

Laboratory Standards — Full Guidance

Complete criterion-by-criterion guidance: worked examples, first steps, common mistakes, implementation plans, and Monitor verification methods for all 64 criteria.

10 standards · 64 criteria · Version 2.0

ASF STANDARDS · LABORATORY · STANDARD 1

Standard 1 — Governance & Document Control

5 criteria · 3 non-negotiable · 2 core · Version 1.0

CRITERIA IN THIS STANDARD

1.1 — Named Accountable Person

1.2 — Document Control: One Current Version

1.3 — Document Approval Before Use

1.4 — Risk Register, Reviewed on a Schedule

1.5 — Retention Schedule Matches Legal Minimum

1.1 Named Accountable Person

NON-NEGOTIABLE

A named individual — the Laboratory Director or an equivalent role — holds documented, final accountability for the quality management system. The name is current, not a vacant title inherited from a predecessor. Financial accountability is named separately, even where the same person holds both roles, and a brief, genuine statement of mission and values exists for the laboratory.

In plain terms: One real person, currently employed, is clearly on the hook if the quality system fails — not a job title nobody updated after the last person left.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

When something goes wrong — a wrong result reaches a clinician, an inspection finds a gap, a complaint arrives — the first question is always “who owns this?” If the honest answer is “whoever happens to pick it up,” accountability has already failed. Laboratories commonly carry a Director title on the organizational chart for someone who left months or years ago, because updating the chart felt less urgent than keeping the lab running. The gap is invisible until the moment it matters most.

WHAT GOOD LOOKS LIKE

- A current staff member holds the role, verifiable against actual payroll or employment records.
- That person has documented authority to halt unsafe testing.
- Frontline staff can correctly name this person without hesitation.

COMMON FAILURE MODES

- The named Director left the organization; the title was never reassigned.
- Authority exists on paper but has never actually been exercised.
- Staff give different answers when asked who is accountable.

WORKED EXAMPLE

IN PRACTICE

A 15-staff clinical laboratory attached to a mid-sized private clinic.

BEFORE

The organizational chart listed Dr. Beridze as Laboratory Director. Dr. Beridze had left for another position fourteen months earlier. The deputy had been running the lab day-to-day but had never been formally appointed, and had no documented authority to halt testing if something went wrong.

ACTION

Management formally appointed the deputy as Acting Laboratory Director, issued a signed appointment letter specifying the scope of authority including the right to halt unsafe testing,

updated the organizational chart, and briefed all staff directly in a team meeting.

AFTER

The Monitor asked three staff members at random who was accountable for the quality system. All three named the same person correctly and described her authority accurately. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check who is actually named as Director on your current organizational chart.
2. Confirm that person is still employed in that role today.
3. If not, formally appoint whoever is actually running the lab, in writing, with explicit authority stated.
4. Tell your staff directly — don't assume the chart update is enough.

The most common mistake: Updating the organizational chart but never actually telling staff, who continue naming the previous person months later when asked.

SELF-ASSESSMENT QUESTIONS

1. Is there a named, current Laboratory Director or equivalent, not a title left over from someone who has since left? — *Verified against actual employment records, not an organizational chart that hasn't been updated.*

Evidence: Current employment record, signed appointment letter

2. Does that person hold documented authority to stop unsafe testing or release of results? — *Authority on paper only is not authority.*

Evidence: Signed delegation of authority document

3. Can staff correctly name this person if asked directly? — *If frontline staff don't know who it is, the accountability is not functioning in practice.*

Evidence: Staff interview during survey

4. Is financial accountability named separately from quality-system accountability, even if held by the same person? — *A distinct, named*

responsibility, not assumed to be covered by the Director role alone.

Evidence: Governance role documentation

5. Does a brief, genuine statement of mission and values exist, specific to this laboratory? — *A real, specific statement, not an absence of one on the assumption a lab doesn't need it.*

Evidence: Mission/values statement

COMMON REASONS FOR A PARTIAL ANSWER

- **A deputy has been running the lab for months without formal appointment.** — Functioning informally is not the same as documented accountability.
- **Authority is assumed rather than written down.** — “Of course she could stop testing if needed” is not a substitute for a signed document.

IMPLEMENTATION PLAN

When	What
Week 1	Verify who is actually, currently accountable versus who is named on paper.
Week 2	Issue or update the formal appointment letter with explicit authority.
Week 3	Brief all staff directly and update the organizational chart.
Ongoing	Review this appointment whenever the role changes hands.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Appointment record check	Reviews the current appointment letter and cross-checks the name against actual payroll or HR records.
ASK	Random staff interview	Asks two or three staff members, separately, who is accountable for the quality system, without prompting.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 5.2 (Laboratory Director). Geneva: ISO; 2022.

1.2 Document Control: One Current Version

NON-NEGOTIABLE

Every controlled policy, procedure, and SOP exists in exactly one current, identifiable version at the bench. Superseded versions are removed from use, not merely marked obsolete while remaining accessible.

In plain terms: The SOP taped next to the analyzer is always the real, current one — never an old printout someone forgot to remove.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A superseded SOP left at the bench is not a harmless historical artifact — it is a live instruction a tired or rushed technician can and will follow by mistake. Document control failures are rarely dramatic; they are a folder with three versions of the same procedure, no date distinguishing them, and no way to know at a glance which one is actually in force. The fix is unglamorous and entirely preventable.

WHAT GOOD LOOKS LIKE

- One current version per document, clearly dated and version-numbered.
- Superseded copies physically removed, not left nearby “for reference.”
- A single master register lists every controlled document’s current version.

COMMON FAILURE MODES

- An old printout left in a binder because reprinting felt unnecessary.
- Multiple section heads keeping their own partial document lists.
- A version marked “obsolete” but still sitting on the shelf.

WORKED EXAMPLE

IN PRACTICE	
A hematology section with two analyzers and a shared SOP binder.	
BEFORE	The binder at Analyzer 1 held a 2023 SOP. The binder at Analyzer 2, three meters away, held a revised 2025 version with a corrected calibration step. Neither technician knew the other binder existed.
ACTION	The Director consolidated to one master binder location, removed the outdated copy entirely, created a single master document register listing every SOP's current version, and required sign-off confirming the old copy's removal.
AFTER	The Monitor selected the hematology SOP at random and verified it matched the master register's stated current version, with no superseded copy found anywhere in the section. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

- 1. Walk every bench and photograph every SOP currently posted or in a binder.
- 2. Compare each against your master list — do the versions match?
- 3. Physically remove anything that doesn't match, on the spot.
- 4. Build one master register if none exists yet.

The most common mistake: Marking an old version “obsolete” with a stamp but leaving it in the same binder, where it still gets read under time pressure.

SELF-ASSESSMENT QUESTIONS

- 1. Pick any SOP at random at the bench — is it the current version, verifiable against the master document register? — *Spot-checked, not taken on the laboratory's word.*
Evidence: Master document register, bench inspection

2. Are superseded versions physically or digitally removed from the work area, not just labeled “obsolete”? — *A marked-obsolete copy still on the shelf gets used under pressure.*

Evidence: Bench inspection

3. Is there a single master document register that lists every controlled document and its current version? — *Not several partial lists kept by different section heads.*

Evidence: Master document register

COMMON REASONS FOR A PARTIAL ANSWER

- **Each section keeps its own list, none of them complete.** — Fragmented ownership is the most common root cause.
- **Digital and printed versions have drifted out of sync.** — An updated digital file with an un-updated printout still in use.

IMPLEMENTATION PLAN

When	What
Week 1	Inventory every controlled document currently in use across every bench.
Week 2	Build or consolidate a single master register.
Week 3	Remove every superseded copy found during the walk-through.
Ongoing	Require physical removal of old versions as part of every document revision process.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Bench spot-check	Selects a document at random bench locations and compares it against the master register.
DOCUMENT	Register review	Confirms a single, complete master register exists covering all controlled documents.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 8.3. Geneva: ISO; 2022.

Clinical and Laboratory Standards Institute. QMS02-A6: Quality Management System: Development and Management of Laboratory

1.3 Document Approval Before Use

NON-NEGOTIABLE

No policy, procedure, or SOP is used at the bench before it has been formally reviewed and approved by the accountable person or their documented delegate.

In plain terms: Nobody starts using a new procedure the day they write it — it gets a real sign-off first, by someone with the authority to give one.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A procedure written by a competent technologist is not automatically a safe one — a second, accountable set of eyes catches errors, omissions, and conflicts with other procedures that the original author, close to their own work, may miss. Skipping approval to save time at the moment of writing almost always costs more time later, when a flawed procedure has already been followed by several staff members before anyone notices.

WHAT GOOD LOOKS LIKE

- Every document shows a named approver and approval date before its effective date.
- Delegation of approval authority, where used, is itself documented.
- Approval records are retrievable on request for any document.

COMMON FAILURE MODES

- A new SOP is used immediately “while we wait for formal sign-off.”
- Informal delegation — “she usually approves these” — with nothing written down.
- Approval records exist somewhere but can’t be quickly located.

WORKED EXAMPLE

IN PRACTICE

A microbiology section adopting a new specimen-handling SOP.

BEFORE	A senior technologist drafted an updated SOP and began training colleagues on it the same week, before the Director had reviewed it. The draft contained an error in incubation time that went unnoticed for three weeks.
ACTION	The Director instituted a rule: no SOP trains or goes into use until a dated, signed approval exists. A simple approval log was created, checked before any new training session.
AFTER	The Monitor selected a recently introduced SOP and found a signed approval dated six days before the first recorded training session. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether your most recently introduced SOP has a dated approval signature.
2. If approval is delegated, write down who holds that delegation.
3. Create a simple approval log if none exists.
4. Make clear to staff: no use before approval, no exceptions.

The most common mistake: Treating approval as a formality to complete “soon” while the procedure is already in active use.

SELF-ASSESSMENT QUESTIONS

1. Does every controlled document show a named approver and approval date before its effective date? — *Not a document in active use with no visible sign-off.*
Evidence: Approval log, signed document header
2. Where approval is delegated, is the delegation itself documented and current? — *An informal “they usually handle it” is not a documented*

delegation.

Evidence: Delegation of authority record

3. Can the laboratory produce the approval record for any document the Monitor selects at random? — *On request, not after a delay to “find it.”*

Evidence: Approval log, retrievable on request

COMMON REASONS FOR A PARTIAL ANSWER

- **Verbal approval was given but never recorded in writing.** — A real conversation that nonetheless leaves no retrievable record.
- **Training began before the approval was finalized.** — Enthusiasm to roll out an improvement outpacing the control process meant to protect against error.

IMPLEMENTATION PLAN

When	What
Week 1	Audit recent SOP introductions for a documented approval date.
Week 2	Create or formalize a simple approval log.
Week 3	Brief staff that no new procedure trains before logged approval.
Ongoing	Check the approval log as a standing step before any new training session.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Approval record check	Selects a document at random and verifies a dated approval exists before its effective or first-use date.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 8.3.2. Geneva: ISO; 2022.

1.4 Risk Register, Reviewed on a Schedule

CORE

A risk register identifies specific risks to result accuracy and patient safety across the specimen pathway, with a named owner and review date for each entry, reviewed on a fixed schedule rather than only after an incident.

In plain terms: The lab keeps a real, specific list of what could go wrong and who’s responsible for watching it — checked on purpose, not only after something already has.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Most laboratories can describe their risks accurately when asked directly, in conversation. Far fewer have that knowledge written down, owned, and checked on a schedule. The gap between “we know about that” and “it’s on the register, someone’s named, and it gets reviewed every quarter” is exactly where risks that were once understood quietly drift out of anyone’s active attention.

WHAT GOOD LOOKS LIKE

- Specific, named risks — not generic entries applicable anywhere.
- Each entry has a named owner, not the Director by default on everything.
- Review happens on a genuine fixed schedule, verifiable by dates.

COMMON FAILURE MODES

- A register exists but hasn’t been opened since it was created.
- Entries like “human error” with no further specificity.
- Risks only get added after something has already gone wrong.

WORKED EXAMPLE

IN PRACTICE

A laboratory preparing for its first external review in two years.

BEFORE	A risk register existed from an initial setup exercise eighteen months earlier. It had never been reopened. Several listed risks had since been resolved; several new, real risks — a recently added point-of-care testing site, a new courier route — weren't on it at all.
ACTION	The Director assigned named owners to each entry, added the two missing recent risks, scheduled quarterly review meetings on the calendar, and retired resolved entries with a dated note rather than deleting them silently.
AFTER	The Monitor reviewed the register and found entries specific to the laboratory's actual operations, each with a named owner and a review date within the past quarter. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. List five actual risks specific to your own specimen pathway — not generic ones.
2. Assign a real, named owner to each.
3. Put a recurring review date on the calendar now, not “eventually.”
4. Review once, for real, before claiming this is in place.

The most common mistake: Creating a thorough risk register once, during a specific project, and never opening it again afterward.

SELF-ASSESSMENT QUESTIONS

1. Does the risk register name specific risks — not generic entries like “human error” with no detail? — *Vague entries that could apply to any laboratory anywhere are not genuine risk identification.*

Evidence: Risk register

2. Does each entry have a named owner responsible for it? — *A risk with no owner does not get managed.*

Evidence: Risk register with owner field

3. Is the register reviewed on a fixed schedule, verifiable by actual review dates, not only reactively after something goes wrong? — A register untouched for over a year despite a stated quarterly cycle fails this.

Evidence: Review meeting minutes or log

COMMON REASONS FOR A PARTIAL ANSWER

- **The register was built once for an audit and never revisited.** — A one-time exercise rather than a living document.
- **Review happens but isn't documented.** — An informal conversation leaves no verifiable trace.

IMPLEMENTATION PLAN

When	What
Week 1	Review and update the existing register, or build one if none exists.
Week 2	Assign named owners to every entry.
Week 3	Schedule the first formal review meeting, recurring quarterly.
Ongoing	Hold the scheduled review every quarter without exception.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Register and minutes review	Examines the register's specificity and checks review dates against meeting minutes or equivalent records.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 5.6 (Risk Management). Geneva: ISO; 2022.

International Organization for Standardization. ISO 31000:2018, Risk management — Guidelines. Geneva: ISO; 2018.

1.5 Retention Schedule Matches Legal Minimum

CORE

A documented retention schedule states how long each record type — patient results, quality control data, equipment maintenance logs, competence records — is kept, and meets or exceeds the applicable national legal minimum.

In plain terms: The lab knows, in writing, exactly how long it must keep each type of record — and actually keeps them that long, provably.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Retention gaps rarely surface during ordinary operation — they surface years later, when a patient, a legal proceeding, or a regulator asks for a record that should still exist and doesn't. Patient result retention tends to be well understood; equipment maintenance history and staff competence records are the specific categories most often discarded too early, simply because nobody wrote down that they needed the same discipline.

WHAT GOOD LOOKS LIKE

- A written schedule names every major record type, not just patient results.
- Each period meets or exceeds the current national legal minimum.
- A record from several years back can actually be retrieved on request.

COMMON FAILURE MODES

- Equipment logs discarded after a shorter, informal period.
- Retention periods based on outdated legal assumptions, never rechecked.
- Records technically retained but practically unretrievable.

WORKED EXAMPLE

IN PRACTICE

A laboratory responding to a legal records request four years after a specific test.

BEFORE	Patient result retention was well documented at ten years. Equipment maintenance logs, however, were being cleared after three years as an informal practice nobody had ever written down or checked against the actual legal requirement, which was seven years.
ACTION	The Director reviewed current national requirements for every record category, wrote a complete retention schedule covering all of them, and corrected equipment log retention going forward, flagging the gap for the records already improperly discarded.
AFTER	The Monitor requested a four-year-old equipment maintenance record and the laboratory retrieved it within minutes. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. List every record type the laboratory generates.
2. Look up the actual current legal minimum for each, don't assume.
3. Write the schedule down, don't leave it as informal practice.
4. Test retrieval of one old record from each category.

The most common mistake: Assuming equipment and competence records need less protection than patient results, when legal minimums often apply to them too.

SELF-ASSESSMENT QUESTIONS

1. Does a written retention schedule exist covering every major record type, not just patient results? — *Equipment and competence records are frequently the gap.*

Evidence: Written retention schedule

2. Does each retention period meet or exceed the national legal minimum for that record type? — *Checked against the actual current*

law, not an assumption carried over from years ago.

Evidence: Legal reference cited in the schedule

3. Can the laboratory retrieve a record from several years back within the stated retention period, not just recent ones? — A retention policy that exists on paper but fails in practice when records are actually needed.

Evidence: Retrieval test during survey

COMMON REASONS FOR A PARTIAL ANSWER

- **The schedule exists but was never checked against current law.** — Legal minimums can change; a schedule set once and never revisited may be outdated.
- **Old records exist but can't be found quickly.** — Retained in principle, but storage and indexing make real retrieval impractical.

IMPLEMENTATION PLAN

When	What
Week 1	Inventory every record type and current informal retention practice.
Week 2	Check each against the actual current national legal minimum.
Week 3	Write the formal schedule and correct any gaps found.
Ongoing	Recheck legal minimums whenever national regulation changes.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Schedule and legal cross-check	Reviews the written schedule against the laboratory's cited legal basis for each record type.
ASK	Retrieval test	Requests a specific older record and times how long genuine retrieval takes.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 8.4. Geneva: ISO; 2022.

← **Laboratory Standards —**
all standards

Standard 2 — Management
Requirements →

© 2026 **Accréditation Sans Frontières · PHIG · Sheni Network**

Standard 2 — Management Requirements

8 criteria · 4 non-negotiable · 4 core · Version 1.0

CRITERIA IN THIS STANDARD

- 2.1 — Internal Audit, On a Fixed Schedule
- 2.2 — Corrective Action Closes the Root Cause
- 2.3 — Preventive Action, Not Only Reactive
- 2.4 — Management Review, With Minutes and Actions
- 2.5 — Complaints Logged, Investigated, Closed
- 2.6 — Impartiality: No Commercial Pressure on Results
- 2.7 — Conflict of Interest Declared and Reviewed
- 2.8 — External Service and Supply Evaluation

2.1 Internal Audit, On a Fixed Schedule

NON-NEGOTIABLE

The full quality management system is internally audited at least once per year against a documented audit schedule, covering every section of the laboratory over a defined cycle, not only the sections most convenient to review.

In plain terms: Every part of the lab gets checked by someone looking specifically for problems, on a real schedule — not just the easy, visible sections.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Internal audit is the laboratory checking itself honestly before an external body does. Audits that only ever cover the same convenient sections — the main chemistry bench, say — while never reaching the satellite point-of-care site or the after-hours coverage arrangement, create a false sense of security. The gaps nobody audits are exactly where problems accumulate unnoticed.

WHAT GOOD LOOKS LIKE

- A schedule covering every section across a defined cycle, not just favorites.
- Audits actually happen on or near their scheduled date.
- Findings are detailed enough for someone outside the audit to understand them.

COMMON FAILURE MODES

- The same easy sections get audited repeatedly; harder-to-reach ones never do.
- Audits slip months behind schedule with no one tracking the slippage.
- Findings are a checklist of ticks with no real detail behind them.

WORKED EXAMPLE

IN PRACTICE

A laboratory with a main site and a small satellite point-of-care testing location.

BEFORE

Three consecutive annual audits had covered the main chemistry and hematology benches in detail. The satellite point-of-care site, five minutes away, had never once been included — it simply wasn't on anyone's list.

ACTION

The quality manager built a formal three-year audit cycle explicitly naming every physical location and section, including the satellite site,

and put the schedule on a shared calendar visible to the whole team.

AFTER

The Monitor reviewed the three-year schedule and confirmed the satellite site's first audit had been completed on time, with detailed findings on file. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. List every physical location and section the laboratory operates.
2. Check which of these your current or most recent audit actually covered.
3. Build a multi-year cycle that explicitly includes everything, not just the obvious parts.
4. Put real dates on a calendar, not a vague annual intention.

The most common mistake: A satellite or after-hours service location quietly falls outside the audit scope because nobody explicitly included it when the schedule was first built.

SELF-ASSESSMENT QUESTIONS

1. Does a documented audit schedule exist covering every laboratory section within a defined cycle? — *Not just the sections an auditor finds easiest to reach.*

Evidence: Audit schedule

2. Did the most recent audit actually happen on or near its scheduled date? — *A schedule that is routinely missed is not functioning.*

Evidence: Audit completion records

3. Are audit findings recorded in enough detail that someone outside the audit could understand what was actually checked? — *A checklist with ticks and no detail is not a usable audit record.*

Evidence: Audit report

COMMON REASONS FOR A PARTIAL ANSWER

- **A remote or satellite location was never explicitly added to scope.**
- **Audits happen but findings are too brief to act on.**

IMPLEMENTATION PLAN

When	What
Week 1	List every section and location requiring audit coverage.
Week 2	Build a multi-year cycle with explicit scheduled dates.
Week 3	Share the schedule and assign an auditor to the first session.
Ongoing	Track schedule adherence and escalate any slippage.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Schedule and report review	Checks the audit schedule's completeness against actual facility sections, and reviews recent audit report detail.

EVIDENCE BASE

- International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 8.8. Geneva: ISO; 2022.
- International Organization for Standardization. ISO 19011:2018, Guidelines for auditing management systems. Geneva: ISO; 2018.

2.2 Corrective Action Closes the Root Cause

NON-NEGOTIABLE

Every nonconformance with potential impact on patient results triggers a documented corrective action that identifies the root cause, not only the immediate symptom, and the action is verified as effective after implementation.

In plain terms: When something goes wrong, the lab fixes the real reason it happened — not just the thing that was visible that day — and checks afterward that the fix actually worked.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

“Staff error” is the single most common entry on a corrective action form, and it is almost always incomplete as a root cause. Staff rarely make errors for no reason — a confusing label, an unclear SOP step, inadequate training, chronic understaffing at a particular shift. Stopping at “staff error, retrained” without asking what allowed the error to happen leaves the actual cause fully intact, waiting to produce the same failure again.

WHAT GOOD LOOKS LIKE

- Root cause identified beyond the immediate symptom.
- Effectiveness checked after a defined interval, not assumed.
- Recurrence of the same nonconformance type triggers fresh investigation.

COMMON FAILURE MODES

- “Staff error, retrained” as the entire investigation.
- No follow-up check that the action actually worked.
- The same failure recurs months later with no connection drawn to the earlier one.

WORKED EXAMPLE

IN PRACTICE

A laboratory investigating a repeated mislabeling incident.

BEFORE

A specimen was mislabeled for the second time in three months. Both incidents were closed with “staff retrained on labeling procedure” and no further investigation.

ACTION	After the second incident, the quality manager investigated further and found both involved the same busy collection window when two phlebotomists worked side by side with visually similar pre-printed labels for different patients. The corrective action changed the label stock design and physically separated the two workstations during that window.
AFTER	The Monitor reviewed the corrective action record and found a clearly identified root cause distinct from “staff error,” plus a documented effectiveness check three months later showing no recurrence. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Pull your last five corrective actions and check how many say only “staff error.”
2. For each, ask what allowed the error to happen — that’s the real root cause.
3. Build in a scheduled follow-up check for every corrective action going forward.

The most common mistake: Treating retraining as both the root cause finding and the complete fix, when retraining addresses only one possible contributing factor.

SELF-ASSESSMENT QUESTIONS

1. Pick a recent corrective action at random — does it name a root cause, or only restate the symptom? — *“Staff error” is a symptom; what allowed the error to happen is the root cause.*

Evidence: Corrective action record

2. Was the corrective action’s effectiveness checked after a defined interval, not just implemented and assumed to have worked? — *A documented follow-up check, not an assumption.*

Evidence: Effectiveness check record

3. Where the same type of nonconformance has recurred, was that recurrence itself investigated as a sign the original action failed? — *A repeat failure without a fresh investigation suggests the corrective*

action process is not functioning.
Evidence: Nonconformance log showing trend review

COMMON REASONS FOR A PARTIAL ANSWER

- Root cause analysis stops at the first obvious answer.
- Effectiveness checks are skipped once the immediate fix is in place.

IMPLEMENTATION PLAN

When	What
Week 1	Review recent corrective actions for root-cause depth.
Week 2	Train staff involved in investigations on basic root-cause techniques.
Week 3	Add a mandatory effectiveness-check field to the corrective action form.
Ongoing	Trend nonconformance types to catch recurrence early.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Corrective action record review	Selects recent corrective actions and assesses root-cause depth and effectiveness follow-up.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 8.7. Geneva: ISO; 2022.

2.3 Preventive Action, Not Only Reactive CORE

The laboratory identifies potential nonconformances before they occur — from trend data, near-misses, risk register entries, or external quality assessment patterns — and acts on them, not only responding after an actual failure.

In plain terms: The lab doesn't just fix things after they break — it actually looks for early warning signs and acts on those too.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A laboratory that only ever acts after an actual failure is, by definition, always one step behind. The data that could have predicted the failure — a slow drift in quality control values, a near-miss that didn't quite become an incident, a pattern across external quality assessment rounds — is usually sitting right there, unused, because nobody is specifically assigned to look for it before something breaks.

WHAT GOOD LOOKS LIKE

- At least one real example of action taken from a trend, not an actual failure.
- External quality assessment performance trended across rounds, not just pass/fail.
- A named person responsible for trend review on a schedule.

COMMON FAILURE MODES

- Every documented action traces back to an actual incident.
- Quality data is collected but nobody is assigned to review trends.
- A slow drift goes unnoticed until it crosses an acceptable limit.

WORKED EXAMPLE

IN PRACTICE

A chemistry section tracking internal quality control trends.

BEFORE

Quality control values for a glucose analyzer had been drifting slowly toward the upper control limit over six weeks, still technically passing each individual run, but nobody had plotted the trend across runs to notice the pattern.

ACTION

A newly assigned quality reviewer, checking Levey-Jennings charts weekly rather than only per-run pass/fail, caught the drift and scheduled

	preventive maintenance before the analyzer actually failed control.
AFTER	The Monitor reviewed the quality reviewer's trend log and found the documented preventive action taken before any actual control failure occurred. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Name a specific person responsible for trend review, not just incident response.
2. Set a weekly or monthly schedule for reviewing quality control trends, not just pass/fail.
3. Look back at external quality assessment results for any multi-round pattern.

The most common mistake: Checking quality control only as pass/fail per run, which can hide a genuine trend developing across multiple passing runs.

SELF-ASSESSMENT QUESTIONS

1. Can the laboratory show at least one preventive action taken from trend data or a near-miss, not triggered by an actual failure? — *If every action on file follows an actual incident, prevention is not genuinely functioning.*

Evidence: Preventive action record

2. Is external quality assessment performance trended over time, not just checked pass/fail each round? — *A single-round pass can mask a worsening trend across several rounds.*

Evidence: EQA trend analysis

3. Is there a named person responsible for reviewing trends on a schedule? — *Trend data nobody is assigned to review does not drive prevention.*

Evidence: Role assignment, review schedule

COMMON REASONS FOR A PARTIAL ANSWER

- **Data is collected but review responsibility isn't clearly assigned.**
- **Trend charts exist but aren't actually looked at regularly.**

IMPLEMENTATION PLAN

When	What
Week 1	Assign a named person to trend review responsibility.
Week 2	Set up Levey-Jennings or equivalent trend charting if not already in use.
Week 3	Review existing EQA history for any missed multi-round patterns.
Ongoing	Hold a scheduled trend review, separate from routine pass/fail checks.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Trend record review	Looks for at least one preventive action genuinely triggered by trend data rather than an actual failure.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 8.5. Geneva: ISO; 2022.

Westgard JO. Basic QC Practices, 4th ed. Madison (WI): Westgard QC; 2016.

2.4 Management Review, With Minutes and Actions

CORE

Senior management formally reviews the quality management system at least annually, with documented minutes, inputs covering audits/complaints/nonconformances/external quality assessment, and tracked output actions with owners and dates.

In plain terms: Leadership actually sits down once a year, looks at the real quality data, writes down what they decided, and someone checks those decisions actually happen.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Management review is where quality data is supposed to actually reach the people with authority to allocate resources and change direction. A review that happens informally in a hallway conversation, with nothing written down and no required inputs reviewed systematically, provides none of the accountability or traceability the formal process is meant to create.

WHAT GOOD LOOKS LIKE

- Documented minutes with named attendees exist for the most recent cycle.
- Required inputs — audits, complaints, nonconformances, EQA — are all covered.
- Output actions from the previous review are traceable to completion.

COMMON FAILURE MODES

- Review happens but only covers budget, not quality inputs.
- No written minutes, just a verbal assurance “we discussed it.”
- Agreed actions from last year’s review were never followed up.

WORKED EXAMPLE

IN PRACTICE

A laboratory’s first formal management review cycle.

BEFORE	Annual “management review” had consisted of the Director briefly mentioning quality metrics during a general staff meeting, with no minutes, no structured agenda, and no tracked actions.
ACTION	The Director instituted a formal annual review meeting with a fixed agenda covering all required inputs, took written minutes with named attendees, and created an action tracker with owners and target dates for every output decision.
AFTER	The Monitor reviewed the minutes from the most recent cycle and the action tracker, confirming

three of four prior actions were completed on time and the fourth had a documented, reasonable extension. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Set a fixed annual date for the formal management review.
2. Build an agenda explicitly covering audits, complaints, nonconformances, and EQA.
3. Take real minutes, name attendees, and assign owners to every output action.

The most common mistake: Holding a review that covers operational and budget topics thoroughly while quality-specific inputs get only a passing mention.

SELF-ASSESSMENT QUESTIONS

1. Do management review minutes exist for the most recent cycle, with named attendees? — *Not a verbal assurance that “we discussed it.”*

Evidence: Signed meeting minutes

2. Do the minutes cover the required inputs — audit results, complaints, nonconformances, external quality assessment performance? — *A review that only covers budget is not a quality management review.*

Evidence: Meeting agenda and minutes

3. Are output actions from the previous review traceable to completion, with a named owner for each? — *Actions agreed and never followed up are a common, specific failure.*

Evidence: Action tracker

COMMON REASONS FOR A PARTIAL ANSWER

- Minutes exist but omit required quality inputs.
- Actions are agreed verbally but never tracked to closure.

IMPLEMENTATION PLAN

When	What
Week 1	Set the annual review date and build a structured agenda template.

When	What
Week 2	Gather required inputs — audit, complaint, nonconformance, EQA data.
Week 3	Hold the review, take formal minutes, assign action owners and dates.
Ongoing	Track output actions to completion before the next cycle.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Minutes and action tracker review	Confirms minutes cover all required inputs and checks prior action completion status.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 8.9. Geneva: ISO; 2022.

2.5 Complaints Logged, Investigated, Closed

CORE

Every complaint, from any source — patient, clinician, referring facility — is logged in a single register, investigated, and closed with a documented outcome communicated back to the complainant where contact information exists.

In plain terms: Every complaint gets written down in one place, actually looked into, and the person who complained finds out what happened.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A complaint handled verbally and resolved on the spot, with nothing logged, is invisible to the quality system — it cannot be trended, cannot inform prevention, and leaves no record that the concern was

ever taken seriously. Complaints are often the earliest, most direct signal a laboratory receives that something in its process isn't working as intended.

WHAT GOOD LOOKS LIKE • A single complaints register captures every complaint, regardless of source. • Each entry has a documented investigation outcome. • The complainant is informed of the outcome where contact exists.	COMMON FAILURE MODES • Complaints handled verbally by whoever answers the phone, never logged. • A complaint is received but the outcome is never communicated back. • Multiple informal logs exist across different staff, none complete.
--	---

WORKED EXAMPLE

IN PRACTICE <i>A laboratory receiving a complaint from a referring clinic about delayed results.</i>	
BEFORE	A referring clinic called to complain about repeatedly delayed turnaround on referred tests. The front-desk staff member apologized, promised to “look into it,” and never logged the call anywhere.
ACTION	The laboratory introduced a mandatory complaint log at every point of contact, investigated the delay — tracing it to a courier scheduling gap — fixed the underlying issue, and called the clinic back with the specific finding and the fix.
AFTER	The Monitor selected the logged complaint and found a documented investigation, a specific root cause, and a dated record of the callback informing the clinic of the outcome. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Create one single, accessible complaints log, not department-specific lists.
2. Tell all staff: every complaint gets logged, no exceptions, even if resolved immediately.
3. Build in a step to close the loop with the complainant.

The most common mistake: Treating a complaint that was resolved quickly and politely as not needing to be logged, when logging matters regardless of how smoothly it was handled in the moment.

SELF-ASSESSMENT QUESTIONS

1. Does a single complaints register exist, or are complaints handled informally by whoever receives them? — *Complaints handled verbally and never logged are effectively invisible to the quality system.*

Evidence: Complaints register

2. Is there a documented outcome for each logged complaint, not just a record that it was received? — *Receipt without resolution is not complaint handling.*

Evidence: Investigation outcome record

3. Where contact information exists, was the complainant actually informed of the outcome? — *Closing a complaint internally without telling the person who raised it undermines trust.*

Evidence: Callback or communication record

COMMON REASONS FOR A PARTIAL ANSWER

- Verbal complaints resolved on the spot are never logged.
- The register exists but outcomes are rarely communicated back.

IMPLEMENTATION PLAN

When	What
Week 1	Build or consolidate a single complaints register.
Week 2	Brief all staff that every complaint, however resolved, gets logged.
Week 3	Add a required closing-the-loop step to the process.

When	What
Ongoing	Trend complaint types quarterly for recurring themes.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Register review	Selects a logged complaint and verifies investigation outcome and complainant communication.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.7 (Complaints). Geneva: ISO; 2022.

2.6 Impartiality: No Commercial Pressure on Results

NON-NEGOTIABLE

No staff member’s remuneration, performance evaluation, or continued employment is tied, directly or indirectly, to the volume or outcome of specific test results. Laboratory personnel are protected from undue commercial or financial pressure that could influence technical judgment.

In plain terms: Nobody’s paycheck depends on what a test result says, and staff genuinely feel safe flagging a problem even if it slows things down.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Impartiality is foundational to laboratory credibility — a result is only trustworthy if nothing in how staff are compensated or evaluated creates an incentive, conscious or not, to produce a particular outcome. Volume-linked bonuses are the most direct version of this

risk, but subtler pressures — an unspoken expectation that flagging problems reflects badly on performance reviews — can be just as corrosive and are harder to detect from policy documents alone.

WHAT GOOD LOOKS LIKE • No compensation link to test volume, patterns, or referral relationships. • A written, genuine non-retaliation policy for raising quality concerns. • Staff report feeling safe raising concerns, even when confidentially asked.	COMMON FAILURE MODES • A volume-based bonus structure for technical staff. • An unwritten culture where flagging delays is discouraged informally. • Staff privately admit hesitation to raise concerns despite a written policy.
---	--

WORKED EXAMPLE

IN PRACTICE <i>A laboratory reviewing its compensation structure during a quality assessment.</i>	
BEFORE	Technical staff received a small monthly bonus tied partly to total specimens processed, originally intended to reward productivity, but which created a subtle incentive to rush rather than pause for a questionable result.
ACTION	Management restructured the bonus to be based entirely on quality metrics — EQA performance, audit findings, documentation completeness — removing any volume component, and communicated the change and its reasoning directly to staff.
AFTER	The Monitor reviewed the compensation structure and confirmed no volume or result-outcome link existed, and confidential staff conversations confirmed genuine comfort raising concerns. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Review every compensation and bonus structure for any volume or outcome link.
2. Write a clear non-retaliation policy if none exists.
3. Ask staff confidentially, separately from management, whether they'd feel safe raising a concern.

The most common mistake: A productivity bonus introduced with good intentions that inadvertently creates volume pressure nobody explicitly designed for.

SELF-ASSESSMENT QUESTIONS

1. Is any part of technical staff compensation linked to test volume, result patterns, or referral relationships? — *A volume-linked bonus for technical staff creates exactly the pressure this criterion prohibits.*

Evidence: Compensation policy

2. Is there a documented policy explicitly protecting staff who report a quality concern from retaliation? — *Protection that exists informally but isn't written down fails under pressure.*

Evidence: Non-retaliation policy

3. Would a technician who identified a result requiring re-testing feel safe raising it, even if it delays turnaround? — *Tested through confidential staff conversation, not management's own assurance.*

Evidence: Confidential staff interview

COMMON REASONS FOR A PARTIAL ANSWER

- A legacy bonus structure was never reviewed for this specific risk.
- A written policy exists but staff don't genuinely feel it applies in practice.

IMPLEMENTATION PLAN

When	What
Week 1	Audit all compensation structures for volume or outcome links.
Week 2	Write or strengthen the non-retaliation policy.
Week 3	Communicate the policy directly and explain any compensation changes.

When	What
Ongoing	Periodically check staff comfort confidentially, not just via policy review.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Compensation structure review	Examines compensation policy for any volume or outcome link.
ASK	Confidential staff interview	Speaks with staff privately, away from management, about comfort raising concerns.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 4.1. Geneva: ISO; 2022.

International Organization for Standardization. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Clause 4.1. Geneva: ISO; 2017.

2.7 Conflict of Interest Declared and Reviewed CORE

Staff and management with influence over testing, purchasing, or reporting decisions declare financial or personal interests that could reasonably affect impartiality, and these declarations are reviewed on a fixed schedule, not only collected once at hiring.

In plain terms: People who make decisions affecting testing or purchasing say upfront if they have a personal financial stake — and this gets checked again periodically, not just once when they were hired.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Circumstances change after hiring — a staff member’s spouse takes a sales role at a reagent supplier, a manager acquires a financial stake in a referral laboratory. A conflict-of-interest declaration collected once, years ago, and never refreshed captures none of this. The purpose of periodic review is specifically to catch exactly these changes before they quietly influence a purchasing or referral decision.

WHAT GOOD LOOKS LIKE • Current declarations exist for everyone in a position of influence. • A named person or body actually reviews declarations and decides on action. • Identified conflicts have a documented mitigation on record.	COMMON FAILURE MODES • Declarations collected once at hiring and never refreshed. • Declarations filed but nobody formally reviews them. • A genuine conflict is identified but no mitigation is documented.
--	---

WORKED EXAMPLE

IN PRACTICE	
<i>A laboratory’s annual conflict-of-interest review cycle.</i>	
BEFORE	Declarations had been collected once, at hiring, for all purchasing-influential staff. No refresh process existed. A purchasing manager’s recent family connection to a reagent distributor had never been captured.
ACTION	The laboratory introduced an annual declaration refresh, reviewed by the quality committee. The purchasing manager’s new family connection was disclosed in the next cycle, and the committee documented a mitigation — a second person co-signing all orders from that specific distributor.
AFTER	The Monitor reviewed the annual refresh process and the specific mitigation record, confirming the conflict had been identified and genuinely addressed. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Identify everyone with real influence over testing, purchasing, or reporting decisions.
2. Collect current declarations if none exist or they're outdated.
3. Set an annual refresh schedule and name who reviews them.

The most common mistake: Treating the hiring-stage declaration as a one-time, permanent record rather than a starting point that needs refreshing as circumstances change.

SELF-ASSESSMENT QUESTIONS

1. Do current declarations exist for everyone in a position of influence, not just a one-time declaration from years ago? — *Circumstances change; a declaration never refreshed becomes stale.*
Evidence: Current declaration records

2. Is there a named person or body responsible for reviewing declarations and deciding what action, if any, is needed? — *A declaration filed and never reviewed by anyone accomplishes nothing.*
Evidence: Review committee record

3. Where a genuine conflict was identified, is there a record of what mitigation was actually applied? — *Identification without documented mitigation is incomplete.*
Evidence: Mitigation record

COMMON REASONS FOR A PARTIAL ANSWER

- **Declarations exist but have never been refreshed since hiring.**
- **A conflict was noted but no concrete mitigation was documented.**

IMPLEMENTATION PLAN

When	What
Week 1	Identify all staff in positions of influence over testing or purchasing.
Week 2	Collect or refresh declarations for everyone identified.
Week 3	Assign review responsibility and set an annual refresh schedule.

When	What
Ongoing	Document mitigation whenever a genuine conflict is identified.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Declaration and mitigation review	Checks declaration currency and any documented mitigation for identified conflicts.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 4.1.4. Geneva: ISO; 2022.

2.8 External Service and Supply Evaluation

CORE

Reference laboratories, equipment service providers, and critical reagent suppliers are formally evaluated before use and periodically thereafter, against documented criteria relevant to the service each provides.

In plain terms: The lab doesn’t just start working with a supplier or reference lab informally — it checks them properly first, and keeps checking over time.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A laboratory’s result quality depends partly on parties it doesn’t directly control — the reference laboratory running referred tests, the technician servicing an analyzer, the supplier shipping reagents. Relationships with these parties often begin informally, through a personal recommendation or convenience, and formal evaluation is treated as paperwork to complete later. Later rarely comes, and the laboratory is left relying on providers it has never actually assessed.

WHAT GOOD LOOKS LIKE

- A documented evaluation exists before the relationship begins in earnest.
- Evaluation is repeated periodically, not only at the start.
- Unsatisfactory performance has a documented laboratory response.

COMMON FAILURE MODES

- A long-standing relationship was never formally evaluated at all.
- Initial evaluation happened but was never repeated.
- Known performance issues continue with no documented response.

WORKED EXAMPLE

IN PRACTICE

A laboratory formalizing its reference laboratory relationship.

BEFORE	The laboratory had referred specialized tests to the same reference laboratory for six years, based on an original personal connection between directors. No formal evaluation had ever been documented.
ACTION	The quality manager built a formal evaluation covering turnaround time, accreditation status, and result accuracy on split samples, completed it retrospectively, and scheduled annual re-evaluation going forward.
AFTER	The Monitor reviewed the evaluation record and the scheduled annual re-evaluation and confirmed the relationship, though long-standing, now had a genuine documented basis. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. List every reference laboratory, equipment servicer, and critical reagent supplier currently used.
2. Check which of these have a documented evaluation on file.

3. Build evaluations for any gaps, even for long-standing relationships.

The most common mistake: Assuming a long-standing, trusted relationship doesn't need formal evaluation because "we know them well" — familiarity is not the same as documented assessment.

SELF-ASSESSMENT QUESTIONS

1. Is there a documented evaluation on file for the laboratory's current reference laboratory and key equipment service providers? — *Not a relationship that began informally and was never formally assessed.*

Evidence: Supplier evaluation record

2. Are these evaluations repeated on a periodic schedule, not only at the start of the relationship? — *A provider's performance can decline over years without a fresh check.*

Evidence: Re-evaluation schedule and records

3. Where a provider's performance has been unsatisfactory, is there a record of how the laboratory responded? — *Continuing with an underperforming provider with no documented response is a gap.*

Evidence: Performance response record

COMMON REASONS FOR A PARTIAL ANSWER

- Long-standing suppliers were grandfathered in without ever being formally evaluated.
- Evaluation happened once years ago and was never repeated.

IMPLEMENTATION PLAN

When	What
Week 1	List all critical external service providers and suppliers.
Week 2	Build or complete formal evaluations for each, including long-standing ones.
Week 3	Set a periodic re-evaluation schedule.
Ongoing	Document any response to identified performance issues.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Evaluation record review	Checks for documented initial and periodic evaluation of key external providers.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.6. Geneva: ISO; 2022.

- ← Laboratory Standards — all standards
- Standard 3 — Personnel & Competence →

ASF STANDARDS · LABORATORY · STANDARD 3

Standard 3 — Personnel & Competence

5 criteria · 2 non-negotiable · 3 core · Version 1.0

CRITERIA IN THIS STANDARD

3.1 — Documented Qualification Before Independent Work

3.2 — Competence Reassessed on a Schedule

3.3 — Orientation Before First Independent Shift

3.4 — Training Records Tied to Specific SOPs

3.5 — Adequate Staffing for Safe Operation

3.1 Documented Qualification Before Independent Work

NON-NEGOTIABLE

No staff member performs a laboratory procedure unsupervised until their competence in that specific procedure has been formally assessed and documented, not merely inferred from a general qualification or job title.

In plain terms: Nobody works alone on a specific test until someone has actually checked they can do that specific test correctly — a degree alone doesn't count as that check.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A medical laboratory science degree demonstrates general competence, not proficiency in a specific instrument, a specific SOP, or a specific laboratory's particular workflow. A newly hired technologist with years of prior experience elsewhere can still make procedure-specific errors on their first unsupervised shift in a new environment. Documented, procedure-specific competence assessment is what actually confirms readiness, not the credential that got someone hired.

WHAT GOOD LOOKS LIKE

- A documented competence record exists for every procedure performed unsupervised.
- Assessment is performed by someone other than the staff member.
- The actual competence-confirmation date is recorded, separate from the hire date.

COMMON FAILURE MODES

- A degree or certificate is treated as sufficient on its own.
- Staff self-certify their own readiness.
- Hire date is recorded as if it were the competence confirmation date.

WORKED EXAMPLE

IN PRACTICE

A laboratory hiring an experienced technologist from another facility.

BEFORE

A technologist with eight years of experience elsewhere was scheduled for independent shifts starting her second week, based on her resume and a brief informal walkthrough, with no documented assessment of her performance on this laboratory's specific instruments and SOPs.

ACTION

The quality manager introduced a mandatory two-week supervised period with a documented, procedure-by-procedure competence checklist, signed off by a senior technologist observing

actual performance, before any unsupervised shift was scheduled.

AFTER

The Monitor selected this staff member's file and found a dated, signed competence record for each procedure she performed independently, distinct from her hire date. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether current staff have documented, procedure-specific competence records.
2. Build a simple checklist per major procedure if none exists.
3. Require sign-off by someone other than the staff member being assessed.

The most common mistake: Treating prior experience at another facility as equivalent to competence on this laboratory's own instruments and procedures, which often differ in meaningful ways.

SELF-ASSESSMENT QUESTIONS

1. Pick a staff member at random — does a documented competence record exist for every procedure they perform unsupervised? — *A nursing or laboratory degree is not, by itself, documented competence in a specific procedure.*

Evidence: Competence assessment record

2. Was the competence assessment performed by someone else, not self-certified by the staff member? — *Self-assessment of one's own competence is not independent verification.*

Evidence: Assessor signature on record

3. Is there a record of the actual date competence was confirmed, not just a start date of employment? — *The two dates are often different and the distinction matters.*

Evidence: Dated competence record

COMMON REASONS FOR A PARTIAL ANSWER

- **Experienced hires skip formal assessment based on assumed competence.**
- **Records exist but lack a distinct competence-confirmation date.**

IMPLEMENTATION PLAN

When	What
Week 1	Audit current staff competence records for gaps.
Week 2	Build procedure-specific competence checklists.
Week 3	Complete assessment for any staff member currently missing one.
Ongoing	Require competence sign-off before any new hire works unsupervised, regardless of prior experience.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Competence record check	Selects a staff member at random and verifies procedure-specific, independently signed competence records.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.2.6. Geneva: ISO; 2022.

Clinical and Laboratory Standards Institute. QMS03-A4: Training and Competence Assessment. Wayne (PA): CLSI; 2016.

3.2 Competence Reassessed on a Schedule

NON-NEGOTIABLE

Staff competence is formally reassessed at defined intervals — not only at hiring — and immediately following any extended absence, procedural change, or identified performance concern.

In plain terms: Competence gets checked again regularly, not just once when someone started — and especially after a long break or whenever a procedure changes.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Skills genuinely can lapse — a procedure performed rarely, a long parental or medical leave, months away from a specific instrument. Treating the initial hiring-stage competence confirmation as permanent ignores this reality entirely. Reassessment triggered specifically by absence, procedural change, or a performance concern catches exactly the situations where competence is most likely to have genuinely changed.

WHAT GOOD LOOKS LIKE

- A fixed reassessment interval is actually met, verifiable by dates.
- Return from extended leave triggers reconfirmation before independent work resumes.
- A performance concern triggers targeted reassessment promptly, not at the next routine cycle.

COMMON FAILURE MODES

- A stated annual cycle that hasn't actually happened in two years.
- Staff resume work immediately after extended leave with no reconfirmation.
- A known performance concern waits months for the next scheduled review.

WORKED EXAMPLE

IN PRACTICE

A technologist returning from six months of medical leave.

BEFORE

The laboratory's policy stated competence would be reassessed "as needed," which in practice meant it rarely happened. A technologist returned from six months of leave and resumed her normal independent schedule the same day, with no reconfirmation of any kind.

ACTION

The quality manager introduced a specific trigger: any absence over thirty days requires supervised reconfirmation before resuming independent

work, alongside a fixed annual reassessment cycle for all staff.

AFTER

The Monitor reviewed the next staff member returning from extended leave and found a documented, dated reconfirmation completed before independent shifts resumed. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Set a specific, fixed reassessment interval — not “as needed.”
2. Define what counts as an “extended absence” triggering reconfirmation.
3. Build a process to flag performance concerns for targeted, prompt reassessment.

The most common mistake: A policy word like “periodically” or “as needed” with no actual defined interval, which in practice means reassessment rarely or never happens.

SELF-ASSESSMENT QUESTIONS

1. Is there a fixed reassessment interval, and does the most recent reassessment date for staff fall within it? — *A policy stating annual reassessment that hasn’t actually happened in two years fails this.*

Evidence: Reassessment schedule and records

2. Following a staff member’s return from extended leave, was competence reconfirmed before they resumed unsupervised work? — *Skills can lapse; resuming without reconfirmation is a real risk.*

Evidence: Return-to-work reconfirmation record

3. Where a performance concern was identified, was a targeted reassessment triggered specifically because of it? — *Not just folded into the next routine cycle months later.*

Evidence: Targeted reassessment record

COMMON REASONS FOR A PARTIAL ANSWER

- The stated interval exists on paper but is routinely missed in practice.
- No specific trigger exists for extended-absence reconfirmation.

IMPLEMENTATION PLAN

When	What
Week 1	Define a specific reassessment interval and extended-absence threshold.
Week 2	Check current staff against the new schedule for overdue reassessment.
Week 3	Complete any overdue reassessments.
Ongoing	Trigger reconfirmation automatically after any qualifying absence.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Reassessment record review	Checks reassessment dates against the defined interval and verifies any recent return-from-leave reconfirmation.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.2.6. Geneva: ISO; 2022.
--

3.3 Orientation Before First Independent Shift CORE

Every new staff member completes a documented orientation covering the laboratory’s quality management system, safety procedures, and their specific role’s SOPs before working an unsupervised shift.
--

In plain terms: Before anyone works alone, they’ve genuinely been shown how this specific lab works — not just handed paperwork to sign.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

General HR onboarding — benefits paperwork, facility tour, policy acknowledgment signatures — is necessary but is not the same thing as safety and quality orientation. A new staff member who has signed a stack of forms may still have no genuine understanding of this laboratory’s specific hazard points, emergency procedures, or quality expectations. The distinction matters most in the first unsupervised shift, when there is no one immediately present to catch a gap in understanding.

WHAT GOOD LOOKS LIKE	COMMON FAILURE MODES
• A signed orientation record is dated before the first unsupervised shift. • Safety procedures are covered specifically, not folded into general HR content. • A recently hired staff member can describe what orientation actually covered.	• Orientation record is signed retroactively, after work has already begun. • Orientation is entirely administrative, with no safety-specific content. • A new staff member can't recall any specific content from their orientation.

WORKED EXAMPLE

IN PRACTICE	
<i>A laboratory onboarding a new phlebotomist.</i>	
BEFORE	New hires signed a general HR orientation form on their first day, covering benefits and facility policies, and were scheduled for independent collection shifts within the week with no documented safety or quality-specific orientation.
ACTION	The laboratory built a separate, specific safety-and-quality orientation checklist — covering exposure response, specimen labeling requirements, and the quality management system basics — completed and signed before any independent shift was scheduled.
AFTER	The Monitor asked a recently hired phlebotomist to describe her orientation and she accurately

described the exposure response procedure and labeling requirements. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Separate safety-and-quality orientation from general HR onboarding.
2. Build a specific checklist covering the actual hazards and procedures of the role.
3. Require sign-off dated before the first unsupervised shift.

The most common mistake: Treating signature on a general HR orientation packet as equivalent to genuine safety and quality orientation specific to the laboratory role.

SELF-ASSESSMENT QUESTIONS

1. Does a signed orientation record exist for current staff, dated before their first unsupervised shift? — *Dated after the fact does not satisfy this criterion.*

Evidence: Signed orientation record

2. Does orientation cover safety procedures specifically, not only administrative onboarding? — *HR paperwork alone is not safety orientation.*

Evidence: Orientation content checklist

3. Can a recently hired staff member describe what their orientation actually covered? — *Verified by asking the person directly, not only checking the signed form.*

Evidence: Staff interview

COMMON REASONS FOR A PARTIAL ANSWER

- **Orientation is administrative only, with no safety-specific content.**
- **The signed record predates actual content delivery, or follows it.**

IMPLEMENTATION PLAN

When	What
Week 1	Build a safety-and-quality-specific orientation checklist.

When	What
Week 2	Pilot it with the next new hire.
Week 3	Refine based on what the pilot revealed as unclear.
Ongoing	Require completion before every new hire's first unsupervised shift.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
ASK	Recent-hire interview	Asks a recently onboarded staff member to describe specific orientation content without prompting.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.2.5. Geneva: ISO; 2022.

3.4 Training Records Tied to Specific SOPs

CORE

Training records name the specific SOP or procedure version a staff member was trained on, and are updated whenever that SOP is revised, so the laboratory can show at any time exactly which version of a procedure each staff member is currently qualified to perform.

In plain terms: The lab can say, for any staff member right now, exactly which version of which procedure they're actually trained and cleared to perform.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A training record reading “trained on specimen handling” tells a Monitor almost nothing — which version, which specific steps, how recently. When an SOP is revised, the gap between the revision date and the

actual retraining date is exactly where staff can continue following an outdated procedure in good faith, genuinely unaware anything has changed.

WHAT GOOD LOOKS LIKE • Records name the specific SOP and version trained on. • Retraining follows every SOP revision before the new version takes effect. • Current qualification status is retrievable for any staff member on request.	COMMON FAILURE MODES • Training records only name a general subject area, not a specific SOP version. • An SOP is revised with no corresponding retraining record. • Qualification status must be reconstructed manually from scattered files.
---	---

WORKED EXAMPLE

IN PRACTICE	
<i>A laboratory revising its hematology specimen-handling SOP.</i>	
BEFORE	Training records simply stated “trained on hematology handling,” with no version reference. When the SOP was revised to add a new mixing step, no systematic retraining record was created — some staff learned of the change informally, others didn’t.
ACTION	The quality manager redesigned training records to name the specific SOP code and version number, and built a rule: every SOP revision triggers a tracked retraining requirement before the new version becomes effective.
AFTER	The Monitor asked for a complete list of SOP versions a specific staff member was currently qualified on, and the laboratory produced it within minutes, matching the master document register exactly. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether current training records name specific SOP versions.
2. Build a rule linking every SOP revision to a tracked retraining requirement.
3. Test retrievability: ask for one staff member's complete current qualification list.

The most common mistake: An SOP revision rolls out with informal verbal notice to staff, leaving no systematic record of who was actually retrained on the new version.

SELF-ASSESSMENT QUESTIONS

1. Do training records name the specific SOP and version, not just a general subject area? — *“Trained on specimen handling” is too vague; which SOP, which version?*

Evidence: Training record with SOP version reference

2. When an SOP was last revised, were affected staff retrained and the record updated before the new version took effect? — *A revised SOP with no corresponding retraining record is a gap.*

Evidence: Revision-linked retraining record

3. Can the laboratory produce, for any current staff member, the exact list of SOP versions they are currently qualified on? — *On request, without needing to reconstruct it from scattered files.*

Evidence: Current qualification list

COMMON REASONS FOR A PARTIAL ANSWER

- Training records exist but don't reference specific SOP versions.
- SOP revisions aren't systematically linked to a retraining requirement.

IMPLEMENTATION PLAN

When	What
Week 1	Redesign training record format to name specific SOP and version.
Week 2	Build the revision-to-retraining linkage into the document control process.
Week 3	Backfill current records to the new format.

When	What
Ongoing	Trigger retraining automatically whenever an SOP is revised.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Qualification retrieval test	Requests a specific staff member's current SOP qualification list and checks it against the master document register.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.2.6. Geneva: ISO; 2022.

3.5 Adequate Staffing for Safe Operation CORE

Staffing levels at all operating hours are sufficient for safe specimen handling, timely result reporting, and compliance with the laboratory’s own written procedures, with a documented plan for covering absence.

In plain terms: There are always enough qualified people on shift to do things safely and on time — including when someone calls in sick.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Understaffing rarely causes a dramatic, single failure — instead, it causes a slow accumulation of skipped steps, delayed quality control checks, and shortcuts taken by an already-stretched single staff member with no one to catch an error. Laboratories, particularly smaller ones, often operate for extended periods on minimum viable staffing with no documented plan for what happens when even that minimum is unavailable.

WHAT GOOD LOOKS LIKE

- A documented minimum staffing level exists for each operating shift.
- A real absence-coverage plan exists, not reliance on an already-stretched remaining staff member.
- Understaffing-driven shortcuts, where they occur, get logged as quality events.

COMMON FAILURE MODES

- Staffing levels are informal, “we manage,” with no documented minimum.
- Unplanned absence routinely leaves a single staff member working alone.
- Shortcuts taken under understaffing pressure go unrecorded.

WORKED EXAMPLE

IN PRACTICE

A small clinic laboratory with three technologists covering all shifts.

BEFORE

With no documented minimum staffing level, a single technologist routinely covered the early shift alone. When she called in sick with no coverage plan, the clinic simply delayed non-urgent testing for the day with no formal decision or documentation of the impact.

ACTION

The Director documented a minimum staffing level per shift and built a simple on-call coverage arrangement with a part-time technologist for exactly this situation, with a clear escalation and documentation process if coverage genuinely couldn't be found.

AFTER

The Monitor reviewed the staffing plan and a recent instance where the on-call arrangement was actually activated, with the response documented. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Document the actual minimum staffing level needed for each shift to operate safely.

2. Build a real, usable absence-coverage plan, not an assumption that staff will manage.
3. Create a way to log when understaffing actually forces a shortcut or delay.

The most common mistake: “We manage” as the entire staffing plan, with no documented minimum and no real coverage arrangement for the inevitable day someone is unexpectedly absent.

SELF-ASSESSMENT QUESTIONS

1. Does the laboratory have a documented minimum staffing level for each operating shift? — *Not an informal assumption of “we manage.”*

Evidence: Staffing policy

2. Is there a documented plan for covering unplanned absence that doesn’t rely on an already-fatigued remaining staff member working alone? — *Relevant especially for small or single-staffed sections.*

Evidence: Absence coverage plan

3. Have critical procedures ever been delayed or skipped due to understaffing, and if so, was this logged as a quality event? —

Understaffing-driven shortcuts that go unrecorded are a hidden risk.

Evidence: Quality event log

COMMON REASONS FOR A PARTIAL ANSWER

- **No documented minimum exists, only informal expectation.**
- **A coverage plan exists on paper but has never actually been tested.**

IMPLEMENTATION PLAN

When	What
Week 1	Document the actual minimum staffing level needed per shift.
Week 2	Build a real absence-coverage arrangement.
Week 3	Create a mechanism to log understaffing-driven shortcuts.
Ongoing	Review staffing adequacy whenever volume or service scope changes.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Staffing policy and log review	Checks for a documented minimum staffing level, coverage plan, and any logged understaffing events.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.2.1. Geneva: ISO; 2022.

← Laboratory Standards — all standards

Standard 4 — Equipment, Reagents & Traceability →

ASF STANDARDS · LABORATORY · STANDARD 4

Standard 4 — Equipment, Reagents & Traceability

5 criteria · 3 non-negotiable · 2 core · Version 1.0

CRITERIA IN THIS STANDARD

- 4.1 — Calibration Current on Every Reportable Instrument
- 4.2 — Preventive Maintenance on a Fixed Schedule
- 4.3 — Reagent Lot Verification Before Use
- 4.4 — Metrological Traceability to a Recognized Reference
- 4.5 — Equipment Malfunction: Documented Response

4.1 Calibration Current on Every Reportable Instrument

NON-NEGOTIABLE

Every instrument used to generate a reportable patient result has a current, traceable calibration record, and no instrument is used past its calibration due date without being formally removed from service first.

In plain terms: Every machine that produces a real patient result is properly calibrated, right now — and nothing overdue for calibration is quietly still being used.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A calibration due date that quietly passes without consequence is one of the clearest signals that a laboratory’s equipment management system exists on paper more than in practice. An instrument producing results a day past its calibration deadline is not meaningfully different from one producing results a month past — the moment the due date is missed, every subsequent result carries unverified uncertainty, often with nobody actively tracking that this has happened.

WHAT GOOD LOOKS LIKE • Every in-use instrument has a current, traceable calibration certificate. • No instrument generates reportable results past its due date. • Out-of-service instruments are physically or digitally flagged, not just verbally known.	COMMON FAILURE MODES • A displayed certificate from a prior cycle, assumed still valid. • An overdue instrument kept running because the backup isn’t ready yet. • Out-of-service status exists only in someone’s memory, not a visible flag.
--	--

WORKED EXAMPLE

IN PRACTICE <i>A chemistry analyzer with a calibration due date tracked on a wall calendar.</i>	
BEFORE	The calibration due date passed on a Friday. The scheduled calibration technician was unavailable until the following Tuesday. The analyzer continued generating reportable results through the weekend because stopping it felt operationally disruptive and nobody had a formal rule against it.
ACTION	The laboratory introduced a hard rule: any instrument reaching its calibration due date is immediately flagged out of service, with a backup plan — manual send-out or a backup instrument — built in advance for exactly this situation.
AFTER	The Monitor checked calibration records against actual usage logs for the past six months and

found no instance of results generated past a due date. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. List every reportable-result instrument and its current calibration due date.
2. Check for any instrument currently past due, right now.
3. Build a hard stop rule and a backup plan for when calibration can't happen on time.

The most common mistake: Continuing to use an overdue instrument “just this once” because stopping would be operationally disruptive, with no formal rule preventing the exception from becoming routine.

SELF-ASSESSMENT QUESTIONS

1. Pick any analyzer in current use — is its calibration record current, with a traceable certificate or reference standard? — *Not a certificate from a prior calibration cycle still displayed.*

Evidence: Current calibration certificate

2. Is there any instrument past its calibration due date still generating reportable results? — *A single instance of this is a direct patient-safety failure.*

Evidence: Calibration log cross-checked against usage log

3. Where an instrument is taken out of service, is it physically or digitally flagged so staff cannot use it by mistake? — *An unflagged out-of-service instrument gets used under time pressure.*

Evidence: Out-of-service flag, physical or digital

COMMON REASONS FOR A PARTIAL ANSWER

- **Calibration is tracked but no hard stop rule exists for overdue instruments.**
- **No backup plan exists, so overdue equipment keeps running by default.**

IMPLEMENTATION PLAN

When	What
Week 1	Audit current calibration status for every reportable-result instrument.
Week 2	Build a hard stop rule and out-of-service flagging system.
Week 3	Establish a backup plan for calibration delays.
Ongoing	Track due dates proactively, not reactively.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Calibration-usage cross-check	Compares calibration due dates against actual result-generation logs to check for any overdue usage.

EVIDENCE BASE

- International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.4. Geneva: ISO; 2022.
- International Organization for Standardization. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Clause 6.4. Geneva: ISO; 2017.

4.2 Preventive Maintenance on a Fixed Schedule

NON-NEGOTIABLE

Every piece of critical equipment is maintained according to the manufacturer’s recommended schedule or a validated equivalent, with maintenance records retained and reviewed before each instrument returns to reportable use after service.

In plain terms: Equipment gets serviced on the schedule the manufacturer actually recommends, and nobody puts it back into use for real patient results without checking it’s genuinely working right afterward.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Preventive maintenance exists specifically to catch gradual degradation before it affects result accuracy — skipping or delaying it trades a scheduled, controlled interruption for the risk of an uncontrolled failure at an unpredictable moment. The return-to-service verification step matters just as much as the maintenance itself: an instrument fresh from service is not automatically trustworthy simply because a technician has finished working on it.

WHAT GOOD LOOKS LIKE

- Maintenance intervals genuinely match the manufacturer's schedule.
- A documented verification step occurs before return to reportable use.
- Maintenance records are retained for the full required period.

COMMON FAILURE MODES

- A schedule exists on paper but is routinely delayed under operational pressure.
- Equipment resumes reporting immediately after service, with no verification.
- Equipment history is the first record type discarded when storage runs short.

WORKED EXAMPLE

IN PRACTICE

A hematology analyzer returning from a scheduled service visit.

BEFORE

After routine servicing, the technician who performed the work signed off and the instrument resumed reporting patient results within the hour, with no independent verification step before return to clinical use.

ACTION

The laboratory introduced a mandatory post-maintenance quality control run, reviewed and approved by someone other than the servicing technician, before any instrument returns to reportable use.

AFTER

The Monitor reviewed the most recent maintenance record and found a documented, independently reviewed quality control check completed before the instrument resumed clinical reporting. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Confirm your maintenance schedule actually matches manufacturer recommendations.
2. Check recent maintenance records for an independent return-to-service verification step.
3. Build this verification into the standard maintenance procedure if missing.

The most common mistake: Treating the servicing technician's own sign-off as sufficient verification, without an independent check before the instrument resumes patient reporting.

SELF-ASSESSMENT QUESTIONS

1. Does a maintenance log exist for critical equipment showing the manufacturer's recommended interval was actually met? — *Not a schedule that exists on paper but is routinely missed.*

Evidence: Maintenance log

2. After servicing, is there a documented verification step before the instrument returns to reporting patient results? — *Returning equipment to use immediately after service, with no verification, is a gap.*

Evidence: Post-maintenance verification record

3. Are maintenance records retained for the full retention period set in Standard 1.5? — *Equipment history is frequently the specific record type that gets discarded early.*

Evidence: Retained maintenance history

COMMON REASONS FOR A PARTIAL ANSWER

- Maintenance happens but documentation is thin.
- Return-to-service verification relies on the servicing technician alone.

IMPLEMENTATION PLAN

When	What
Week 1	Confirm maintenance schedules against manufacturer recommendations.
Week 2	Build an independent post-maintenance verification step.
Week 3	Check maintenance record retention against the Standard 1.5 schedule.
Ongoing	Require independent sign-off before every return to reportable use.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Maintenance record review	Checks maintenance intervals and looks for an independent return-to-service verification step.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.4.9. Geneva: ISO; 2022.

4.3 Reagent Lot Verification Before Use

NON-NEGOTIABLE

Each new reagent lot is verified against the laboratory’s own quality control material before being used for reportable patient results, and expired reagents are physically segregated from, and never used in, active testing.

In plain terms: Before a new batch of reagent goes into real patient testing, it’s checked against the lab’s own quality controls first — and anything expired is kept physically apart so it can’t be grabbed by mistake.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Lot-to-lot variation is a genuine, well-documented source of result drift — a new reagent lot can perform subtly differently from the one it replaces, even from the same manufacturer. Verifying each new lot against the laboratory's own quality control material before clinical use is what catches this drift before it reaches a patient result, rather than discovering it later through an unexplained shift in quality control trends.

WHAT GOOD LOOKS LIKE

- Lot-verification records exist for every currently open reagent lot.
- Expired reagents are physically separated, not just labeled.
- Storage temperature is actively monitored with a documented excursion response.

COMMON FAILURE MODES

- A new lot is opened and used immediately with no verification step.
- Expired reagents sit in the same storage area as current stock.
- Temperature excursions occur with no documented response.

WORKED EXAMPLE

IN PRACTICE

A chemistry section receiving a new shipment of reagent.

BEFORE

A new reagent lot arrived and was put directly into use the same day, with no comparison against the previous lot or the laboratory's own quality control material, because the previous lot had simply run out.

ACTION

The laboratory introduced a mandatory lot-verification protocol: every new lot is run against quality control material and compared to the outgoing lot's performance before being released for clinical use, with a brief overlap period maintained specifically to allow this comparison.

AFTER The Monitor selected the currently open reagent lot and found a documented verification record completed before its first clinical use. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether your currently open reagent lots have documented verification records.
2. Build a simple lot-verification protocol using existing quality control material.
3. Physically separate expired stock from current stock today.

The most common mistake: Skipping lot verification specifically when the previous lot has already run out, under pressure to avoid any gap in testing capability.

SELF-ASSESSMENT QUESTIONS

1. Can the laboratory show lot-verification records for its currently open reagent lots? — *A new lot opened and put directly into use without verification is a direct failure.*

Evidence: Lot verification record

2. Are expired reagents physically separated from current stock, not just marked and left in the same storage area? — *Separation prevents accidental use under time pressure far more reliably than a label alone.*

Evidence: Storage area inspection

3. Is reagent storage temperature monitored and logged, with a documented response procedure for excursions? — *Temperature-sensitive reagents used after an unlogged excursion risk invalid results.*

Evidence: Temperature log, excursion response record

COMMON REASONS FOR A PARTIAL ANSWER

- **Verification is skipped specifically when supply runs tight.**
- **Expired stock is labeled but not physically separated.**

IMPLEMENTATION PLAN

When	What
Week 1	Audit current reagent lot verification practice.

When	What
Week 2	Build a standard lot-verification protocol.
Week 3	Physically separate expired from current stock.
Ongoing	Verify every new lot before clinical release, without exception.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Lot verification record check	Reviews verification records for currently open reagent lots.
OBSERVE	Storage inspection	Physically inspects reagent storage for separation of expired from current stock.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.5. Geneva: ISO; 2022.

4.4

Metrological Traceability to a Recognized Reference

CORE

Calibration of measuring equipment is traceable through an unbroken chain to an internationally recognized reference material or method, documented at each link, not simply asserted by the equipment manufacturer.

In plain terms: The lab can actually show, step by step, how its measurements connect back to a real, internationally recognized reference — not just take the manufacturer’s word that it does.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A manufacturer's general claim that an instrument is "traceable" is a marketing statement until the laboratory itself can document the specific, unbroken chain connecting its own measurements back to a recognized reference. This matters most when results are compared across laboratories or over time — without genuine traceability, two laboratories' "normal" ranges may not actually mean the same thing, a gap that is invisible until directly tested.

WHAT GOOD LOOKS LIKE

- Laboratory-specific documentation exists for the traceability chain, not just a manufacturer claim.
- Reference material certificates are current and on file.
- The chain is reviewed whenever equipment or reference materials change.

COMMON FAILURE MODES

- The laboratory relies entirely on a general manufacturer traceability statement.
- A reference material's own certificate has expired, unnoticed.
- The chain was documented once and never revisited after an equipment change.

WORKED EXAMPLE

IN PRACTICE

A laboratory preparing documentation for an external review.

BEFORE	When asked about metrological traceability, the laboratory produced the instrument manufacturer's general product brochure stating the device was "traceable to international standards," with no laboratory-specific documentation connecting its own actual calibration practice to that claim.
ACTION	The quality manager built a specific traceability record for each major analyte, documenting the actual reference material used, its certificate, and each link in the chain from that reference to the laboratory's own working calibrators.
AFTER	The Monitor selected a specific analyte and the laboratory produced its complete, documented

traceability chain with current reference material certificates. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Select one major analyte and trace its actual calibration chain back to its reference.
2. Check whether the reference material's own certificate is current.
3. Document this chain formally, then repeat for other major analytes.

The most common mistake: Relying on a general manufacturer traceability claim as if it were laboratory-specific documentation, when the standard requires the laboratory itself to demonstrate the chain.

SELF-ASSESSMENT QUESTIONS

1. Can the laboratory produce documentation showing the traceability chain for a selected instrument back to a recognized reference? — *A manufacturer's general claim of traceability, with no laboratory-specific documentation, is insufficient.*

Evidence: Traceability chain documentation

2. Where a reference material is used, is its own certificate of traceability on file and current? — *An expired reference material certificate breaks the chain.*

Evidence: Reference material certificate

3. Is the traceability chain reviewed whenever equipment or reference materials change? — *A chain established once and never revisited can silently break.*

Evidence: Review record following equipment change

COMMON REASONS FOR A PARTIAL ANSWER

- **Documentation relies entirely on manufacturer claims.**
- **A reference material certificate has quietly expired.**

IMPLEMENTATION PLAN

When	What
Week 1	Select major analytes and trace their current calibration chains.
Week 2	Check reference material certificate currency.
Week 3	Document the complete chain formally for each.
Ongoing	Review the chain whenever equipment or reference materials change.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Traceability chain review	Selects an analyte and requests complete, laboratory-specific traceability documentation.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.4.6. Geneva: ISO; 2022.

Bureau International des Poids et Mesures. The International System of Units (SI), 9th ed. Sèvres: BIPM; 2019.

4.5

Equipment Malfunction: Documented Response

CORE

A written procedure governs the laboratory's response to equipment malfunction, including immediate removal from reportable use, assessment of results produced since the last verified-good check, and notification of affected clinicians where results may be unreliable.

In plain terms: When equipment breaks, the lab has a real plan that includes checking back through recent results that might already be affected — not just fixing the machine and moving on.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A malfunction is typically identified after it has already begun affecting results, not at the exact moment it starts. A response procedure that only addresses fixing the equipment going forward, without looking backward to results produced since the last confirmed-good check, leaves potentially affected results sitting in patient charts with nobody aware they may be unreliable.

WHAT GOOD LOOKS LIKE

- The procedure explicitly requires assessing results since the last known-good check.
- A documented instance exists of a clinician being notified after affected results.
- The procedure is genuinely accessible to staff during an actual event.

COMMON FAILURE MODES

- The procedure addresses only going-forward fixes, not backward-looking review.
- No clinician notification process exists for potentially affected prior results.
- The procedure exists in a manual nobody can locate quickly during an actual event.

WORKED EXAMPLE

IN PRACTICE

A chemistry analyzer discovered to be malfunctioning mid-shift.

BEFORE

A malfunction was identified when a quality control run failed. The instrument was immediately taken out of service and repaired, but no review occurred of patient results generated since the previous passing quality control run, roughly ninety minutes earlier.

ACTION

The laboratory built a formal malfunction response procedure requiring identification and clinical review of every result generated since the last confirmed-good quality control, with a defined notification process for any clinician whose patient's result fell in that window.

AFTER

The Monitor reviewed the laboratory's most recent malfunction event and found a

documented list of results reviewed back to the last known-good check, with one clinician notification on record. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether your current malfunction procedure addresses backward-looking result review.
2. Build in a clear notification process for affected clinicians.
3. Make sure the procedure is physically accessible at the point of need, not filed away.

The most common mistake: Focusing malfunction response entirely on fixing the equipment itself while overlooking the backward-looking review of results already reported before the malfunction was noticed.

SELF-ASSESSMENT QUESTIONS

1. Does the malfunction procedure require assessing results produced since the last known-good check, not only results produced after the malfunction was noticed? — *A malfunction is often identified after it began, not at its onset.*

Evidence: Written malfunction procedure

2. Is there a documented instance of a clinician being notified after a malfunction affected previously reported results? — *If this has never happened, ask whether it's because it's never been needed, or because the step is skipped.*

Evidence: Clinician notification record

3. Is the malfunction procedure accessible to staff during an actual event, not only during planned audits? — *A procedure staff can't locate under pressure is not functioning.*

Evidence: Procedure location check

COMMON REASONS FOR A PARTIAL ANSWER

- **The procedure covers equipment repair but not backward result review.**
- **No clinician notification step exists in the written procedure.**

IMPLEMENTATION PLAN

When	What
Week 1	Review the current malfunction procedure for backward-review and notification gaps.
Week 2	Build the missing elements into a revised procedure.
Week 3	Brief staff and post the procedure where it's actually accessible during an event.
Ongoing	Review and refine the procedure after every actual malfunction event.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Procedure and incident record review	Checks the written procedure for backward-review requirements and reviews any recent malfunction incident record.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 7.3.7. Geneva: ISO; 2022.

← Laboratory Standards — all standards

Standard 5 — Facilities, Environment & Suppliers →

ASF STANDARDS · LABORATORY · STANDARD 5

Standard 5 — Facilities, Environment & Suppliers

6 criteria · 3 non-negotiable · 2 core · 1 standard-level · Version 1.0

CRITERIA IN THIS STANDARD

- 5.1 — Environmental Conditions Monitored and Logged
- 5.2 — Physical Separation of Incompatible Activities
- 5.3 — Access Control to the Testing Area
- 5.4 — Utility Failure: Documented Contingency
- 5.5 — Waste Segregated by Hazard Class
- 5.6 — Critical Supplier Agreements, Documented

5.1 Environmental Conditions Monitored and Logged

NON-NEGOTIABLE

Temperature, humidity, and other environmental conditions affecting test validity are continuously monitored in each relevant area, logged, with a documented, time-bound response procedure for excursions outside defined limits.

In plain terms: The lab actually tracks temperature and humidity where it matters, writes it down, and has a real plan for when something goes outside the acceptable range.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A thermometer mounted on the wall is not environmental monitoring unless someone is actually reading and recording it, and a recorded excursion with no documented response is barely better than no monitoring at all. The gap between having a sensor and having a functioning monitoring system is exactly where temperature-sensitive reagents and specimens quietly degrade without anyone noticing until results start looking unusual.

WHAT GOOD LOOKS LIKE

- Monitoring is actually logged, not just displayed on a device nobody checks.
- Every excursion has a documented response action on record.
- Limits are specific to each area's actual requirements.

COMMON FAILURE MODES

- A thermometer exists but nobody records its readings anywhere.
- Excursions are noted but no follow-up action is documented.
- One generic temperature range is applied regardless of area-specific needs.

WORKED EXAMPLE

IN PRACTICE

A reagent refrigerator in a small clinic laboratory.

BEFORE

The refrigerator had a built-in digital display, checked visually by whoever happened to walk past, with no log and no record of what happened the time it briefly read ten degrees above range over a weekend.

ACTION

The laboratory installed a continuous logging thermometer with an alarm, assigned daily log review to a named staff member, and wrote a specific excursion response procedure including reagent quarantine and assessment.

AFTER

The Monitor reviewed six months of continuous temperature logs and found one documented excursion with a complete, timely response record. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Identify every area with environmental requirements affecting test validity.
2. Check whether monitoring in each area is actually logged, not just displayed.
3. Write a specific excursion response procedure if none exists.

The most common mistake: Treating a visible thermometer display as equivalent to actual monitoring, when nobody is recording readings or would notice an after-hours excursion.

SELF-ASSESSMENT QUESTIONS

1. Is environmental monitoring actually logged, not just equipped with a sensor nobody checks? — *A thermometer on the wall with no log is not monitoring.*

Evidence: Temperature/humidity log

2. Where an excursion occurred, is there a documented record of what action was taken and when? — *An excursion logged with no follow-up action recorded is incomplete.*

Evidence: Excursion response record

3. Are defined limits specific to each area's actual requirements, not one generic range applied everywhere? — *Reagent storage and specimen processing areas often have different real requirements.*

Evidence: Area-specific limit documentation

COMMON REASONS FOR A PARTIAL ANSWER

- **Monitoring exists but after-hours excursions go uncaught.**
- **One blanket temperature range is applied to areas with different real needs.**

IMPLEMENTATION PLAN

When	What
Week 1	Identify all environmentally sensitive areas and their actual requirements.
Week 2	Install or verify continuous logging with alarm capability.
Week 3	Write a specific excursion response procedure.
Ongoing	Review logs on a fixed schedule, not only when an alarm triggers.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Log and response review	Reviews environmental logs for consistency and checks any excursion for a documented response.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.3. Geneva: ISO; 2022.

5.2 Physical Separation of Incompatible Activities

NON-NEGOTIABLE

Activities that could cross-contaminate or interfere with each other — specimen reception and clean processing, molecular amplification stages, biohazardous waste handling and clean workspace — are physically separated according to recognized practice for each discipline operated.

In plain terms: Activities that could contaminate each other happen in genuinely separate physical spaces — not just at separate ends of the same open room.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Cross-contamination risk from inadequate physical separation is often invisible until it produces a specific, puzzling result pattern — a molecular test contaminated by amplified product from a prior run, a clean specimen compromised by proximity to waste handling. Recognized separation practice exists precisely because these failure modes have been documented repeatedly across laboratories that assumed informal spatial distance within one open room was sufficient.

WHAT GOOD LOOKS LIKE

- Specimen reception is physically separated from clean processing areas.
- Molecular pre- and post-amplification areas are separated per recognized practice.
- Waste handling is physically separated from clean workspace.

COMMON FAILURE MODES

- Reception and processing share one open room with no real barrier.
- Molecular testing stages share equipment or space without separation.
- Waste handling occurs adjacent to active clean bench work.

WORKED EXAMPLE

IN PRACTICE

A small laboratory performing molecular testing in a single shared room.

BEFORE

Pre-amplification specimen preparation and post-amplification analysis occurred at different benches within the same single room, sharing the same air space and general work area, with occasional unexplained contamination-pattern results.

ACTION

The laboratory invested in physical separation, converting an adjacent small space into a dedicated post-amplification area with separate equipment and a controlled workflow direction

preventing material from moving backward into the pre-amplification space.

AFTER

The Monitor inspected the physical layout and confirmed genuine separation per recognized molecular testing practice, and the laboratory's contamination-pattern result incidents had stopped since the change. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Map every activity in your laboratory that could cross-contaminate another.
2. Check current physical separation against recognized practice for each discipline.
3. Identify and plan for any genuine gaps found.

The most common mistake: Assuming that working at different benches within the same open room constitutes adequate separation, when shared air space and surfaces can still allow cross-contamination.

SELF-ASSESSMENT QUESTIONS

1. Is specimen reception physically separated from areas where processed samples are handled? — *Shared space for both creates genuine cross-contamination risk.*

Evidence: Facility layout inspection

2. Where molecular testing is performed, are pre- and post-amplification areas separated per recognized practice? — *This is a well-established, specific requirement where applicable, not a general suggestion.*

Evidence: Facility layout, workflow documentation

3. Is biohazardous waste handling physically separated from clean workspace and specimen processing? — *Shared pathways between waste and clean work areas are a recurring, identifiable risk.*

Evidence: Facility layout inspection

COMMON REASONS FOR A PARTIAL ANSWER

- **Space constraints have never been formally addressed with recognized separation practice.**

- Separation exists for some activities but not molecular-specific stages.

IMPLEMENTATION PLAN

When	What
Week 1	Map all activities requiring physical separation.
Week 2	Assess current layout against recognized separation practice.
Week 3	Plan any required physical changes.
Ongoing	Reassess separation adequacy whenever services or layout change.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Facility walkthrough	Physically inspects the layout for genuine separation of incompatible activities.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.3.2. Geneva: ISO; 2022.

Clinical and Laboratory Standards Institute. MM19-A2: Establishing Molecular Testing in Clinical Laboratory Environments. Wayne (PA): CLSI; 2011.

5.3 Access Control to the Testing Area

CORE

Access to the active testing area is restricted to authorized personnel, with visitor and non-laboratory staff access logged and escorted, protecting both specimen integrity and staff safety.

In plain terms: Only people who are supposed to be in the testing area can actually get in — and anyone else who enters is logged and accompanied.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Uncontrolled access to a testing area creates risk on two fronts simultaneously: specimen integrity, since unauthorized individuals might inadvertently disturb or contaminate samples, and staff safety, since the area typically contains biohazards and chemicals unfamiliar visitors aren't trained to navigate safely. Restricted, logged, escorted access addresses both at once, which is why it's treated as a single combined requirement rather than two separate concerns.

WHAT GOOD LOOKS LIKE

- Physical access restriction, not an honor-system open door.
- Visitor access is logged with who, when, and why.
- Visitors are genuinely escorted, not left to move through unaccompanied.

COMMON FAILURE MODES

- The testing area door is unlocked with no real access control.
- Visitors enter without any log entry.
- An escort policy exists but is not actually followed in practice.

WORKED EXAMPLE

IN PRACTICE

A laboratory with a testing area adjacent to a general clinic corridor.

BEFORE	The testing area had a door that was simply kept closed but unlocked, relying on an unwritten expectation that non-laboratory staff wouldn't enter without reason. Maintenance staff occasionally entered unaccompanied with no log entry.
ACTION	The laboratory installed a badge-controlled lock restricted to authorized staff, created a visitor log at the entrance, and required any non-laboratory personnel — including maintenance — to be escorted and logged.
AFTER	The Monitor reviewed the visitor log and confirmed a recent maintenance visit was logged

with an escort name recorded, and verified the door's access control was functioning. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether your testing area door actually restricts access, or just happens to be closed.
2. Create a simple visitor log if none exists.
3. Brief staff that all non-laboratory personnel must be escorted and logged, no exceptions.

The most common mistake: Assuming a closed door functions as access control, when anyone can simply open it and enter with no actual restriction or record.

SELF-ASSESSMENT QUESTIONS

1. Is the testing area physically restricted, not an open space any staff member can enter? — *A locked door or controlled entry point, not an honor-system expectation.*

Evidence: Access control mechanism

2. Is non-laboratory visitor access logged, with a record of who entered and when? — *Unlogged access makes any later investigation of a contamination or security concern impossible.*

Evidence: Visitor log

3. Are visitors actually escorted, or left to move through the space unaccompanied? — *A stated escort policy that isn't followed in practice fails this.*

Evidence: Observed practice, log entries

COMMON REASONS FOR A PARTIAL ANSWER

- A closed but unlocked door is treated as sufficient access control.
- Maintenance or other recurring visitors are exempted from logging in practice.

IMPLEMENTATION PLAN

When	What
Week 1	Assess current access control adequacy.

When	What
Week 2	Install or formalize a real access restriction mechanism.
Week 3	Create a visitor log and escort requirement, brief all staff.
Ongoing	Review the visitor log periodically for compliance.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Access control test	Checks the physical access restriction and reviews the visitor log for recent entries.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.3.3. Geneva: ISO; 2022.

5.4 Utility Failure: Documented Contingency CORE

A written contingency plan covers loss of power, water, or network connectivity, including protection of in-process specimens and stored reagents, and is tested at a defined interval rather than existing only as an untested document.

In plain terms: There’s a real, tested plan for what happens if the power or network goes out — not just a document nobody’s ever actually tried.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

A contingency plan that has never been tested frequently fails in ways nobody anticipated when it was written — a backup generator that doesn’t actually start, a battery backup with far less runtime than assumed, staff who don’t know their specific role during an actual

event. Testing is what converts a plan from a theoretical document into something the laboratory can genuinely rely on at 2am during a real outage.

WHAT GOOD LOOKS LIKE • The plan specifically addresses in-process specimens and stored reagents. • Testing has actually occurred within a defined interval, with findings recorded. • Staff on shift know their specific role in the plan.	COMMON FAILURE MODES • A generic continuity plan exists but doesn't address specimens or reagents specifically. • The plan has never actually been tested since it was written. • Only management knows the plan exists; frontline staff don't.
---	--

WORKED EXAMPLE

IN PRACTICE	
<i>A laboratory conducting its first power-failure contingency test.</i>	
BEFORE	A written contingency plan existed, referencing a backup generator, but had never been tested. During the test, the generator failed to start automatically and required manual intervention that took eleven minutes — well beyond what the plan assumed for protecting reagent cold storage.
ACTION	The laboratory had the generator serviced and the automatic start mechanism repaired, revised the plan to reflect realistic response timing, and scheduled annual testing going forward with findings documented each time.
AFTER	The Monitor reviewed the test record from the most recent annual test, which showed successful automatic generator start within the expected window. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

- 1. Check whether a written utility-failure plan exists at all.
- 2. If it exists but has never been tested, schedule a real test now.

3. Brief staff on shift about their specific role during an actual event.

The most common mistake: Writing a plausible-sounding contingency plan and treating it as complete without ever actually testing whether it works in practice.

SELF-ASSESSMENT QUESTIONS

1. Does the plan specifically address protection of specimens and reagents already in process at the moment of failure? — *Generic continuity language without this detail misses the point most relevant to patient safety.*

Evidence: Written contingency plan

2. Has the plan been tested within a defined interval, with a record of what the test found? — *An untested plan frequently fails in ways nobody anticipated.*

Evidence: Test record

3. Do staff on shift know where to find the plan and what their specific role in it is? — *A plan known only to management does not function during an actual event at 2am.*

Evidence: Staff interview

COMMON REASONS FOR A PARTIAL ANSWER

- The plan exists but has never been physically tested.
- Staff are unaware of their specific role during an actual event.

IMPLEMENTATION PLAN

When	What
Week 1	Review or write the written contingency plan.
Week 2	Schedule and conduct a real test.
Week 3	Revise the plan based on what the test revealed and brief staff.
Ongoing	Test on a fixed annual or more frequent schedule.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Plan and test record review	Reviews the written plan’s specificity and checks for a genuine, dated test record.
ASK	Staff role interview	Asks on-shift staff to describe their role during a utility failure.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.3.4. Geneva: ISO; 2022.

5.5 Waste Segregated by Hazard Class

NON-NEGOTIABLE

Biohazardous, chemical, and sharps waste are segregated at the point of generation into clearly marked, appropriate containers, with documented disposal through a licensed contractor or equivalent regulated pathway.

In plain terms: Different kinds of hazardous waste go into the right container right where they’re generated, and disposal happens through a real, licensed route — not an informal arrangement.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Segregation only works when the correct container is physically present and within easy reach at the exact point waste is generated — a centralized disposal station two rooms away encourages mixing waste types out of simple convenience under time pressure. Overfilled sharps containers and informal, unlicensed disposal arrangements are two of the most common, specific, and directly dangerous gaps found during facility reviews.

WHAT GOOD LOOKS LIKE

- Correct waste containers are present at each bench, not centralized.
- Disposal is documented through a licensed, regulated contractor.
- Sharps containers are replaced before reaching unsafe fill levels.

COMMON FAILURE MODES

- A single waste station is shared across a distant work area, encouraging mixing.
- Disposal relies on an informal, undocumented arrangement.
- Sharps containers are overfilled before replacement.

WORKED EXAMPLE

IN PRACTICE

A hematology section with a single waste station at the room's entrance.

BEFORE

The only waste containers were located by the door, a short walk from the benches where specimens were actually processed. Under time pressure, staff occasionally discarded mixed waste types into whichever container was closest to their workflow at that moment.

ACTION

The laboratory installed correctly labeled sharps, biohazard, and general waste containers directly at each bench, and formalized a written disposal contract with a licensed waste management company, retaining manifests as proof of proper disposal.

AFTER

The Monitor inspected each bench and found correct containers within immediate reach, none overfilled, and reviewed a current disposal manifest from the licensed contractor. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. Check whether correct waste containers are actually present at each bench.

2. Confirm your disposal arrangement is licensed and documented, not informal.
3. Check current sharps container fill levels right now.

The most common mistake: Centralizing waste disposal at one convenient location rather than the point of generation, which predictably leads to mixed-waste shortcuts under time pressure.

SELF-ASSESSMENT QUESTIONS

1. Are the correct waste containers actually present and in use at each bench, not centralized in a way that encourages mixing? — *Segregation only works if the right container is within reach at the point of generation.*

Evidence: Bench inspection

2. Is there documentation of licensed, regulated disposal, not an informal arrangement? — *A disposal manifest or equivalent record, verifiable on request.*

Evidence: Disposal manifest, contractor license

3. Are sharps containers replaced before reaching unsafe fill levels, verified by spot check? — *An overfilled sharps container is an immediate, specific injury risk.*

Evidence: Sharps container inspection

COMMON REASONS FOR A PARTIAL ANSWER

- Containers are centralized rather than at point of generation.
- Disposal happens but documentation is incomplete or missing.

IMPLEMENTATION PLAN

When	What
Week 1	Inspect current waste container placement against point-of-generation practice.
Week 2	Relocate or add containers as needed.
Week 3	Confirm or establish a licensed disposal contract with retained manifests.
Ongoing	Spot-check sharps container fill levels regularly.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
OBSERVE	Bench inspection	Checks for correct, appropriately filled waste containers at each bench.
DOCUMENT	Disposal manifest review	Reviews current licensed disposal contractor documentation.

EVIDENCE BASE

World Health Organization. Safe management of wastes from health-care activities, 2nd ed. Geneva: WHO; 2014.

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.3.5. Geneva: ISO; 2022.

5.6

Critical Supplier Agreements,
Documented

STANDARD

Agreements with critical suppliers — reagent manufacturers, waste contractors, reference laboratories — are documented in writing, specifying the service or product, quality expectations, and renewal terms.

In plain terms: Important supplier relationships are backed by a real written agreement, not just a standing informal arrangement.

Facility category	Standalone lab	Hospital lab	Clinic lab
Applicability	Full	Full	Full

WHY THIS MATTERS

Written agreements do more than formalize a commercial relationship — they create a documented baseline of quality expectations that both parties can be held to, and they prevent long-standing relationships from quietly drifting without anyone noticing a decline in service, because nothing was ever specified in writing to measure against.

WHAT GOOD LOOKS
LIKE

COMMON FAILURE
MODES

- A written agreement exists for every critical supplier.
- Agreements specify quality expectations, not just commercial terms.
- A process exists for renewing or re-evaluating agreements before they lapse.

- A long-standing relationship was never formalized in writing.
- Agreements cover price and delivery but say nothing about quality.
- An agreement has lapsed but the relationship continues unchanged.

WORKED EXAMPLE

IN PRACTICE

A laboratory's long-standing relationship with its primary reagent supplier.

BEFORE	The laboratory had purchased from the same reagent supplier for over a decade, based entirely on an informal, never-renewed verbal arrangement with no written quality expectations specified anywhere.
ACTION	The quality manager formalized a written agreement specifying delivery reliability, quality certification requirements, and an annual renewal review date.
AFTER	The Monitor reviewed the written agreement and confirmed it specified quality expectations and had a current, unexpired renewal date. Criterion verified.

IF YOU ARE STARTING FROM ZERO — DO THIS FIRST

1. List every critical supplier currently operating without a written agreement.
2. Draft agreements specifying both commercial and quality terms.
3. Set renewal review dates for each.

The most common mistake: Assuming a long and reliable relationship doesn't need formal documentation, when the

absence of written quality expectations leaves nothing to point to if performance later declines.

SELF-ASSESSMENT QUESTIONS

1. Does a written agreement exist for each critical supplier, not an informal, undocumented working relationship? — *Especially relevant for long-standing suppliers where formal paperwork is sometimes allowed to lapse.*

Evidence: Written supplier agreement

2. Do agreements specify quality expectations relevant to patient safety, not only commercial terms? — *A contract covering price and delivery but silent on quality standards is incomplete for this purpose.*

Evidence: Agreement quality clause

3. Is there a process for renewing or re-evaluating agreements before they lapse? — *An expired agreement still being operated under is a gap worth noting even if the relationship itself continues smoothly.*

Evidence: Renewal schedule

COMMON REASONS FOR A PARTIAL ANSWER

- **Long-standing suppliers were never formally documented.**
- **Agreements exist but have quietly lapsed without renewal.**

IMPLEMENTATION PLAN

When	What
Week 1	List critical suppliers lacking a written agreement.
Week 2	Draft agreements specifying quality and commercial terms.
Week 3	Finalize and set renewal review dates.
Ongoing	Review agreements before each renewal date, not after it lapses.

HOW THE MONITOR VERIFIES THIS

Method	What	Detail
DOCUMENT	Agreement review	Checks for written, current agreements with critical suppliers, including quality terms.

EVIDENCE BASE

International Organization for Standardization. ISO 15189:2022, Medical laboratories — Requirements for quality and competence, Clause 6.6. Geneva: ISO; 2022.

[← Laboratory Standards — all standards](#)

[Standard 6 — Pre-Examination: Specimen Pathway →](#)

© 2026 Accréditation Sans Frontières · PHIG · Sheni Network