

Trust every reading. Know what to do when you can't.

For quality, engineering and laboratory teams choosing software to manage the equipment register, calibration status, as-found results and the impact review that follows an out-of-tolerance reading.



A register you can defend

Criticality, intervals, tolerances and standards, with what each field means.

One out-of-tolerance, worked

As-found, as-left, error against tolerance and a person's impact assessment.

Questions that expose gaps

Calibration versus maintenance, migration, RACI, RFP questions and a scored checklist.

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Who this is for

Quality managers, metrology and laboratory leads, maintenance and engineering managers, and IT. It applies to balances, scales, thermometers, pH meters, pressure gauges, test equipment and any instrument whose readings support a quality decision.

Important. This guide explains calibration workflows for software evaluation. It is not legal or metrology advice. Requirements depend on your sector and markets; your procedures define intervals, tolerances and what happens when an instrument is found out of tolerance. People decide impact and product disposition.

1 • THE PROBLEM

Why calibration evidence fails audits

The calibration usually happened. What fails is proving it applied to the instrument, the date, the tolerance and the products in question.

SYMPTOM	TYPICAL CAUSE	WHAT GOOD LOOKS LIKE
Overdue instrument still in use	Due dates in a spreadsheet nobody opens	Due list in front of the people who use the instrument
Certificate can't be found	PDFs in email or shared drives	Certificate attached to the calibration record
Only 'pass' recorded	As-found not captured before adjustment	As-found and as-left both recorded
Out-of-tolerance ignored	No link from failed reading to products made	Impact assessment with the period since last good calibration
Wrong tolerance applied	Tolerance not tied to the process need	Tolerance per instrument and use, with change history
Standard itself out of date	Reference weights or standards untracked	Standards in the register with their own certificates
Maintenance and calibration mixed	One 'service' record for both	Separate records; linked where one affects the other

The outcome to buy. For any reading that supported a decision, show the instrument was in calibration — or show what was done when it wasn't.

Avoid buying a calendar. Reminders are easy. Ask how an out-of-tolerance result leads to an impact review.

The equipment register

Every calibrated instrument needs a record that answers: what is it, where is it, what does it measure, how accurately must it, and when was it last proven.

FIELD	EXAMPLE	WHY IT MATTERS
Asset ID	QC-BAL-07	Unique; printed on the instrument
Description / make / model / serial	Analytical balance, 220 g × 0.1 mg	Identifies the physical unit
Location / area	QC lab, bench 2	Who uses it; where to find it
Measured quantity and range	Mass, 0–220 g; used 50–200 g	Calibrate across the range you use
Tolerance	±0.02 g at 200 g	Derived from the process need, not the brochure
Criticality	High — release testing	Drives interval and impact rules
Interval	6 months + daily check	Your procedure sets it
Calibrated by	External accredited lab / internal	Competence and traceability
Status	In calibration / due / overdue / out of service	What users should see
Owner	QC lab supervisor	Who acts on due and failed results

Ask in a demo: "Add an instrument with a usage range narrower than its full range and a tolerance set by the process. Show me where each is used."

3 • RISK

Criticality and intervals

Not every instrument needs the same care. Rank by what a wrong reading could do.

High

Readings support release, dosing, safety or regulatory records. Short intervals, routine checks between calibrations, formal impact review on any failure.

Medium

Readings support process control with other safeguards. Standard intervals, impact review proportionate to use.

Low / indication only

Readings are informative. Longer intervals or "calibration not required" with documented rationale.

INSTRUMENT	USE	CRITICALITY	INTERVAL (EXAMPLE)	BETWEEN-CALIBRATION CHECK
Analytical balance	Release assays	High	6 months	Daily check weight
Floor scale	Ingredient dispensing	High	6 months	Daily check weight
Probe thermometer	Cook-step temperature	High	3 months	Ice-point / reference check
pH meter	In-process checks	Medium	Per buffer schedule	Buffer before use
Pressure gauge	Utility indication	Low	24 months	None

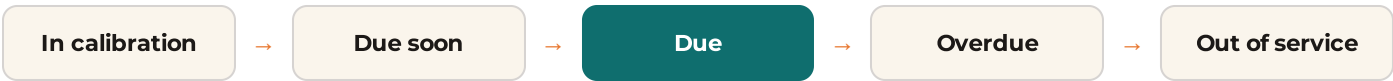
Adjusting intervals

- Use as-found history: repeated drift towards a limit suggests a shorter interval; years of stable results may justify a longer one.
- Record the reason and approver for every interval change.
- Ask whether the system shows as-found trends per instrument.

4 • PLAN

The calibration plan and status

Status is the single most useful thing an operator can see. Make it accurate and visible.



DUE LIST • NEXT 30 DAYS	DUE	CALIBRATED BY	CRITICALITY	STATUS
QC-BAL-07 analytical balance	12 Nov	External lab	High	Due soon
SC-14 floor scale, dispensary	15 Nov	Internal	High	Due soon
TH-22 probe thermometer	3 Nov	Internal	High	Overdue
PH-03 pH meter	28 Nov	Internal	Medium	Due soon

CHECK	WHAT GOOD LOOKS LIKE	OK
Due list by owner and area	Each owner sees their own instruments.	☐
Lead time	External calibrations scheduled before the due date, not on it.	☐
Overdue visible to users	Status shown where the instrument is chosen or used, as your set-up allows.	☐
Out of service	Removed instruments clearly marked; reason and date recorded.	☐
What happens if overdue	Your procedure decides; confirm what the system displays or prevents.	☐

Check, don't assume. Whether a system stops an overdue instrument being used, or only shows its status, varies by product and configuration. Ask to see it.

5 • RECORD

Recording a calibration: as-found and as-left

As-found tells you whether past readings were trustworthy. As-left tells you whether future readings will be. You need both.

Worked example: QC-BAL-07, 200 g reference weight, tolerance ± 0.02 g

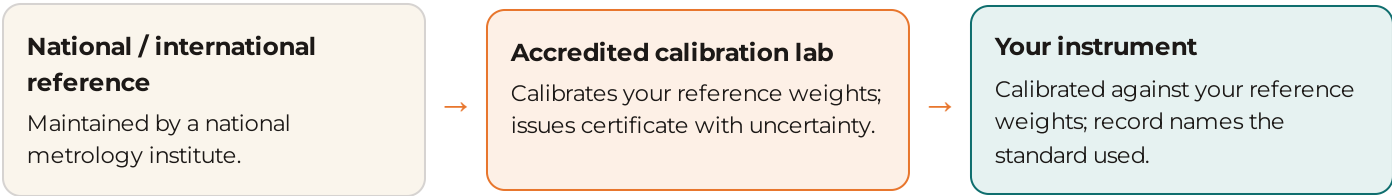
POINT	REFERENCE	AS-FOUND	ERROR	IN TOLERANCE?	AS-LEFT	ERROR
Low	50.0000 g	50.0060 g	+0.0060 g	Yes	50.0010 g	+0.0010 g
Mid	100.0000 g	100.0140 g	+0.0140 g	Yes	100.0020 g	+0.0020 g
High	200.0000 g	200.0310 g	+0.0310 g	No	200.0030 g	+0.0030 g

Error = reading – reference. The high point was outside ± 0.02 g before adjustment; after adjustment all points are within tolerance. The calibration passes as-left, but the as-found failure triggers an impact assessment (page 9).

1	Identify Instrument, standard used, environment	RECORDED Asset ID, standard ID, conditions	WHO DECIDES Technician
2	As-found Readings before any adjustment	RECORDED Value per point, error	WHO DECIDES Technician
3	Adjust Only if needed and allowed	RECORDED What was adjusted	WHO DECIDES Technician
4	As-left Readings after adjustment	RECORDED Value per point, error	WHO DECIDES Technician
5	Review Result against tolerance; certificate attached	RECORDED Reviewer, date, signature where required	WHO DECIDES Reviewer

Standards, certificates and traceability

A calibration is only as good as the standard it was compared with. That standard needs its own calibration, unbroken back to national or international references.



CERTIFICATE FIELD	CHECK
Issuing lab and accreditation	Accreditation scope covers the quantity and range
Instrument identity	Asset ID and serial match your register
Date and next due	Matches your interval, or note differences
As-found and as-left values	Both present where your procedure requires
Measurement uncertainty	Small enough relative to your tolerance
Standards used	Identified and themselves in calibration
Approval	Reviewed and accepted by your team before filing

Uncertainty matters. If the calibration uncertainty is a large fraction of your tolerance, a "pass" may not mean much. Many labs aim for a ratio of at least 4:1; agree your own rule.

Out of tolerance: a worked impact assessment

When as-found is out, ask: what did this instrument measure since we last knew it was good, and does the error matter for those results?

QUESTION	QC-BAL-07 ANSWER	WHO
Last good calibration	12 May (as-left in tolerance)	Record
Period at risk	12 May – 12 Nov	Record
Size and direction of error	+0.031 g at 200 g; ~+0.016% of reading	Technician
Was it used near the failing point?	Assay sample weights 150–200 g	Lab supervisor
Daily checks in the period	All within ± 0.02 g until 9 Nov; 9–12 Nov not recorded	Record
Results potentially affected	Assays on 6 lots, 9–12 Nov	Lab supervisor
Effect on results	Error small relative to assay limits; recalculation shows all 6 still within specification	Qualified reviewer
Decision	No product impact; document rationale; investigate missed daily checks	Quality — a person decides
Actions	Deviation for missed checks; retrain; review interval	Quality

What makes this defensible. The period at risk, the affected uses and the reasoning are recorded, with the person who decided.

No automatic disposition. Software can gather the facts; your quality team decides whether any product is affected.

Linking instruments to use

An impact assessment is fast only if you can find where the instrument was used. That depends on how readings are captured.

HOW READINGS REACH THE RECORD	CAN YOU FIND USES LATER?	ASK
Connected scale or instrument writes the value	Usually yes: device ID is on the record	Is the device ID stored with every reading?
Operator selects the instrument, types the value	Yes, if selection is required	Is instrument selection mandatory for that step?
Value typed with no instrument field	No — only by memory or logbook	Can we add an instrument field to the step?
Paper log scanned later	Partly; depends on review	Who checks the instrument ID during review?

What to see demonstrated

- Pick an instrument and a date range. List the jobs, lots or tests where it was used — or explain what the system records and what it doesn't.
- Show the instrument's calibration status at the time of a given reading.
- Open a lot record and see which instruments produced its key readings.

Be precise in the RFP. "Linked to use" means different things. Ask for a demonstration on your own instrument types, connected and manual.

Calibration, maintenance and OEE

They share an asset register but answer different questions. Keep the records separate and the links visible.

Calibration Is the measurement correct? Compared with a traceable standard; as-found and as-left recorded.	Preventive maintenance Is the equipment in good condition? Scheduled tasks, parts and service history.	OEE and downtime Is the equipment performing? Availability, performance and quality losses with reasons.
EVENT	CALIBRATION CONSEQUENCE	EXAMPLE
Repair to a measuring part	Recalibrate before use	Load cell replaced on floor scale
Relocation	Check or recalibrate per procedure	Balance moved between labs
Software or firmware change	Assess; may need verification	Instrument firmware update
Repeated downtime on a device	Review as-found history	Checkweigher stopping on drift
PM task includes a check	Record check separately from calibration	Daily verification during PM round
Don't conflate. A maintenance work order closed as "serviced" is not a calibration record. Ask how the system distinguishes them and links one to the other.		

Roles, evidence and change control

ACTIVITY	QUALITY	METROLOGY / LAB	MAINTENANCE	AREA OWNER	USERS
Define tolerance and criticality	A	R	C	C	I
Set and change intervals	A	R	C	I	—
Schedule calibrations	I	R	C	A	—
Perform and record	—	R	R (if internal)	I	—
Review certificates	A	R	—	I	—
Assess out-of-tolerance impact	A	R	C	C	I
Remove from service	A	R	R	I	I
Daily checks	I	C	—	A	R

Evidence to keep

CHECK	WHAT GOOD LOOKS LIKE	OK
Audit trail	Who created or changed each record, when, old and new values.	☐
Signatures	Review and approval signatures with meaning, where your regulations require.	☐
Change history	Tolerance, interval and criticality changes with reason and approver.	☐
Retention	Records kept for your required period, including retired instruments.	☐

11 • IMPLEMENTATION

Migration and implementation

STEP	WHAT TO DO	DONE WHEN
1 • Inventory	Walk the site; tag every instrument; reconcile with your spreadsheet	Every physical instrument has one register entry
2 • Classify	Set criticality, tolerance and interval with rationale	Each instrument has a reviewed tolerance
3 • Load history	Last calibration date, result and certificate for each	Status correct on day one
4 • Standards	Register reference weights and standards with certificates	Every calibration names its standard
5 • Capture at use	Decide where instrument ID is recorded on steps and tests	Uses can be found for high-criticality instruments
6 • Procedures	Update calibration and out-of-tolerance procedures to match the system	Users trained on the new procedure
7 • Verify	Replay a past out-of-tolerance in the new system	Impact assessment completed end to end

Migration responsibilities

- **You** decide which history to migrate and verify it; keep legacy certificates accessible.
- **You** validate the system for intended use where your regulations require it. Ask what documentation and services the supplier provides, and in which plan.
- **Start** with high-criticality instruments; add the rest once the flow works.

RFP questions and scored checklist

Register and plan

- Which register fields are standard; which configurable?
- How are due, overdue and out-of-service shown to users?
- What, exactly, happens when someone selects an overdue instrument?

Recording

- Can as-found and as-left be recorded per point, with error calculated?
- How are certificates attached and reviewed?

Impact

- From an out-of-tolerance result, how do we find uses since last good calibration?
- How is the impact decision recorded and signed?

Assets

- How are calibration and maintenance records separated and linked?
- Which plan includes calibration, maintenance and OEE?

AREA	WHAT TO SEE DEMONSTRATED	SYSTEM A	SYSTEM B
Register	Our instrument with usage range, tolerance and criticality.	_____	_____
Status	Due/overdue shown where it is used.	_____	_____
As-found / as-left	Worked example on page 7 recorded with errors.	_____	_____
Certificates	Attached, reviewed, standard identified.	_____	_____
Impact	Page-9 assessment completed and signed.	_____	_____
Use links	Uses of one instrument listed for a date range.	_____	_____
Maintenance link	Repair triggers recalibration visibly.	_____	_____
Audit trail	Tolerance change shown with reason and approver.	_____	_____
Total (0–3 each)		_____	_____

Where V5 fits, plans and sources

- **Calibration (every plan):** instrument register with schedules and tolerances, due list, calibration records and certificates. As-found and as-left are recorded where your set-up keeps those fields.
- **Impact:** out-of-tolerance results are reviewed by a person, who assesses impact; deviation management for that review is Professional and Enterprise.
- **Signatures:** electronic signatures with meaning are Professional and Enterprise.
- **Assets:** maintenance, downtime and OEE are Professional and Enterprise, alongside the same asset register.
- **Confirm in evaluation:** what is shown or prevented when an overdue instrument is selected, which steps record instrument IDs, and certificate fields for your set-up. V5 does not decide product disposition.

Primary sources for context; applicability depends on your sector and markets. Links reviewed 1 October 2026.

Law and regulation (where they apply to you)

- **US 21 CFR 211.68 and 211.160 — equipment and laboratory controls (pharmaceuticals)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211
- **US 21 CFR Part 820 — Quality Management System Regulation (devices)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820
- **US 21 CFR Part 117 — food CGMP (incl. 117.165 verification, calibration)** — www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117
- **US 21 CFR Part 11 — electronic records and signatures** — www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11

Guidance

- **EudraLex Volume 4 — EU GMP Ch. 3 premises and equipment, Annex 15** — health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en
- **NIST — Metrological traceability policy** — www.nist.gov/calibrations/traceability

Voluntary standards (certification is your choice)

- **ISO/IEC 17025:2017 Testing and calibration laboratories** — www.iso.org/standard/66912.html
- **ISO 10012:2003 Measurement management systems** — www.iso.org/standard/26033.html
- **ISO 9001:2015 clause 7.1.5 Monitoring and measuring resources** — www.iso.org/standard/62085.html

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