Gap Analysis

ISO / IEC 17025 : 2017

A clause-by-clause self-assessment tool for calibration and testing laboratories

seeking initial accreditation or maintaining ongoing compliance

Zero Point Consulting

ISO 17025 Accreditation Consulting Services

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Laboratory Information

Laboratory Name:

Accreditation Body (NVLAP / A2LA / Other):

Cert / Scope #:

Address:

Primary Contact:

Phone / Email:

Assessment Details

Assessment Date:

Completed By:

Revision:

Accred. Status:

ISO / IEC 17025 : 2017 — CLAUSE STRUCTURE

CLAUSE 8 — Management System
Documentation | Internal Audits | Corrective Action | Management Review

CLAUSE 7 — Process Requirements
Methods | Uncertainty | Reporting | Complaints | Nonconforming Work

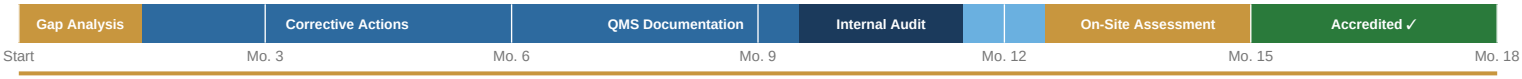
6.2	6.3	6.4 / 6.5	6.6
Personnel	Facilities & Environment	Equipment & Traceability	External Providers

Resource Requirements — Clause 6

CLAUSE 5 — Structural Requirements
Legal Entity | Organizational Structure | Technical Manager

CLAUSE 4 — FOUNDATION
General Requirements: Impartiality & Confidentiality

TYPICAL PATH TO ACCREDITATION — 12 TO 18 MONTHS



How to Use This Gap Analysis

Purpose & Approach

This document serves two purposes:

1. A **free self-assessment tool** for laboratories to independently identify gaps against ISO/IEC 17025:2017.

2. The **same working document** used by Zero Point Consulting during formal gap analysis engagements.

Complete every row. Be honest — gaps found now are far less costly than findings during an accreditation audit.

Tip: Walk through each clause with the technical manager AND a bench-level analyst.

Compliance Status Definitions

Fully Compliant — Evidence exists; requirement is consistently met.

Partially Compliant — Partially met or inconsistently applied. Document the gap.

Non-Compliant — Requirement is not currently met. Immediate action required.

Not Applicable — Clause does not apply to this lab's scope. Document justification.

Priority Levels

Critical — Prevents accreditation or creates immediate risk to result validity.

High — Will be cited as a major finding. Resolve before audit.

Medium — Likely an observation/minor finding. Resolve within 60–90 days.

Low — Best practice improvement. Resolve within 6 months.

Target Date — Set realistic deadlines. Missed dates create a paper trail of non-compliance.

Five Steps to Readiness

Step 1: Complete the laboratory information fields on this page.

Step 2: Work through each clause — assess status, document evidence, and identify gaps.

Step 3: Use Priority and Target Date columns to build your roadmap.

Step 4: Assign each action to a responsible person and track to closure.

Step 5: Re-assess after actions are complete. A clean gap analysis signals audit readiness.

Questions? **zeropointiso.com · alberto@zeropointiso.com**

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Clause	Requirement Summary	Status	Current Evidence / Notes	Gap / Finding	Action Required	Priority	Target Date
Clause 1–3 — Scope, Normative References & Terms (Summary — No Direct Audit Requirements)							
1	Scope — ISO/IEC 17025:2017 specifies requirements for laboratories performing testing, calibration, and sampling. It applies to all laboratories regardless of personnel count or scope, and supports recognition of competence by regulatory bodies and accreditation organizations.						
2	Normative References — This standard references ISO/IEC Guide 99 (International Vocabulary of Metrology, VIM). Familiarity with metrology terminology used throughout the standard is expected of all technical personnel.						
3	Terms & Definitions — Key terms used in this standard are defined in ISO/IEC Guide 99 and the standard itself. Commonly referenced: impartiality, laboratory, technically competent person, method verification, method validation, measurement uncertainty, metrological traceability, and proficiency testing (PT).						
Clause 4 — General Requirements							
4.1	Impartiality — The laboratory conducts activities impartially, free from commercial, financial, or other pressures that could compromise technical judgment.						
4.1.4	Risks to impartiality are identified on an ongoing basis and documented. A commitment to impartiality is maintained and communicated.						
4.2	Confidentiality — The laboratory has documented policies to protect confidential information and proprietary rights of customers, including electronic data.						
Clause 5 — Structural Requirements							
5.1	Legal entity — The laboratory (or its parent organization) is a legal entity that can be held legally responsible for its activities.						
5.2	Management has issued a documented commitment to impartiality and communicates its importance throughout the laboratory.						
5.3	The organizational structure, authority, and responsibilities are documented, including the laboratory's place within any parent organization.						
5.4	Personnel with authority and resources to identify deviations from requirements and initiate corrective actions are designated.						
5.5	Internal communication channels ensure personnel receive relevant information about the management system and laboratory activities.						
5.6	A technically competent manager or designee oversees and ensures the quality of all laboratory activities and results.						

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Clause	Requirement Summary	Status	Current Evidence / Notes	Gap / Finding	Action Required	Priority	Target Date
Clause 6.2 — Resource Requirements — Personnel							
6.2.1	All personnel affecting laboratory outcomes are competent and authorized, whether internal employees or external contractors.						
6.2.2	Competence requirements are documented for each role: education, qualifications, training, technical knowledge, skills, and experience.						
6.2.3	Personnel are formally authorized to perform specific activities: developing/modifying/validating methods, analyzing results, approving and signing reports, operating specific equipment.						
6.2.4	A training program exists. The effectiveness of training actions is evaluated and documented.						
6.2.5	Personnel performing laboratory activities are appropriately supervised. Ongoing competence is demonstrated and recorded.						
6.2.6	Signed authorization and competency records are maintained for all personnel performing laboratory activities.						
Clause 6.3 — Resource Requirements — Facilities & Environment							
6.3.1	Facilities and environmental conditions are appropriate for laboratory activities and do not invalidate results or adversely affect measurement quality.						
6.3.2	Requirements for environmental conditions are documented. Relevant parameters (temperature, humidity, vibration, cleanliness) are monitored, controlled, and recorded.						
6.3.3	Measures are in place to prevent contamination, separate incompatible activities, and control access to areas that affect result quality.						
6.3.4	Facilities are maintained in an orderly, clean condition with defined housekeeping and maintenance procedures.						
Clause 6.4 — Resource Requirements — Equipment							
6.4.1	Equipment (instruments, standards, reference materials, software) required to perform laboratory activities is available, adequate, and maintained.						
6.4.2	Equipment used outside the laboratory's permanent control is verified before use to confirm it still meets specified requirements.						
6.4.3	All equipment is uniquely identified, including software/firmware version and hardware configuration details.						

Clause	Requirement Summary	Status	Current Evidence / Notes	Gap / Finding	Action Required	Priority	Target Date
6.4.4	Equipment records include: unique ID, manufacturer, model, serial number, date received, condition on receipt, location, calibration records, maintenance history, and any damage or malfunction history.						
6.4.5	Equipment suspected of being compromised (overloading, incorrect use, damage, suspect results) is taken out of service, labeled, and investigated. Impact on previous results is evaluated.						
6.4.6	A calibration program and schedule is established for all equipment requiring calibration or contributing to measurement uncertainty.						
6.4.7	Calibration status and traceability to SI units is established and maintained through an unbroken chain of calibrations. Status is visibly indicated on equipment.						
6.4.8	Intermediate checks are performed between calibrations to maintain confidence in equipment performance and detect drift.						
6.4.9	Correction factors from calibration certificates are applied and updated in procedures, worksheets, and software as required.						
6.4.10	Equipment is protected from unauthorized adjustments, contamination, and deterioration that would invalidate calibration status or measurement results.						
Clause 6.5 — Resource Requirements — Metrological Traceability							
6.5.1	All measurement results are traceable to the International System of Units (SI) through an unbroken chain of calibrations with documented measurement uncertainty.						
6.5.2	Calibration providers used to establish traceability are competent and accredited (e.g., NVLAP, A2LA) at uncertainty levels appropriate for the laboratory's needs.						
6.5.3	Where SI traceability is technically not possible, the reference standard used (certified reference material, consensus standard, ratio technique) is documented and justified.						
Clause 6.6 — Resource Requirements — Externally Provided Products & Services							
6.6.1	A procedure exists for evaluating, selecting, monitoring, and re-evaluating external providers (calibration services, PT providers, sub-contractors, reagent/material suppliers).						
6.6.2	Specifications and requirements are communicated to external providers, including technical requirements, qualifications, and quality system expectations.						
6.6.3	Products and services from external providers are verified to meet specified requirements before use or incorporation into laboratory activities.						

Clause	Requirement Summary	Status	Current Evidence / Notes	Gap / Finding	Action Required	Priority	Target Date
Clause 7.1 — Process Requirements — Requests, Tenders & Contracts							
7.1.1	A procedure for reviewing requests, tenders, and contracts ensures customer requirements are understood, capability is confirmed, and resources are available.						
7.1.2	Capability to meet requirements is confirmed before undertaking work. Any deviations or limitations are communicated to the customer.						
7.1.3	Records of contract reviews, including significant changes and deviations, are maintained and accessible.						
7.1.4	When the scope of work changes materially after commencement, a new contract review is performed and communicated to all affected personnel.						
Clause 7.2 — Process Requirements — Selection, Verification & Validation of Methods							
7.2.1	Appropriate test/calibration methods are selected and used. Standard methods are verified before use to confirm the laboratory can apply them correctly.						
7.2.2	Customers are informed when a requested method is considered inappropriate, outdated, or outside the laboratory's scope.						
7.2.3	Non-standard and in-house methods are validated before use. Performance characteristics (uncertainty, range, linearity, repeatability) are documented.						
7.2.4	Method verification records are retained, including performance data and acceptance criteria.						
7.2.5	Methods are kept current; transitions to updated standard methods are documented and training provided.						
Clause 7.3 — Process Requirements — Sampling							
7.3.1	A sampling plan and procedure are available when the laboratory performs sampling. Records include method, date/time, location, environmental conditions, and personnel. (Mark N/A if not applicable.)						
7.3.2	Deviations from the sampling plan requested by the customer are documented and included in the test/calibration report.						
Clause 7.4 — Process Requirements — Handling of Test / Calibration Items							
7.4.1	Procedures cover transportation, receipt, handling, protection, storage, retention, and disposal of test and calibration items.						
7.4.2	Items are uniquely identified throughout the laboratory. Identification is maintained on sub-samples, parts, and all related documentation.						

Clause	Requirement Summary	Status	Current Evidence / Notes	Gap / Finding	Action Required	Priority	Target Date
7.4.3	Anomalies or departures from normal/specified conditions noted upon receipt are recorded. The customer is consulted before proceeding.						
7.4.4	Special storage or conditioning requirements are controlled, monitored, and recorded to prevent deterioration or contamination.						
Clause 7.5 — Process Requirements — Technical Records							
7.5.1	Technical records contain sufficient information to reproduce the activity: personnel, dates, equipment IDs, raw data, calculations, environmental conditions, and reports issued.						
7.5.2	Amendments to records include reason for change, date, and identity of person making the change. Original data remains preserved and legible.						
7.5.3	Records are retained for a defined, documented period consistent with contractual, regulatory, and accreditation body requirements.						
Clause 7.6 — Process Requirements — Evaluation of Measurement Uncertainty							
7.6.1	All contributions to measurement uncertainty are identified and documented. Where full evaluation is not feasible, a reasonable estimate is made and documented with justification.						
7.6.2	For calibration laboratories: measurement uncertainty is evaluated for all calibrations. All components and combined uncertainty are documented and updated when conditions change.						
7.6.3	For testing laboratories: uncertainty is evaluated where relevant; at minimum, major sources of uncertainty are identified and their relative magnitudes estimated.						
Clause 7.7 — Process Requirements — Ensuring Validity of Results							
7.7.1	A procedure monitors the validity of results using: replicate testing, use of reference materials, control charts, intermediate checks, interlaboratory comparisons, or proficiency testing.						
7.7.2	Monitoring data are analyzed using statistical methods. Pre-defined acceptance criteria are established. Data outside criteria trigger investigation and corrective action.						
7.7.3	PT results are reviewed. Performance outside acceptable criteria is investigated; corrective actions are documented and tracked to closure.						
Clause 7.8 — Process Requirements — Reporting of Results							
7.8.1	Results are reported accurately, clearly, and unambiguously, including all information required by the method, the customer, and the accreditation body.						

Clause	Requirement Summary	Status	Current Evidence / Notes	Gap / Finding	Action Required	Priority	Target Date
7.8.2	Test/calibration reports include: title, laboratory identity, unique report ID, customer information, item description and condition, date received, method reference, results with units, measurement uncertainty, and authorizing personnel.						
7.8.3	Calibration certificates also include: traceability statement, conditions under which calibration was performed, corrections or correction factors, and next calibration due date (if agreed).						
7.8.4	Amended reports are clearly marked as amendments, reference the original report, and document the reason for amendment.						
7.8.5	Verbal reporting is followed by written confirmation, which is retained as a record.						
7.8.6	Opinions and interpretations are clearly identified as such and justified based on documented facts.						
Clause 7.9 — Process Requirements — Complaints							
7.9.1	A documented procedure handles receipt, evaluation, and resolution of complaints. The procedure is available to any interested party upon request.						
7.9.2	Complaints are acknowledged, investigated, and the outcome communicated to the complainant. All complaint records and actions taken are retained.						
Clause 7.10 — Process Requirements — Nonconforming Work							
7.10.1	A procedure defines actions when laboratory work or results do not conform: work is stopped, reports are withheld, the customer is notified, and corrective action is initiated.						
7.10.2	Work resumes only upon authorization by designated personnel. The impact on previously reported results is evaluated and documented.						
Clause 7.11 — Process Requirements — Data Control & Information Management							
7.11.1	The laboratory has access to data and information systems (LIMS or equivalent) required to perform activities. Systems are validated for functionality before use.						
7.11.2	Information management systems protect data integrity and confidentiality. Unauthorized access, modification, or deletion is prevented. All changes are traceable.						
7.11.3	Calculations and data transfers are systematically checked. Software validation records are maintained and accessible.						

Clause	Requirement Summary	Status	Current Evidence / Notes	Gap / Finding	Action Required	Priority	Target Date
Clause 8 — Management System Requirements							
8.1	A documented management system is established, implemented, and maintained, capable of supporting consistent achievement of ISO 17025:2017 requirements (Option A or ISO 9001 equivalent — Option B).						
8.2	Management system documentation includes: quality policy, quality objectives, scope, procedures, roles and responsibilities, and cross-references to related documents.						
8.3	Document control procedure covers creation, review, approval, distribution, revision, access, and withdrawal of obsolete documents. Current approved versions are available to personnel.						
8.4	Records control procedure covers identification, storage, protection, retrieval, retention period, and disposal of technical and quality records.						
8.5	Risks and opportunities affecting impartiality, ability to deliver services, or validity of results are identified and addressed through planned actions. Effectiveness is evaluated.						
8.6	Opportunities for improvement are identified through audits, management review, corrective actions, and customer feedback. Actions are taken and effectiveness evaluated.						
8.7	Corrective action procedure includes: identifying nonconformity, root cause analysis, evaluating need for action, implementing actions, monitoring effectiveness, and updating risk assessments.						
8.8	An internal audit program is planned, conducted, and documented at defined intervals covering the full scope. Findings are reported to management; corrective actions are tracked to closure.						
8.9	Management reviews are conducted at planned intervals. Review inputs and outputs meet ISO 17025 requirements. Actions are assigned, tracked, and reported at subsequent reviews.						

Consolidated Action Plan — Prioritized Gap Closure Roadmap

Total Requirements Assessed	Fully Compliant	Partially Compliant	Non-Compliant	Not Applicable

#	Gap / Action Description	Clause	Priority	Responsible Person	Est. Hours	Target Date	Status / Notes
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							

Assessor Notes / Overall Observations: