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IMPLEMENTATION GUIDE | ISO/IEC 17025:2017

The ISO 17025 Implementation Roadmap

Seven phases that take a laboratory from first read of the standard to a working, assessable management system.

A PRACTICAL GUIDE FOR LABORATORY OWNERS, QUALITY MANAGERS, AND TECHNICAL LEADS

Most laboratories do not stall on ISO/IEC 17025 because their science is weak. They stall because they treat implementation as a paperwork exercise and start writing procedures before they understand what the standard asks of them.

This guide sequences the work into seven phases, names the evidence an assessor expects at each one, and converts the whole project into a checklist you can assign and track.

STANDARD	APPLIES TO	OUTCOME
ISO/IEC 17025:2017	**Testing & calibration labs**	**Accreditation readiness**

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FRONT MATTER

About This Guide

What this guide covers, how to use it, and what it does not do.

This guide turns ISO/IEC 17025:2017 into a sequenced project. Each phase groups the tasks that belong together, so you can work them in order instead of chasing sixteen unrelated items at once. Clause references appear throughout, so you can check every statement against your own controlled copy of the standard.

One correction before you start, because it costs laboratories credibility in front of customers. ISO/IEC 17025 leads to **accreditation**, granted by an accreditation body such as A2LA, ANAB, PJLA, or IAS in the United States. ISO 9001 leads to **certification**, granted by a certification body. The two words are not interchangeable. Use them correctly from your first email to your final scope.

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How to Use This Guide

- Read Section 1 and Section 2 first to confirm the guide matches your situation.
- Work Sections 4 and 5 in phase order. Later phases depend on evidence produced by earlier ones.
- Use Section 7 as a live checklist. Assign an owner and a due date to every line.
- Verify every clause number against your organization's controlled copy of the standard before you rely on it.
- Confirm accreditation body requirements directly with your chosen body. Their rules sit on top of the standard.

NAVIGATION

Contents

Eight sections, seven implementation phases, and one working checklist.

FOX TIP

Do not read this guide once and file it. Print Section 7, put an owner beside every line, and review it at your weekly meeting. The laboratories that finish fastest are the ones that treat implementation as a tracked project rather than background work.

SECTION 1

Executive Summary

Give decision makers the essential message before the technical detail.

ISO/IEC 17025:2017 governs the competence, impartiality, and consistent operation of testing and calibration laboratories. Meeting it takes a real project plan, a budget, named owners, and enough operating time to generate evidence before an assessor arrives. Laboratories that underestimate any of those four run twice as long as they planned.

The common failure pattern is predictable. A laboratory buys a generic quality manual, swaps in its name, and books an assessment. The assessor then finds a system that exists on paper but has never operated. Findings pile up around competence records, equipment control, measurement uncertainty, and corrective action, because those areas demand evidence that only accumulates over time.

This guide replaces that pattern with a sequence. Phase 1 establishes an honest baseline through a clause-by-clause gap analysis. Phase 2 converts that baseline into a funded project with named owners. Phase 3 builds the management system and puts documents and records under control from day one. Phase 4 produces the technical evidence: competence, equipment control, traceability, method validation, and measurement uncertainty. Phase 5 verifies the system through internal audits, management review, and real corrective action. Phase 6 engages the accreditation body. Phase 7 keeps the system running afterward.

> **KEY TAKEAWAY**
>
> Sequence the work, run the system live for several months before you invite an assessor, and build your evidence as you go. A management system that has operated is the only kind an assessor can evaluate.

At a Glance

Evidence beats paperwork

Assessors evaluate records, interviews, and witnessed work. A binder that has never been used produces findings, not confidence.

Sequence protects you

Writing procedures before the gap analysis means documenting a process you will rewrite. Assess first, then build.

The standard is the floor

Your accreditation body publishes its own rules on symbols, claims, and proficiency testing. Confirm them early.

SECTION 2

Purpose and Scope

What this guide covers, who should use it, and where its recommendations apply.

Purpose

This guide gives laboratory leadership a defensible sequence for implementing ISO/IEC 17025:2017. It explains what each phase produces, which clauses drive the work, and what evidence to retain. After working through it, a reader can build a project plan, assign owners, and judge readiness before contacting an accreditation body.

Intended Audience

- **Laboratory owners and managers** at small laboratories and SMBs pursuing accreditation for the first time. No prior ISO experience is assumed.
- **Quality managers and ISO professionals** building, rebuilding, or expanding a laboratory management system. Clause references support your own verification.
- **Technical leads and metrologists** responsible for methods, equipment, traceability, and measurement uncertainty.

Scope

Included	Project sequencing, gap analysis, resourcing, management system build, technical competence evidence, internal audit and management review, accreditation body engagement, and post-accreditation maintenance.
Excluded	Method-specific technical procedures, discipline-specific validation protocols, detailed uncertainty derivations, regulatory frameworks outside ISO/IEC 17025, and accreditation body fee schedules.
Dependencies	A controlled copy of ISO/IEC 17025:2017, your accreditation body's current published requirements and symbol policy, and applicable ILAC guidance documents.

USE WITH CARE

Clause numbers in this guide reference ISO/IEC 17025:2017. If a newer revision is published, confirm the current edition and clause numbering before relying on any reference here. Accreditation body policies change independently of the standard, so verify them directly with your body rather than from any third-party summary, including this one.

SECTION 3

Key Concepts and Definitions

Build a common vocabulary before introducing requirements or methods.

TERM	WORKING DEFINITION	REFERENCE
Accreditation	Third-party attestation of a laboratory's technical competence to perform specific tests or calibrations, granted by an accreditation body against ISO/IEC 17025.	ISO/IEC 17025:2017
Certification	Third-party attestation that a management system conforms to a standard such as ISO 9001. Certification does not attest to technical competence for specific measurements.	ISO 9001:2015
Scope of accreditation	The specific tests, calibrations, item types, ranges, and uncertainties an accreditation body has granted. Results outside this scope cannot be reported as accredited.	Clause 5
Impartiality	Freedom from conflicts of interest that could compromise laboratory activities. Management identifies and addresses risks to impartiality on an ongoing basis.	Clause 4.1
Metrological traceability	The property of a result that relates it to a reference through a documented, unbroken chain of calibrations, each contributing to the measurement uncertainty.	Clause 6.5
Measurement uncertainty	A parameter describing the spread of values that could reasonably be attributed to the measurand. Reported as an expanded uncertainty with a stated coverage factor.	Clause 7.6
Nonconforming work	Any laboratory activity or result that does not conform to the laboratory's own procedures or the customer's agreed requirements.	Clause 7.10
Corrective action	Action taken to eliminate the cause of a nonconformity so it does not recur. Requires root cause analysis and an effectiveness review.	Clause 8.7
Technical record	Records of the data and information generated by a laboratory activity, containing enough detail to allow the measurement to be repeated under conditions as close as possible to the original.	Clause 7.5
Option A / Option B	Two routes to satisfying the management system requirements. Option A implements the elements the standard specifies. Option B relies on an existing ISO 9001 conforming system that covers the intent of Clause 8.	Clause 8.1

TERMINOLOGY NOTE

Use **nonconformity**, not "non-conformance," unless you are quoting a source that uses the other form. Use **accreditation** for ISO/IEC 17025 and **certification** for ISO 9001. Assessors read terminology as a proxy for how well a laboratory understands the standard, and mixed usage invites closer scrutiny.

SECTION 4

Core Guidance: The Seven Phases

Each phase groups tasks that belong together, names the driving clauses, and ends with the evidence you retain.

4.1 Phase 1: Assess Where Your Laboratory Stands

Everything later depends on an honest picture of today. Rushing this phase is the single most common reason a project runs twice as long as planned.

Understand what the standard actually requires

Buy the standard and read it end to end before you write a single procedure. Reading a summary of the standard is not the same as reading the standard. The document breaks into five clauses that matter to you.

- **Clause 4, general requirements.** Impartiality and confidentiality. Assessors probe these harder than most new laboratories expect.
- **Clause 5, structural requirements.** Legal identity, defined scope, organizational structure, and the authority to run laboratory activities.
- **Clause 6, resource requirements.** Personnel, facilities and environmental conditions, equipment, metrological traceability, and externally provided products and services.
- **Clause 7, process requirements.** Contract review, method selection and validation, sampling, item handling, technical records, measurement uncertainty, validity of results, reporting, complaints, nonconforming work, and data control.
- **Clause 8, management system requirements.** Documents, records, risk, improvement, corrective action, internal audit, and management review.

Two decisions belong here. First, choose Option A or Option B under Clause 8.1. Laboratories that already hold ISO 9001 certification often take Option B and save months of duplicated effort. Second, define your intended scope of accreditation: the tests or calibrations, the item types, the ranges, and the uncertainties you intend to claim. Your scope drives equipment needs, proficiency testing, staffing, and fees. A vague scope produces a vague project.

Run a gap analysis before you write anything

A gap analysis compares what you do today against what each clause requires. Work clause by clause, and record evidence rather than opinions. "We calibrate our balances" is an opinion. A calibration certificate from an accredited provider, filed against an equipment record, is evidence.

Build the output as a register with these columns: clause, requirement in plain language, current state, gap, owner, target date, and priority. That register becomes your project plan. It also becomes the first thing you show leadership when you ask for budget.

FOX TIP

Most laboratories discover the same pattern in their gap analysis. The technical work is stronger than the records that prove it. That is good news. Closing a records gap costs far less than fixing a competence gap, and you still have time to do both.

Define clear objectives for the project

Name why you are doing this. Common drivers include a customer requirement, a regulatory expectation, market access, or eligibility for contracts that specify accredited results. The driver shapes your scope and your deadline. Then set objectives you can measure: the scope you will submit, the date you will submit it, the budget you will spend, and the staff hours you will protect each week. Vague goals such as "get accredited this year" collapse under operational pressure.

EVIDENCE TO RETAIN FROM PHASE 1

- Completed gap analysis register, dated and signed
- Documented decision on Option A or Option B
- Draft scope of accreditation
- Project objectives and approved timeline

4.2 Phase 2: Resource the Implementation

A gap register with no owner and no budget is a wish list. This phase turns it into a funded project.

Secure genuine leadership commitment

Clause 5 requires management to define the laboratory's structure, assign responsibility and authority, and make sure personnel understand how their work affects results. Clause 8.9 puts top management into the management review. The standard writes leadership into the system on purpose.

Real commitment looks specific. Leadership protects staff hours instead of expecting people to absorb the work after shift. Leadership funds calibrations, proficiency testing, and accreditation fees. Leadership attends management reviews and acts on what those reviews surface. Clause 4.1 also makes impartiality a leadership responsibility. If your sales team can lean on a technician to soften a result, no procedure fixes that. Only leadership can.

Allocate people, time, and budget

Plan for the standard itself, accreditation body application and assessment fees, assessor travel, proficiency testing enrollment, accredited calibration of your reference equipment, training, and in some cases new equipment or facility work. Fees vary widely by body and by scope, so request a written quote from each body you consider rather than working from a rumor.

Staff time is the cost laboratories underestimate most. Someone has to write procedures, run validations, build uncertainty budgets, train people, and audit the system. Appoint a project lead with authority to make decisions. Small laboratories often split the role: a technical lead owns methods, equipment, traceability, and uncertainty, while a quality lead owns documents, records, audits, corrective action, and management review.

Bring stakeholders along early

Tell customers what you are doing and when you expect to complete it, especially customers who need accredited results for their own compliance. Ask which methods matter most to them, because that feedback sharpens your scope. Your suppliers matter here too. Clause 6.5 requires metrological traceability and Clause 6.6 requires you to evaluate externally provided products and services. Check that your calibration provider's accredited scope covers the parameters and ranges you send them. Do it now, not two weeks before your assessment.

EVIDENCE TO RETAIN FROM PHASE 2

- Approved project budget and resource plan
- Appointment of the project lead and quality manager, with defined authority
- Written quotes from candidate accreditation bodies
- Scope of accreditation verification for each calibration supplier

4.3 Phase 3: Build the Management System

This is the stage where implementation either produces a system your staff use every day, or a binder that impresses an assessor once and then gathers dust.

Choose Option A or Option B and build the QMS

Under Option A, Clause 8 requires documented policies and procedures covering document control (8.3), control of records (8.4), actions to address risks and opportunities (8.5), improvement (8.6), corrective actions (8.7), internal audits (8.8), and management reviews (8.9). Clause 8.2 requires the policies and objectives themselves, along with evidence of management commitment. Under Option B, your existing ISO 9001 system carries those elements. You still meet every requirement in Clauses 4 through 7 in full. Option B removes duplication. It does not lower the technical bar.

Whichever option you choose, map your documents to clauses. A simple cross-reference matrix showing which procedure addresses which clause saves hours during document review and gives your assessor a clean path through your system.

Write procedures people will actually follow

Build a document hierarchy and hold to it. A quality manual or policy set states what you do and why. SOPs describe the process at the procedure level. Work instructions describe the task at the bench level. Forms and templates capture the records.

Write from observed practice. Walk the process, watch the work, and document what competent staff actually do. Then improve it where the standard requires more. Procedures written in a conference room without watching the bench get ignored within a month, and an assessor spots that gap in one interview.

Give priority to the procedures that touch every result: document and record control; personnel competence and authorization; equipment control and calibration; metrological traceability; method selection, verification, and validation; evaluation of measurement uncertainty; sampling and item handling; ensuring the validity of results; reporting including decision rules; complaints and nonconforming work; and internal audit, corrective action, and management review.

Control documents and records from day one

Clause 8.3 governs management system documents: which version is current, where people access it, who approves changes, and how you handle obsolete copies. Clause 8.4 governs records through identification, storage, protection, retrieval, retention, and disposal.

Clause 7.5 adds technical records, and this is where laboratories get caught. Your technical records must contain enough information to allow you to repeat the measurement under conditions as close as possible to the original. That means raw data, calculations, equipment identity, the operator, the date, and the conditions. Clause 7.5.2 also requires amendments to stay traceable to the previous version, with the person who made the change identified. Overwriting a spreadsheet cell destroys that traceability. Where records live in software, Clause 7.11 applies: validate the system for its intended use, control access, and protect the data.

FOX TIP

Turn on document control before you write procedure number one. Laboratories that draft fifty documents first and add version control later end up revising all fifty. Starting controlled costs one afternoon. Retrofitting costs a month.

EVIDENCE TO RETAIN FROM PHASE 3

- Approved quality manual or policy set, under version control
- Clause-to-document cross-reference matrix
- Controlled SOPs, work instructions, and forms with revision history
- Master document list showing current revisions and approval dates

4.4 Phase 4: Prove Technical Competence

Clauses 6 and 7 carry the technical weight of the standard. This phase produces the evidence that your results mean something, and assessors scrutinize it harder than any other part of the project.

Build and evidence staff competence

Clause 6.2 requires you to define the competence requirements for each function that affects results, document the education, qualification, training, technical knowledge, skills, and experience each person needs, authorize personnel for specific activities, and monitor competence over time.

Build an authorization matrix. List each person down one side and each method or activity across the top. Record who is authorized for what, and on what date. Back each authorization with training records, witnessed demonstrations, or acceptable results on a known sample. An assessor will ask how you know a specific analyst is competent, and "she has been here twelve years" is not the answer they are looking for.

Get equipment, calibration, and traceability under control

Clause 6.4 requires access to equipment that meets your methods' requirements, along with control over calibration, maintenance, and status. Clause 6.5 requires metrological traceability of your results through a documented, unbroken chain of calibrations. Put these in place:

- An equipment register with unique identification for every item that affects results
- Calibration and verification schedules, with intervals you can justify
- Calibration certificates from providers whose accredited scope covers your parameters and ranges
- Intermediate checks between calibrations where they are needed to maintain confidence
- Clear status labeling, so nobody uses equipment that is out of calibration
- A documented response when equipment is found out of tolerance, including review of results already reported

That last point creates more findings than most laboratories expect. When a balance returns out of tolerance, you have to consider the results you issued since the last good calibration. Write that procedure before you need it. Clause 6.3 also covers facilities and environmental conditions: where conditions influence the validity of results, you monitor, control, and record them.

Evaluate measurement uncertainty and validate methods

Clause 7.2 requires you to use appropriate methods, verify that you can perform them properly before use, and validate non-standard, modified, or laboratory-developed methods. Keep the validation records, including the results obtained and a statement that the method fits the intended use.

Clause 7.6 requires you to identify the contributions to measurement uncertainty. Calibration laboratories evaluate uncertainty for every calibration. Testing laboratories evaluate it too, and where a rigorous evaluation is impractical, you make a reasonable estimate based on sound theory and practical experience. Build an uncertainty budget for each method: identify the contributors, collect repeatability and reproducibility data, convert every source to a standard uncertainty, combine them, and apply a coverage factor. Then reuse that budget for each job, updating only the values that change.

Plan proficiency testing and interlaboratory comparisons

Clause 7.7 requires you to monitor the validity of your results, and Clause 7.7.2 requires you to monitor performance by comparison with other laboratories where that comparison is available and appropriate. Plan the program against your scope. Identify an available scheme for each area, check the frequency your accreditation body expects, and enroll early enough to have results in hand before your assessment.

Decide in advance how you will respond to a questionable or unsatisfactory result. That response runs through your nonconforming work procedure (Clause 7.10) and your corrective action procedure (Clause 8.7). A poor proficiency testing result handled well demonstrates a functioning system. A poor result filed away without investigation demonstrates the opposite.

FOX TIP

Uncertainty budgets cost new laboratories more time than any other technical task. Start yours in month one, not month nine. The first budget takes days. The fifth takes an hour, because the structure repeats across methods.

EVIDENCE TO RETAIN FROM PHASE 4

- Competence requirements per function, training records, and a dated authorization matrix
- Equipment register, calibration schedule, certificates, and intermediate check records
- Traceability chain documentation for every reference standard
- Method verification and validation records
- Uncertainty budget for each method on your scope
- Proficiency testing plan, enrollment confirmations, and results with any resulting actions

4.5 Phase 5: Verify That the System Works

Building the system is not the same as proving it works. This phase generates the operating evidence your assessor will look for.

Address risks and drive corrective action

Clause 8.5 requires you to consider risks and opportunities associated with laboratory activities, plan actions to address them, and evaluate whether those actions worked. The standard does not require a formal risk management method or a documented risk process. It does expect deliberate thinking about risk and evidence of the result. Practical topics include single points of failure in equipment or staffing, method limitations, supplier reliability, data integrity, and threats to impartiality under Clause 4.1.

Clause 7.10 covers nonconforming work. Clause 8.7 covers corrective action and asks for real root cause analysis: react to the nonconformity, evaluate the need to eliminate the cause, implement the action, review its effectiveness, and record the sequence. Weak root cause analysis is one of the most common findings across accredited laboratories. "Analyst error, retrained analyst" rarely survives scrutiny. Ask why the process allowed the error to happen and reach the customer.

Run internal audits and management reviews

Clause 8.8 requires internal audits at planned intervals, covering your own management system requirements and the requirements of the standard. Auditors must be objective and impartial, which means nobody audits their own work. In a small laboratory, that often means training a second person or bringing in an external auditor.

Clause 8.9 requires management review at planned intervals with defined inputs and outputs. Inputs include audit results, customer feedback and complaints, proficiency testing performance, corrective actions, resource adequacy, and changes affecting the system. Outputs include decisions on improvement, resource needs, and changes to the system.

TIMING MATTERS MORE THAN MOST LABORATORIES REALIZE

Complete at least one full internal audit cycle covering every clause, and hold at least one management review, before your assessment. Assessors look for evidence that the system has actually operated, not just that it exists on paper. Give yourself three to six months of live operation and real records before you invite anyone in.

EVIDENCE TO RETAIN FROM PHASE 5

- Risk and opportunity register with planned actions and effectiveness evaluations
- Nonconforming work records and corrective action files with root cause analysis
- Internal audit programme, auditor competence and independence records, audit reports
- Management review agenda, inputs, minutes, and action outputs

4.6 Phase 6: Take the Implementation Through Assessment

With the system running and evidence on file, your project reaches the accreditation body. Choose that body carefully, because the relationship lasts for years.

Choose an accreditation body

Accreditation bodies that signed the ILAC Mutual Recognition Arrangement produce accreditation that other signatories recognize internationally. In the United States, A2LA, ANAB, PJLA, and IAS are common choices. Confirm current signatory status and program coverage directly, because programs change. Ask each body the same questions:

- Does their program cover your testing or calibration field and your intended scope?
- Do your key customers and regulators recognize them?
- What are the application, assessment, and annual fees, including assessor travel?
- What is the realistic timeline from application to decision?
- What is their proficiency testing policy for your discipline?
- What are their rules for using the accreditation symbol and claiming accredited status on reports?

That last question saves laboratories from an avoidable finding. A report can satisfy Clause 7.8 in full and still draw a nonconformity, because it breaks the body's symbol and claims policy.

Prepare for the on-site assessment

Assessment usually runs in two parts. The body reviews your documentation first, then sends assessors on site. On site, they interview staff, review records, and witness your people performing actual tests or calibrations against your scope.

Prepare your team rather than rehearsing scripts. Staff should know where procedures live, how to retrieve records, and how to explain what they do and why. Run the methods you claim, using your documented procedures and your own equipment. Assessors trust demonstrated competence far more than a polished binder. Expect findings, because almost every first assessment produces some. The body gives you a defined window to respond with root cause analysis, corrective action, and evidence. Handle findings the way your own corrective action procedure describes, and you demonstrate a working system.

4.7 Phase 7: Sustain the System After Accreditation

Accreditation is an operating mode, not a finish line. Your body will schedule surveillance activities and a full reassessment on a defined cycle. Between those visits, the requirements stay live every day. Calibrations come due. Proficiency testing rounds arrive. Audits run on schedule. Management review happens on time.

Track a small set of metrics and review them honestly: proficiency testing results and on-time participation; nonconformity volume, aging, and closure effectiveness; customer complaints and their root causes; equipment found out of tolerance at calibration; internal audit findings by clause; and on-time delivery of reports and certificates. Clause 8.6 asks you to identify and select opportunities for improvement, including through customer feedback. Feed those metrics into management review, and act on what they tell you.

ASSESSMENT PROMPT

What objective evidence would demonstrate that each phase above is implemented consistently, not just once? If the honest answer for any phase is "we did it for the assessment," that phase is a finding waiting to happen at your next surveillance visit.

SCOPE CHANGES

When you add a method, a location, or a measurement range, notify your accreditation body and follow their process for extending your scope. Reporting results as accredited when they sit outside your granted scope is a serious problem, and it is entirely avoidable.

SECTION 5

Implementation Framework

Translate the guidance into a repeatable sequence you can assign and audit.

#	PHASE	WHAT HAPPENS	PRIMARY CLAUSES
1	**Assess**	Read the standard, choose Option A or B, define the scope, and complete a clause-by-clause gap analysis.	4 through 8, 8.1
2	**Resource**	Secure leadership commitment, fund the project, appoint owners, and verify supplier scopes.	5, 4.1, 6.5, 6.6
3	**Build**	Construct the management system, write procedures from observed practice, and control documents and records.	8.2 to 8.4, 7.5, 7.11
4	**Prove**	Evidence competence, control equipment and traceability, validate methods, build uncertainty budgets, and enroll in proficiency testing.	6.2 to 6.5, 7.2, 7.6, 7.7
5	**Verify**	Address risks, handle nonconforming work, run internal audits, and hold management review.	8.5 to 8.9, 7.10
6	**Assess externally**	Select the accreditation body, submit documentation, host the on-site assessment, and close findings.	7.8, body policy
7	**Sustain**	Operate the cycle, track metrics, improve, and manage scope changes.	8.6, 8.9

Roles and Responsibilities

Assign each role below to a named person. In a small laboratory one person may hold several, provided the internal audit role stays independent of the work being audited.

ROLE	PRIMARY ACCOUNTABILITY	REQUIRED RECORD
Top management	Commitment, resources, structure and authority, impartiality, management review participation.	Management review minutes; organizational chart
Project lead	Overall implementation plan, schedule, budget tracking, and phase closure.	Gap register; project plan and status reports
Quality manager	Document and record control, internal audit programme, corrective action, complaints, management review inputs.	Master document list; audit and CAPA files
Technical manager	Methods, validation, equipment, traceability, measurement uncertainty, proficiency testing.	Validation records; uncertainty budgets; equipment register

ROLE	PRIMARY ACCOUNTABILITY	REQUIRED RECORD
Authorized personnel	Performing methods, recording technical records, releasing results within their authorization.	Training and authorization records; technical records
Internal auditor	Independent audit of the management system against the standard and your own requirements.	Auditor competence record; audit reports

SECTION 6

Examples and Visuals

A phase map and a worked example make the framework easier to apply.

PHASE 1	**Assess** Gap analysis, Option A or B decision, draft scope. Output: a prioritized register.
PHASE 2	**Resource** Leadership commitment, budget, owners, supplier verification. Output: a funded plan.
PHASE 3	**Build** Management system, procedures, document and record control. Output: a controlled document set.
PHASE 4	**Prove** Competence, equipment, traceability, validation, uncertainty, proficiency testing. Output: technical evidence.
PHASE 5	**Verify** Risk, corrective action, internal audit, management review. Output: operating records.
PHASE 6	**Assess externally** Body selection, document review, on-site assessment, findings closure. Output: an accreditation decision.
PHASE 7	**Sustain** Surveillance, metrics, improvement, scope changes. Output: a system that stays ready.

Figure 1. The seven phases in sequence. Notice that each phase produces an output the next phase consumes, which is why working them out of order creates rework.

Worked Example: One Line of a Gap Analysis Register

A gap analysis only helps when each line is specific enough to assign. This example shows one clause worked through to a closure criterion.

Clause	6.2, Personnel
Requirement	Define competence requirements for each function affecting results; authorize personnel for specific activities; monitor competence.

Current state	Three analysts perform the method. Training happened informally on the bench. No written competence requirements exist. No authorization records exist.
Gap	No documented competence criteria, no authorization matrix, no evidence of ongoing competence monitoring.
Action	Write competence requirements per function. Build an authorization matrix. Witness each analyst performing the method against a known sample and record the result. Define an annual competence monitoring activity.
Owner	Technical manager
Priority	High. Blocks Phase 4 closure and draws findings at assessment.
Closure criterion	Signed authorization matrix on file, supported by dated witnessed-demonstration records for all three analysts, plus a scheduled monitoring activity in the quality calendar.

FOX TIP

Write the closure criterion before you start the work. If you cannot describe the record that will prove the gap is closed, the action is not defined well enough to assign.

SECTION 7

Checklist and Action Plan

Convert the guide into a practical implementation and review tool.

	READINESS CHECK	PHASE	OWNER	DUE
☐	Controlled copy of ISO/IEC 17025:2017 purchased and read end to end	1		
☐	Option A or Option B decision documented	1		
☐	Draft scope of accreditation defined, including ranges and uncertainties	1		
☐	Clause-by-clause gap analysis complete, with owners and due dates	1		
☐	Budget approved and project lead appointed with defined authority	2		
☐	Impartiality risks identified and addressed by management	2		
☐	Calibration suppliers verified against their accredited scopes	2		
☐	Document control operating before procedure writing begins	3		
☐	Quality manual or policy set approved and under version control	3		
☐	Clause-to-document cross-reference matrix complete	3		
☐	Technical record format allows the measurement to be repeated	3		
☐	Competence requirements defined and authorization matrix signed	4		
☐	Equipment register, calibration schedule, and status labeling in place	4		
☐	Out-of-tolerance response procedure written and tested	4		
☐	Method verification or validation records complete for every method on scope	4		
☐	Uncertainty budget built for every method on scope	4		
☐	Proficiency testing enrolled, with results expected before assessment	4		
☐	Risk and opportunity actions recorded and evaluated	5		
☐	Full internal audit cycle completed across all clauses	5		

	READINESS CHECK	PHASE	OWNER	DUE
☐	At least one management review held, with documented outputs	5		
☐	Corrective actions closed with root cause analysis and effectiveness review	5		
☐	Accreditation body selected; symbol and claims policy obtained and applied	6		
☐	Report and certificate templates checked against Clause 7.8 and body policy	6		
☐	Staff briefed on the assessment format and able to locate records	6		
☐	Quality calendar built for surveillance, audits, calibrations, and reviews	7		

Priority Actions

First 30 days	Complete the clause-by-clause gap analysis and document the Option A or Option B decision. Owner: project lead. Deliverable: a prioritized gap register with owners and dates. Completion criterion: every clause assessed with recorded evidence, reviewed by top management.
Next 60 days	Stand up document control, then write the priority procedures from observed practice. Owner: quality manager. Deliverable: a controlled document set with a clause cross-reference matrix. Completion criterion: master document list current, with approval dates and revision history for every document.
Ongoing	Operate the system and accumulate evidence. Owner: quality manager and technical manager jointly. Deliverable: audit records, management review minutes, proficiency testing results, and closed corrective actions. Completion criterion: at least one full audit cycle and one management review before you request assessment.

Mistakes That Slow Down an Implementation

- **Writing procedures before the gap analysis.** You end up documenting a process you later rewrite.
- **Buying a generic manual and changing the logo.** Templates give structure, not a finished system.
- **Underestimating measurement uncertainty work.** Budgets take longer than people expect, especially the first few.
- **Skipping intermediate checks.** Annual calibration alone rarely maintains confidence between visits.
- **Booking the assessment too early.** Without operating records, the system cannot demonstrate itself.
- **Treating impartiality as a formality.** Clause 4.1 gets tested through interviews, not a signed statement.
- **Weak root cause analysis.** Retraining an analyst rarely addresses the actual cause.
- **Ignoring the accreditation body's own requirements.** The standard sets the floor. Your body adds rules on top.

SECTION 8

References and Resources

Authoritative sources and next-step resources. Verify each source in its current edition before you rely on it.

References

1. International Organization for Standardization. *ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories.* Available from iso.org and national standards bodies.
2. International Organization for Standardization. *ISO 9001:2015, Quality management systems, Requirements.* Relevant to laboratories electing Option B under Clause 8.1.
3. International Laboratory Accreditation Cooperation. ILAC guidance documents on traceability, uncertainty, and accreditation symbol use. Available from ilac.org. Confirm the current revision of each document before use.
4. Joint Committee for Guides in Metrology. *JCGM 100:2008, Evaluation of measurement data, Guide to the expression of uncertainty in measurement (GUM).* The reference method for uncertainty evaluation.
5. Your accreditation body's current published program requirements, proficiency testing policy, and accreditation symbol and claims policy. Obtain these directly from the body.

Related Precision ISO Resources

- **ISO 17025 Reporting Requirements for Testing Labs**, a companion article covering Clause 7.8 in detail, including decision rules and statements of conformity.
- **Calculating Measurement Uncertainty: A Plain-Language Guide for New Labs**, covering contributors, Type A and Type B evaluation, distributions, and budget construction.
- **SOP-011 Document Management** and **SOP-008 Reporting Results**, controlled templates you can tailor to your organization.
- **Template library**, SOPs, work instructions, and forms built for ISO/IEC 17025 and ISO 9001, designed to be customized rather than adopted as-is.

A note on accuracy. This guide teaches; it does not provide legal, regulatory, or accreditation advice, and it guarantees no assessment outcome. Clause numbers reference ISO/IEC 17025:2017. Before relying on any clause number, accreditation body policy, fee, or timeline stated here, verify it against your organization's controlled copy of the standard and your accreditation body's current published requirements. Precision ISO templates and guides are professionally built starting points that must be reviewed and adapted to your organization's scope and processes.

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