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STANDARDS & GUIDANCE REPORT · INTERNATIONAL · ACCREDITATION STANDARD

ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories

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EDITION	Third edition (2017)	STATUS CHECKED	October 24, 2026
INDUSTRIES	Laboratories & Calibration, Pharmaceutical, Medical Devices, Consumer Products & Toys, Textiles & Materials	ONLINE	qesisbest.com/standard-iso-iec-17025.html

CURRENT EDITION No revision has been announced; accreditation bodies assess to the 2017 text.

What It Covers

What a laboratory must show to be accredited as competent, impartial and consistent in its testing, calibration or sampling, and therefore able to produce results others can rely on.

Who It Applies To

Testing and calibration laboratories of every kind, first-, second- or third-party, that seek accreditation or whose customers or regulators require it.

Key Requirements

- Impartiality and confidentiality managed as risks, with commitments from management (clause 4).
- Competent personnel, suitable facilities, calibrated equipment, and metrological traceability (clause 6).
- Methods verified or validated, with measurement uncertainty evaluated (7.2, 7.6).
- Validity of results assured through monitoring such as proficiency testing (7.7).
- Reports that are accurate and unambiguous, with decision rules agreed when conformity is stated (7.8, 7.1.3).

Structure at a Glance

PART	TOPIC	WHAT IT ASKS FOR
Clause 4	General requirements	Impartiality and confidentiality.
Clause 5	Structural requirements	Legal entity, management, defined scope of laboratory activities, responsibilities.
Clause 6	Resource requirements	Personnel, facilities and environment, equipment, metrological traceability, external products, and services.
Clause 7	Process requirements	Requests and contracts, methods, sampling, handling, records, uncertainty, validity of results, reporting, complaints, nonconforming work, data control.

PART	TOPIC	WHAT IT ASKS FOR
Clause 8	Management system requirements	Option A (the clauses themselves) or Option B (a system meeting ISO 9001), documents, records, risks, improvement, audits, reviews.

What an Auditor Asks to See

- The scope of accreditation, and a report for a test or calibration within it.
- The uncertainty budget for a key method.
- Proficiency testing results for the last cycle and the action on any outlier.
- How the decision rule for statements of conformity was agreed with the customer.

Requirements Checklist

Work down the list with the evidence in hand; write where each item is evidenced in the right-hand column.

#	REQUIREMENT	EVIDENCE ON FILE
1	Risks to impartiality identified and addressed on an ongoing basis (4.1).	
2	Scope of laboratory activities defined and matched to the accreditation scope (5.3).	
3	Competence requirements defined, with authorization of personnel for specific activities (6.2).	
4	Environmental conditions monitored where they affect results (6.3).	
5	Equipment calibrated where it affects results, with intermediate checks planned (6.4).	
6	Metrological traceability to SI units established and documented (6.5).	
7	External providers of products and services evaluated and approved (6.6).	
8	Decision rule agreed with the customer when conformity statements are requested (7.1.3).	
9	Methods verified before use, and non-standard methods validated (7.2).	
10	Measurement uncertainty evaluated for each calibration and, where relevant, each test (7.6).	
11	Validity of results monitored, including proficiency testing or interlaboratory comparisons (7.7).	
12	Reports contain the required information and identify any opinions and interpretations (7.8).	
13	Nonconforming work managed, with recall of results where needed (7.10).	
14	Data and information management systems validated before use (7.11).	
15	Internal audits and management reviews performed at planned intervals (8.8, 8.9).	

Implementation Roadmap

1. Scope	Define the activities and methods to be accredited, and choose Option A or Option B for the management system.
2. Resources	Confirm competence and authorization, equipment calibration and traceability, and environmental control.
3. Methods and uncertainty	Verify or validate each method, and build its uncertainty budget.
4. Results assurance	Set up proficiency testing, intermediate checks, and the decision rule for conformity statements.

5. System and assessment	Internal audit, management review, then a pre-assessment before the accreditation body visits.

How It Fits With Other Requirements

ISO/IEC 17020 covers inspection bodies and ISO 15189 medical laboratories in the same family. The GUM sets how uncertainty is evaluated, ISO 10012 how a user organization manages its measurements, and NIST or another national metrology institute anchors traceability.

Findings We See Most Often

- Measurement uncertainty not evaluated, or incomplete (7.6).
- Metrological traceability not demonstrated for a calibration supplier (6.5).
- Method verification records missing for a standard method (7.2.1).
- Monitoring of the validity of results not planned or reviewed (7.7).

Where Systems Fall Short

- Uncertainty budgets that omit the largest contributor.
- Statements of conformity made without an agreed decision rule.
- Intermediate checks on equipment that are planned but not done.

How QES helps. Readiness assessments for accreditation, and uncertainty budgets reviewed term by term. See the mock assessment: qesisbest.com/services.html#mock-audit · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. ISO — ISO/IEC 17025:2017 — www.iso.org/standard/66912.html; de Grandson — ISO management system revisions, 2026–2030 (September 2026) — www.degrandson.com/blog/iso-management-system-standards-revisions-2026-2030.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.