

ISO/IEC 17025 calibration and traceability: what auditors look for.

ISO/IEC 17025 does not tell a chromatography lab how to build a calibration curve. It sets what the lab must be able to prove about one, and the auditor's questions follow the clauses.

SUMMARY

ISO/IEC 17025:2017 sets requirements for equipment calibration, metrological traceability, monitoring the validity of results and the control of data. In a chromatography laboratory those clauses apply twice: to the balances, pipettes and thermometers behind every standard, and to the initial calibration that converts response into a reported result. This paper maps each clause to the evidence an auditor will ask for and traces an ICAL back to the SI.

THE SHORT VERSION

- 01 ISO/IEC 17025 calibration rules apply twice in your lab: to the balances and pipettes, and to the ICAL itself.
- 02 An auditor will trace one result back, record by record, to the reference material and the SI.
- 03 The usual gaps are the ICAL decision record and a check of the calculations used to accept the curve.

Two kinds of ISO/IEC 17025 calibration.

The auditor picks one reported result and asks where it came from. You pull the ICAL, the prep log, the balance and pipette certificates, and the certificate for the stock. Each record has to point to the next one.

ISO/IEC 17025:2017 sets the rules for that walk. It is the international standard for the competence of testing and calibration labs. It is also the basis for most lab accreditation programs, including the TNI standard used by environmental labs ^[1]. It covers every kind of lab, so it never mentions a calibration curve.

In a chromatography lab, its calibration rules apply in two places. The first is the equipment behind every standard: balances, pipettes, volumetric glassware and thermometers. An outside provider calibrates them.

The second is the ICAL, which turns a peak area into a concentration. The standard treats both as measuring equipment. Expect the auditor to ask about both.

The ISO/IEC 17025 clauses that matter.

The table paraphrases the ISO/IEC 17025:2017 clauses as accreditation bodies present them in training material ^{[2][3][4]}. The right column shows the evidence that usually answers each clause for an ICAL.

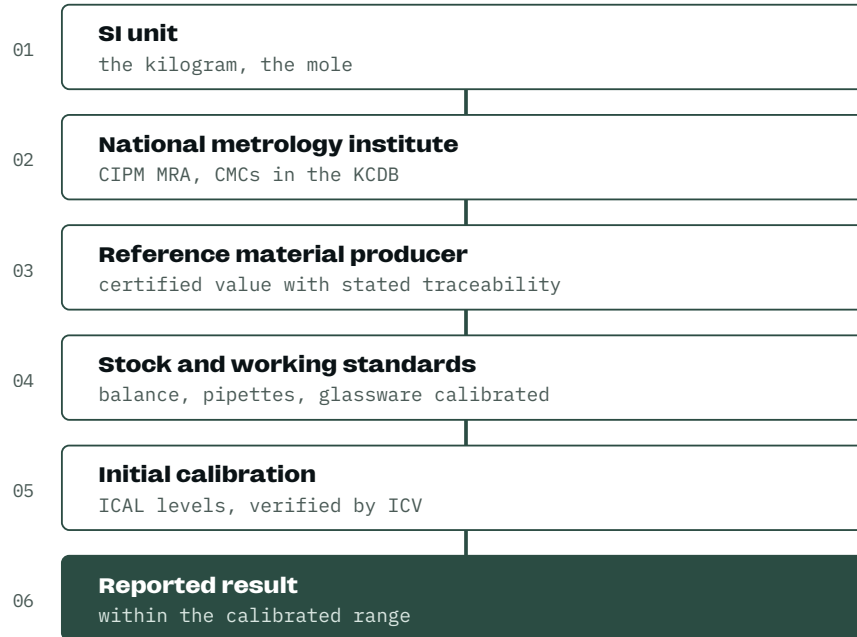
CLAUSE	WHAT IT REQUIRES, IN BRIEF	EVIDENCE FOR A CHROMATOGRAPHIC ICAL
6.4.4	Equipment is checked against specified requirements before it goes into, or back into, service.	Post-maintenance checks before the instrument is recalibrated and returned to sample work.
6.4.6	Measuring equipment is calibrated where its accuracy affects whether results are valid, or where calibration sets up traceability.	The ICAL itself, plus calibration certificates for the balances and volumetric equipment used to make the standards.
6.4.7	A calibration programme is set up, reviewed and adjusted to keep confidence in calibration status.	Written ICAL frequency and recalibration triggers, such as a failed CCV or major maintenance.
6.4.8	Equipment that needs calibration is identified so its calibration status is clear.	Instrument status and the current ICAL shown in the data system and the run log.
6.4.10	Intermediate checks, where needed, follow a procedure.	CCV procedure and frequency.
6.4.13	Records are kept for equipment that can affect lab activities.	ICAL raw data, model choice, acceptance results and the analyst's decisions.
6.5	Results are metrologically traceable to the SI through calibration, certified reference materials or direct realization.	Certificates of analysis for reference standards, prep logs and the chain from stock to ICAL.
7.7.1	Validity of results is monitored, including intermediate checks and check standards with control charts where they apply.	ICV and CCV results, control charts, trend review.
7.11.6	Calculations and data transfers are checked in a suitable, systematic way.	Checks of CDS calculations and any spreadsheet used to judge the ICAL.

Clause summaries are paraphrases. The standard itself is the authority and is available from ISO and national standards bodies.

Tracing an ICAL back to the SI.

Clause 6.5 asks for an unbroken chain of calibrations that links a result to a reference. Each link adds to the measurement uncertainty, and a gap in any link breaks the chain. For a chemical result, the usual route to the SI runs through a certified reference material. It comes from a competent producer and states its traceability to the SI ^[3].

FIGURE 1 The traceability chain behind a reported result



ILAC P10 is the policy accreditation bodies apply to traceability. It recognizes calibrations from national metrology institutes covered by the CIPM Mutual Recognition Arrangement. It also recognizes calibrations from accredited calibration labs, and reference values from competent reference material producers [5].

In practice, the auditor follows the chain one link at a time. First comes the certificate of analysis for the stock, then the balance and pipettes used to dilute it. Next is the prep record for each ICAL level, and last the ICAL that used them.

Two links are often the weakest. The first is the prep record, where the dilution is written down and the equipment is not. The second is the last link. The chain only covers results inside the calibrated range, so a result above the top standard is diluted and never extrapolated.

Showing results stay valid.

Clause 7.7 asks for a procedure to monitor the validity of results. It lists checks that equipment works, and intermediate checks on measuring equipment. They also include check or working standards, with control charts where they apply [4]. So do proficiency testing and comparisons between labs.

In chromatography, these map straight onto routine work. The second-source ICV checks the standards behind the curve. The CCV is the intermediate check.

Control charts of CCV recovery and ICAL response show drift before it becomes a failure. [Insights 09](#) covers how to judge each one. A chart only counts if someone reviews it and acts on what it shows.

The calculation is part of the record.

Clause 7.11 covers control of data and information management. A LIMS must be checked to work before use. It must be kept safe from unauthorized access, tampering and loss. Calculations and data transfers must be checked in a suitable and systematic way ^[6].

That last rule reaches further than many labs assume. The model you fit is a calculation. So are its weighting, the back-calculated errors, and any spreadsheet you use to judge RSE or relative error.

If your lab relies on a calculation to accept a curve, you need evidence that the calculation is correct.

The same goes for the CDS regression itself, which most labs accept without a separate check. Check both, and keep a record that you did.

An ISO/IEC 17025 readiness checklist.

01 Trace one result end to end.

Go from the reported value to the ICAL, the prep record, the equipment certificates and the reference material certificate.

02 Confirm equipment status at the time of use.

The balances and pipettes used for the standards were in calibration on the prep date.

03 Write down the calibration programme.

Record ICAL frequency, recalibration triggers and the CCV procedure, and follow them.

04 Keep the ICAL decision record.

Keep the model, weighting, excluded points and acceptance results, along with the final curve.

05 Show results stay valid.

Review the ICV, CCV and control charts, and act on what they show.

06 Check the math.

Check the CDS and spreadsheet calculations used to accept a calibration, and record the check.

Where WLTR fits.

Most of the evidence an auditor asks for already exists in the lab. What is usually missing is the ICAL decision record and a check of the math behind it, both kept so they can be produced on request.

WLTR is calibration data integrity infrastructure for regulated analytical laboratories. For each analyte, it derives nine calibration regression models: average response factor, plus linear and quadratic fits across four weightings each. It scores every model against fifteen ICAL parameters, including RSE. All of it is computed orthogonally to the CDS, under U.S. Patent 12,038,448 B2 ^[P].

CALIBRATION VERIFICATION

See how your ICAL records map to the evidence an ISO/IEC 17025 auditor asks for, analyte by analyte.

[GET COMPLIANCE GAP ASSESSMENT](#)

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SOURCES

1. The NELAC Institute, NELAP program overview, noting that TNI Volume 1 is modeled after ISO/IEC 17025. nelac-institute.org/content/NELAP/index.php
2. Perry Johnson Laboratory Accreditation, "Requirements in Section 6.4 'Equipment'," October 2023. www.pjllabs.com/downloads/webinar_slides/10.26.2023_Equipment64.pdf
3. Perry Johnson Laboratory Accreditation, "Metrological Traceability," March 2019. www.pjllabs.com/downloads/webinar_slides/3.28.19_Traceability.pdf
4. Perry Johnson Laboratory Accreditation, "Ensuring the Validity of Results," January 2020. www.pjllabs.com/downloads/webinar_slides/1.24.2020_Ensuring-Validity-of-Results.pdf
5. ILAC P10:07/2020, *ILAC Policy on Metrological Traceability of Measurement Results*, published July 2020, implemented July 2021. ilac.org/latest_ilac_news/revised-ilac-p10-published/
6. Perry Johnson Laboratory Accreditation, "Section 7.4 and Section 7.11," August 2024. www.pjllabs.com/downloads/webinar_slides/8.14.2024_74-711.pdf
7. ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*. www.iso.org/standard/66912.html
8. U.S. Patent 12,038,448 B2, inventor Walter "Chip" Hinchman Sr. patents.google.com/patent/US12038448B2

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