference state, clear interpretation criteria, or evidence that identified deviations have been examined.

WHY THIS MATTERS

The availability of information is not the same as effective surveillance. A trend may show a progressive increase in control effort, increasingly slow recovery, or recurring alarms without any of those changes informing operational or maintenance decisions.

The problem is not that data become routine, but that their review stops distinguishing expected behavior, justified changes, and potential deterioration. A facility may continue producing records while losing the ability to recognize what those records reveal.

WHAT TO REVIEW

- which trends and records are actually reviewed and for what purpose;
- whether comparisons are made with a justified reference state;
- whether recurring alarms and gradual changes are interpreted and documented;
- who has the competence, access, and responsibility to examine the information;
- whether a conclusion or intervention can be traced to the evidence used.

RESPONSE

Establish a proportionate review of records describing critical functions and relevant changes, identifying who interprets trends and when a deviation requires broader investigation.

Not all data need to be reviewed at the same frequency. The objective is for retained information to support defensible comparisons and decisions.

ESCALATION

Broader review is warranted when trends show accumulated changes without interpretation, recurring alarms have become normalized without explanation, or available data do not support decisions concerning the performance of critical functions.

SURVEILLANCE MODE

Periodic review and **event-triggered review**.

11 Responding to a change

The purpose of surveillance is not simply to accumulate observations. Once something changes, the facility needs to determine whether the signal represents normal variation, a local fault, a known consequence of an intentional change, or evidence that the operating condition itself may be shifting.

The initial response should remain proportionate. Many observations will have straightforward explanations and can be resolved locally. The important point is to avoid correcting the visible symptom in a way that removes the evidence before the cause has been understood.

11.1 Confirm that the change is real

SIGNAL

A value, behavior, condition, or operating practice appears different from what is normally expected.

Examples include:

- pressure has shifted;
- alarms recur;
- a door behaves differently;
- equipment sounds or responds differently;
- room temperature has changed;
- a workaround has appeared;
- a previously temporary condition remains in place.

WHY THIS MATTERS

Not every unusual observation represents a meaningful change.

Instrumentation can drift. A single excursion may reflect ordinary variation. A door can develop a purely mechanical fault. One abnormal autoclave cycle may result from an atypical load.

Acting immediately on an unconfirmed signal can introduce new changes into the system before the original observation has been understood.

WHAT TO REVIEW

Confirm the observation using the information available.

Depending on the signal, this may include:

- repeat observation;
- independent measurement;
- recent trend data;
- calibration status;
- comparison with adjacent spaces or similar equipment;
- operator reports;
- recent maintenance history.

RESPONSE

Establish whether the condition is repeatable, persistent, or supported by another source of evidence.

If it appears to be an isolated anomaly and subsequent behavior is normal, retain the observation where appropriate and continue surveillance.

ESCALATION

Move to further investigation when the signal persists, recurs, appears in several related parameters, or coincides with another known change.

SURVEILLANCE MODE

Routine observation, **periodic review**, and **event-triggered review**.

11.2 Look for what changed around the same time

SIGNAL

A confirmed change has occurred, but the immediate cause is not obvious.

WHY THIS MATTERS

The location of the symptom does not necessarily identify the origin of the problem.

A pressure shift may follow ventilation work, but it may also follow installation of a heat-generating instrument. A recurring door issue may originate in the hardware or in a changing pressure relationship. Room instability may begin after work elsewhere in the building.

Recent change history can therefore narrow the investigation before additional adjustments are made.

WHAT TO REVIEW

Look back over the period preceding the signal and identify relevant changes such as:

- maintenance or repairs;
- controls adjustments;
- equipment installation or relocation;
- workload change;
- new procedures;
- altered room use;
- adjacent construction;
- changes in utilities;
- staffing or responsibility changes.

The presence of a recent change does not prove causation. It identifies a plausible relationship that can be tested.

RESPONSE

Prioritize explanations that are consistent with both the timing and the mechanism of the observed change.

Avoid assuming that the most recent event caused the problem merely because it occurred first.

ESCALATION

Expand the investigation when no local or recent change adequately explains the condition, or when several simultaneous changes make the relationship difficult to isolate.

SURVEILLANCE MODE

Event-triggered review.

11.3 Compare the current condition with the reference state

SIGNAL

The change has been confirmed, but its significance remains uncertain.

The current condition may still fall within an allowable limit, which makes comparison with the previous justified operating condition especially important.

WHY THIS MATTERS

A current value can be acceptable while still representing a meaningful departure from previous behavior.

Comparison with the reference state is not simply a same/different check. It asks whether the difference is understood, whether it follows from a known and justified change, whether the assumptions supporting the reference state still apply, and whether the current condition remains compatible with the facility's operating basis.

This becomes particularly important where controls are compensating successfully and the final output still appears normal. A stable room pressure, for example, may conceal substantially different fan effort, damper position, leakage, or recovery behavior.

WHAT TO REVIEW

Compare, where available:

- current and historical pressure behavior;
- airflow quantities;
- fan or damper operating points;
- alarm patterns;
- recovery behavior;
- relevant process or validation data;
- the operating assumptions associated with the reference state.

Also confirm whether the reference itself remains valid for the work currently being performed.

RESPONSE

Determine whether the change:

- falls within understood variation;
- reflects a known and justified modification;
- requires correction back toward the previous condition;
- or indicates that a new operating condition may need to be established and verified.

ESCALATION

Escalate when the current state cannot be reconciled with the reference state, or when the reference state itself is too uncertain to support interpretation.

SURVEILLANCE MODE

Periodic review and **event-triggered review**.

11.4 Determine whether the problem is local

SIGNAL

The immediate component or room has been checked, but the observed condition remains unexplained or repeatedly returns.

WHY THIS MATTERS

Local troubleshooting is usually the correct place to begin, but recurrence can show that the component is responding to a condition elsewhere.

A door repeatedly adjusted for closing force may be responding to changed room pressure. A room repeatedly rebalanced may be affected by a shared exhaust system. A BSC alarm may reflect a device issue or altered airflow in the room.

Continuing to repair the same visible symptom can delay recognition of the wider mechanism.

WHAT TO REVIEW

Ask whether:

- adjacent rooms are also changing;
- the affected system shares infrastructure with other areas;
- the symptom follows changes in workload or equipment;
- the problem returns after apparently successful repair;
- correction in one location creates an effect elsewhere.

RESPONSE

Begin with the smallest plausible system boundary and expand it only when the evidence requires it.

The purpose is not to assume every problem is systemic, but to avoid keeping the investigation local after the local explanation has stopped being convincing.

ESCALATION

Escalate when several systems or spaces are implicated, repeated correction does not resolve the condition, or the mechanism crosses technical or organizational boundaries.

SURVEILLANCE MODE

Event-triggered review.

11.5 Correct the identified cause, not only the visible symptom

SIGNAL

A plausible mechanism has been identified and corrective action is being considered.

WHY THIS MATTERS

Some interventions restore the visible parameter without resolving the condition that produced the change.

Increasing exhaust can restore room pressure. Extending an alarm delay can reduce alarm frequency. Adjusting a door closer can restore closure. These actions may be appropriate, but the disappearance of the symptom does not establish that the underlying cause has been removed.

A correction should therefore be judged against the mechanism that was identified, not solely against the parameter that originally attracted attention.

WHAT TO REVIEW

Before implementing the correction, consider:

- what condition the intervention is intended to restore;
- whether it will affect other systems;
- whether it introduces a new operating state;
- whether temporary controls are required;
- what evidence will show that the correction was successful.

RESPONSE

Implement the proportionate corrective action and retain enough information to compare the resulting condition with the intended outcome.

If the intervention intentionally establishes a different operating state, document that change rather than treating the new values as though they were unchanged from the previous reference state.

ESCALATION

Escalate when correction of one condition creates another, requires repeated compensating adjustment, or cannot restore a technically defensible operating state.

SURVEILLANCE MODE

Event-triggered review.

11.6 Verify that the correction restored an acceptable containment condition

SIGNAL

The immediate fault or abnormal condition appears to have been corrected.

WHY THIS MATTERS

Completion of the repair does not always demonstrate restoration of containment.

A fan can operate after replacement while airflow balance remains different. A new sensor can provide a stable reading while alarm behavior has changed. A repaired penetration can appear complete without demonstrating that the affected boundary performs as required.

The verification required should be proportionate to the intervention, but some evidence of restoration is necessary where the change could affect containment relationships.

WHAT TO REVIEW

Determine:

- whether the original signal has resolved;
- whether related parameters returned to expected behavior;
- whether new abnormalities appeared elsewhere;
- whether relevant failure or recovery behavior remains acceptable;
- whether the resulting condition corresponds to the previous reference or a newly justified state.

RESPONSE

Close the issue only when the facility has enough evidence to show that the intended condition has been restored or that the new condition is acceptable.

Administrative closure and technical closure should not be assumed to be the same thing.

ESCALATION

Escalate when the immediate repair succeeds but the wider system does not return to an understood condition.

SURVEILLANCE MODE

Event-triggered review and **periodic review**.

11.7 Escalate when the explanation no longer remains local or sufficiently certain

SIGNAL

The facility cannot confidently explain or resolve the observed change through ordinary local troubleshooting.

Typical indicators include:

- repeated recurrence after correction;
- several related signals changing together;
- declining operating margin;
- loss of functional redundancy;
- correction in one system producing effects elsewhere;
- uncertainty about the reference state;
- unresolved interaction between technical and operational changes;
- known deficiencies remaining unresolved because of institutional constraints.

WHY THIS MATTERS

The need for escalation is not determined simply by the severity of the first symptom.

A relatively small recurring problem may reveal a broader unresolved mechanism, while a more dramatic fault may be straightforward to diagnose and repair. The relevant threshold is reached when the facility can no longer connect the observation to a sufficiently credible explanation and from that explanation to an acceptable operating condition.

At that point, additional local adjustment may make the problem less rather than more visible.

WHAT TO REVIEW

Before escalating, assemble enough context to describe:

- what changed;
- when it began;
- what has already been checked;
- relevant recent modifications;
- historical behavior;
- corrective actions attempted;
- unresolved uncertainty.

This information helps prevent the broader investigation from starting again at the level of the original symptom.

RESPONSE

Move the issue to the level of expertise and scope needed to resolve the remaining uncertainty.

Depending on the problem, this may involve internal engineering, biosafety, facilities management, specialist service providers, or a broader containment-system evaluation.

ESCALATION

A system-level evaluation becomes particularly appropriate when:

- the cause remains unclear after reasonable local investigation;
- several systems or spaces are implicated;
- operating margin continues to decline;
- the facility lacks a defensible reference state;
- technical performance cannot be demonstrated after correction;
- or the institutional arrangements needed to sustain containment have themselves become part of the problem.

SURVEILLANCE MODE

Event-triggered review.

12 Interpreting recurring patterns

Some signals become more meaningful when they are considered together. This does not require a separate diagnostic methodology at the public-guide level, but several recurring patterns are useful for facility personnel and managers to recognize because they can make changing conditions appear more stable than they are.

12.1 Different forms of compensation accumulate around the same condition

SIGNAL

An expected containment condition continues to be maintained, but different technical or operational measures are gradually being added around it.

Examples may include:

- a ventilation system operating with higher control effort;
- more frequent manual intervention;
- an operating sequence altered to avoid recurring instability;
- temporary cooling or other support measures remaining in place;
- maintenance or adjustment becoming more frequent;
- alarm handling being modified around a persistent condition.

WHY THIS MATTERS

A single compensating response may be appropriate and fully justified. The pattern becomes more significant when compensation begins to migrate across systems or activities while the visible outcome remains apparently unchanged.

At that point, the facility may be maintaining the same result through a combination of technical reserve, operator adaptation, temporary measures, and repeated intervention. No individual measure necessarily demonstrates deterioration, but the accumulation can make a changed operating condition appear stable.

This pattern is broader than increasing technical control effort alone, which is addressed in Section 4.4. The concern here is whether several different forms of compensation are beginning to support the same unresolved condition.

WHAT TO REVIEW

Look across technical, operational, and maintenance records for measures that appeared during the same period and determine whether they respond to a common condition.

RESPONSE

Assess the underlying condition rather than treating each compensating measure as an independent solution. Where the measures are intentional and justified, ensure that the resulting operating state is understood and documented.

ESCALATION

Escalate when several forms of compensation are required to sustain normal operation, when one compensating measure creates the need for another, or when the underlying condition remains unexplained.

SURVEILLANCE MODE

Periodic review.

12.2 An abnormal condition has become familiar

SIGNAL

A condition that originally attracted attention is now treated as ordinary. The issue here is not the existence of a temporary condition or workaround itself, but the loss of attention to it through familiarity.

Examples include:

- recurring alarms;
- repeated temporary repair;
- unavailable redundancy;
- manual workaround;
- persistent small defect;
- modified operating sequence.

WHY THIS MATTERS

Familiarity can change the way evidence is interpreted without changing the underlying condition.

An alarm may attract immediate investigation the first time it occurs and little attention after the fiftieth occurrence. A temporary condition may cease to be discussed because staff have learned to work around it.

The decrease in attention does not demonstrate technical improvement.

WHAT TO REVIEW

Look for conditions that have persisted long enough that their original reason, intended duration, or unresolved status is no longer clear.

RESPONSE

Reassess whether the condition remains technically justified rather than allowing familiarity to determine acceptability.

ESCALATION

Escalate when the normalized condition affects containment performance, removes redundancy, or depends on a workaround that was never formally accepted.

SURVEILLANCE MODE

Routine observation and **periodic review**.

12.3 Several small changes begin to reinforce one another

SIGNAL

No single change appears serious, but several occur during the same period.

For example:

- workload rises;
- a technical position remains vacant;
- maintenance response slows;
- room temperature increases;
- alarm frequency begins to rise.

WHY THIS MATTERS

The effect of several changes may be greater than the significance of any one considered alone.

Increased workload may consume capacity that previously accommodated filter loading. Loss of technical staff may delay recognition of the resulting trend. A deferred corrective action may then remain in place longer because the institution is already operating under greater demand.

The interaction is what changes the risk.

WHAT TO REVIEW

During periodic review, compare technical, operational, and governance changes occurring during the same period rather than reviewing each category separately.

RESPONSE

Identify whether the changes are linked by a plausible mechanism and whether their combined effect alters the operating condition or available resilience.

ESCALATION

Escalate when several simultaneous changes make it difficult to establish which conditions the facility can still rely on.

SURVEILLANCE MODE

Periodic review.

12.4 The symptom repeatedly appears in the wrong place

SIGNAL

The same visible problem returns despite competent local correction, or different local symptoms repeatedly appear around the same period or system.

Examples include a door repeatedly becoming difficult to close after pressure changes, a recurring room-temperature problem after process load increases, or a pressure alarm that returns after local sensor checks because the disturbance originates in shared ventilation or building infrastructure.

WHY THIS MATTERS

Recurrence may indicate that the affected component is responding to a condition elsewhere rather than generating the problem itself.

A door can reflect room pressure. A temperature problem can reflect changed process load or airflow. A pressure alarm can originate in shared infrastructure. A technical deficiency can persist because procurement, responsibility, access, or another governance constraint prevents permanent correction.

When competent local correction repeatedly fails to produce durable resolution, the location of the symptom should not be assumed to identify the location of the cause.

WHAT TO REVIEW

Look beyond the affected component for:

- shared systems;
- recent operational changes;
- external building work;
- unresolved governance constraints;
- repeated compensating adjustments.

RESPONSE

Expand the investigation only as far as necessary to explain the recurring condition.

ESCALATION

Escalate when the causal chain crosses several systems or institutional responsibilities and cannot be resolved through local intervention.

SURVEILLANCE MODE

Event-triggered review.

13 Using the guide by surveillance interval

The previous sections organize signals according to where change may be occurring. In practice, however, most facilities will need a simpler way to use the guidance over time. The same condition may need to be noticed routinely, reviewed as a trend several months later, and formally verified at a longer interval. The surveillance interval therefore reflects what can reasonably be learned at each stage rather than the importance of the system itself.

The frequencies below should not override regulatory requirements, manufacturer instructions, validation schedules, or frequencies established through facility-specific risk assessment. They provide a surveillance rhythm for recognizing change between those formal activities.

13.1 Routine / approximately monthly review

The monthly review is primarily concerned with what has changed since the facility was last looked at deliberately.

It should remain close to operating experience. Most of the useful evidence at this stage does not require specialist testing.

Look for changes in room and system behavior

Review whether:

- pressure readings are behaving differently from their usual pattern;
- pressure alarms are becoming more frequent;
- recovery after ordinary door opening appears different;
- doors have become harder to open, slower to close, or less reliable in latching;
- room temperature, humidity, noise, vibration, or other environmental conditions have changed;
- operators report that a BSC or other critical device behaves differently.

A single observation may require little more than follow-up. Recurrence, persistence, or several changes appearing together deserves more attention.

Look for visible changes in the physical containment condition

Review whether:

- seals, joints, finishes, or penetrations have changed;
- previously repaired defects have returned;
- new cables, pipes, fixings, or other penetrations have appeared;
- water ingress, corrosion, or material deterioration is visible;
- containment doors or interfaces show progressive wear.

The aim is not to record every cosmetic defect, but to preserve evidence where a condition is new, recurring, or progressing.

Look for changes in how the laboratory is actually being used

Consider whether, during the previous month:

- equipment was added or relocated;
- workload noticeably increased;
- more people routinely use the space;
- room functions or staging practices changed;
- material or personnel routes changed;
- working hours expanded;
- new procedures began;
- waste volume or handling changed.

Small operational changes can be easy to absorb individually. Recording them when they occur makes their cumulative effect easier to recognize later.

Look for temporary or compensating conditions

Identify whether:

- a temporary repair remains in place;
- equipment remains unavailable;
- an interlock or alarm has been bypassed or altered;
- manual monitoring has replaced an automated function;
- portable equipment is compensating for a technical problem;
- staff are relying on a recurring workaround.

The useful question is not simply whether the temporary condition is working, but whether the reason it was introduced has been resolved.

Look for unresolved institutional conditions

Note where:

- a containment-related corrective action remains open;
- a key service or maintenance activity has been delayed;
- specialist support has become unavailable;
- responsibility for an issue remains unclear;
- a relevant technical position has become vacant.

These observations may have no immediate technical consequence, but retaining them allows later technical changes to be interpreted in context.

What should come out of the monthly review

The monthly review should not produce a declaration that the facility “passes.”

Its useful outputs are much simpler:

- no meaningful change identified;
- change identified and explained;
- change identified and follow-up required;
- temporary condition remains unresolved;
- evidence should be carried forward for trend review.

13.2 Periodic / approximately six-month review

The periodic review changes the scale of observation. Its purpose is to identify patterns that were not necessarily meaningful when individual events occurred.

This review should bring together operating observations, technical records, maintenance history, and known institutional changes rather than treating them as separate reporting streams.

Review what keeps happening

Look across the previous months for:

- recurring pressure alarms;
- repeated door problems;
- repeated sensor or control faults;
- repeated repairs in the same location;
- recurring autoclave or decontamination issues;
- workarounds that continue to reappear.

Several individually minor events may describe one unresolved mechanism.

Review whether the same output now requires more effort

Where data are available, compare:

- fan speed;
- damper position;
- filter differential pressure;
- control output;
- cooling demand;
- recovery behavior.

A stable room-pressure value means something different if the system now requires substantially more effort to maintain it.

Review whether operating demand has moved

Look back far enough to see gradual changes in:

- throughput;
- equipment population;
- occupancy;
- hours of operation;
- process scale;
- room use;
- waste generation.

The useful comparison is not only with six months earlier, but with the operating conditions associated with the current reference state.

Review unresolved temporary conditions

Identify measures that were temporary at the time of introduction but remain active.

Determine whether the institution still intends to restore the previous condition or whether the temporary arrangement has effectively become permanent.

Where it has become permanent, it should no longer remain technically unevaluated simply because it began as an interim measure.

Review governance changes alongside technical evidence

Consider whether the same period has included:

- personnel turnover;
- changes in leadership or responsibility;
- reduced maintenance support;
- procurement constraints;
- growing corrective-action backlog;
- loss of specialist services;
- changed institutional mandate.

These conditions become particularly important when they coincide with technical trends. A slowly increasing fan demand means something different if it occurs during the same period that filter replacement has repeatedly been deferred.

Look for interactions rather than isolated abnormalities

The most useful part of the periodic review is often the comparison across categories.

A warmer room, increased workload, and increasing fan effort may be related. Recurrent alarms, repeated controls adjustments, and loss of redundancy may describe the same developing technical condition. A pattern of temporary repairs may be inseparable from procurement difficulty.

The review should therefore ask not only what changed, but whether several changes could be part of the same sequence.

What should come out of the periodic review

By the end of the review, the facility should be able to distinguish between:

- isolated events that have been resolved;
- expected trends that remain adequately controlled;
- recurring conditions that need further investigation;
- cumulative operational changes that may require reassessment;
- governance changes that are beginning to affect containment support;
- issues that should be carried into annual verification.

13.3 Annual review and verification

The annual interval should move beyond observation and trend interpretation to ask what the facility can still demonstrate about the operating condition it relies on.

The precise testing required will depend on the containment strategy, facility design, applicable requirements, and previous changes. The surveillance guide does not replace those technical protocols.

A useful question at the start of the review is: What can we no longer demonstrate that we could demonstrate before? Loss of evidence, competence, redundancy, traceability, or technical knowledge can be as important as a visible change in the system.

Confirm that the reference state still makes sense

Review whether:

- the documented operating basis still reflects the facility;
- significant changes during the year have been incorporated;
- current work remains consistent with the assumptions supporting the reference state;
- unresolved uncertainty has increased or decreased;
- a new reference state needs to be established.

A facility that has changed materially during the year may legitimately end the annual review with a different reference state from the one with which it began.

Demonstrate relevant containment performance

As applicable to the facility, establish that the systems on which containment depends still perform under current operating conditions.

This may include demonstration of:

- pressure relationships;
- directional airflow;
- appropriate recovery after disturbance;
- alarm and monitoring function;
- relevant airflow quantities;
- performance of critical protective systems.

The purpose is not merely to reproduce historical numbers, but to establish that the current technical condition remains consistent with the current containment strategy.

Consider capacity and resilience

Review whether the facility retains adequate ability to respond when normal conditions are disturbed.

This includes questions such as:

- Is adequate operating margin still available?
- Is redundancy actually functional?
- Do emergency systems behave as expected?
- Has increased workload consumed capacity that was previously available for failure or disturbance?

A system that performs adequately under normal conditions may still have changed significantly if the resilience behind that performance has been reduced.

Review the accumulated change history

Bring together significant:

- equipment changes;
- maintenance interventions;
- controls modifications;
- operational changes;
- temporary conditions;
- corrective actions;
- incidents or near misses.

The annual review should determine whether these still resolve into a coherent operating condition or whether too many changes remain weakly understood.

Review whether the institution can sustain what has been demonstrated

Technical verification describes the facility at the time of review. The institution must also retain the capacity to sustain that condition.

Consider whether:

- responsibilities remain clear;
- specialist competence remains available;
- corrective actions are being closed effectively;
- change control is functioning;
- critical external support remains accessible;
- resource constraints are producing unmanaged technical consequences.

What should come out of the annual review

The useful outcome is not simply a collection of current certificates and test reports.

The facility should be able to state, with appropriate supporting evidence:

- what operating condition it is maintaining;
- what significant changes occurred during the year;
- whether those changes have been assessed;
- whether the containment strategy remains appropriate for current operations;
- whether unresolved conditions remain;
- and what reference state should be carried into the next surveillance cycle.

13.4 Review when something significant changes

Some changes should not wait for the next scheduled interval.

The need for immediate review depends less on the size of the intervention than on whether it can affect an assumption supporting the current containment condition.

Examples include:

- significant ventilation or controls work;
- software or firmware updates, controller replacement, sequence changes, alarm reconfiguration, sensor remapping, or network/BMS modifications that may affect control, monitoring, or data interpretation;
- fan or major filter replacement;
- modification of containment barriers;
- new penetrations;
- relocation of major containment equipment;
- installation of high-heat-load or directly exhausted equipment;
- significant change in agents, procedures, or process scale;
- room repurposing;
- abrupt workload expansion;
- prolonged shutdown;
- major power event;
- flooding or water ingress;
- adjacent construction affecting shared infrastructure;
- serious incident or near miss;
- major institutional restructuring or mandate change;
- loss of key specialist competence.

The review should be proportionate. A like-for-like replacement may require only confirmation of restored function. A change that affects several interacting systems may require broader verification.

The governing question is whether the previous operating condition can still be assumed to apply after the change. If that cannot be established confidently, the change should remain open until sufficient evidence supports either restoration of the previous condition or acceptance of a new one.

RELATED BIOLAB GUIDANCE

This guide is intended to identify when a containment condition deserves closer attention. It does not attempt to provide the detailed technical methodology required to investigate every type of signal described above.

Where a signal points toward a more specific question, the reader should move to the relevant BioLab technical guide, note, or other specialized resource dealing with that system or issue.

Examples may include guidance on:

- pressure relationships and directional airflow;
- containment HVAC performance;
- doors and containment boundaries;
- biological safety cabinets and their operating environment;
- decontamination and sterilization systems;
- change control;
- emergency operation and resilience;
- commissioning, verification, and recommissioning;
- maintenance interventions in containment facilities;
- reconstruction or establishment of a reference state where reliable historical data do not exist.