



THE REFERENCE MATERIAL & ANALYTICAL STANDARD PRODUCTION GUIDE

Every gram weighed. Every certificate reviewed.

ISO 17034 production records in practice, from neat material to customer

A practical evaluation guide for teams that produce reference materials, certified reference materials and analytical standards: what the production record should hold at each step, where specialist metrology stays with your people and tools, and what to ask any software before you rely on it.



ISO 17034

ISO 33401 / 33405

PEOPLE SIGN CERTIFICATES

International edition / October 2026

v5ultimate.com

Scope: practical orientation, not accreditation advice. Photos are staged; lots, values and results are worked examples.

INSIDE THE GUIDE

One lot, neat material to customer.

A reference material is only as good as the evidence behind its values. This guide follows one solution standard lot and shows which records each stage should produce, and who makes each decision.

01 / FRAME

pp. 03–04

What you make, which standards

RM, CRM, analytical standard and QC material; ISO 17034, ISO 33401, ISO 33405 and accreditation.

02 / PREPARE

pp. 05–07

Materials, weighing, units

Starting-material evidence, gravimetric preparation, balance status and unit numbering.

03 / STUDY

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Homogeneity, value, stability

Study plans and results, value assignment and uncertainty kept with your tools.

04 / CERTIFY

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Certificate, label, decision

Certificate and label content, and the named person who approves release.

05 / SUSTAIN

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Monitor, trace, improve

Post-certification monitoring, customer trace, complaints and software records.

06 / APPLY

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V5 fit, worksheets, sources

Where V5 fits and does not, two worksheets, a four-week evaluation and ten sources.

Who it is for. Quality managers, production and preparation leads, metrologists and laboratory leads, and anyone choosing a production and quality system for a reference material or standards operation.

How to read it. Operational pages end with a teal Where V5 fits panel. ISO standards are purchased documents; this guide paraphrases their scope and clause topics and never quotes them. Check your own copies.

THREE TAKEAWAYS

01 Hold every starting material until a named person accepts its evidence.

02 Keep each weight, unit range and study result with the lot it supports.

03 Certified values, uncertainty and release stay with your people and methods.

WHERE V5 FITS

V5 records receiving, preparation, filling, testing, certificate approval, labeling and customer shipments. It does not certify materials, assign certified values, calculate measurement uncertainty or traceability, or confer accreditation. Those stay with your people, methods and accreditation body.

FRAME / 01

Name what you make before you record it.

Reference materials, certified reference materials, analytical standards and in-house QC materials differ in what the producer states and must evidence. The record you need follows from the claim on the certificate.



- Reference material (RM)**
Sufficiently homogeneous and stable for one or more specified properties, fit for its intended use in measurement (VIM, paraphrased) [6].
- Certified reference material (CRM)**
An RM with certified values accompanied by an uncertainty and a statement of metrological traceability, issued under a valid procedure [6].

PRODUCT	WHAT THE PRODUCER STATES	TYPICAL FRAMEWORK
Certified reference material	Certified value, uncertainty, traceability	ISO 17034 + ISO 33401
Reference material (non-certified)	Property of interest, homogeneity, stability	ISO 17034 + ISO 33401
Analytical standard (catalogue)	Depends on claim: check what the label says	Your product claims
In-house QC material	Fitness for your own control use	ISO/TR 33402 practice

The claim sets the record
A certified value needs characterization, uncertainty and traceability evidence; a catalogue standard may claim only identity and nominal concentration.

Property of interest
ISO 33401 asks that the property of interest be stated for every RM, because an RM works only for properties assessed for homogeneity and stability [2][4].

Accreditation is separate
An accreditation body assesses a producer against ISO 17034. Software does not make a producer competent or accredited [1].

WHERE V5 FITS
V5 product master data can carry the product type, property of interest and intended use, so the right preparation, study plan and certificate template follow. V5 does not decide what you may claim.

FRAME / 02

The standards that shape the record.

ISO/TC 334 turned the former ISO Guides into international standards in 2024, alongside ISO 17034. Each covers a different part of the producer's work [4].

ISO 17034:2016	Competence and consistent operation of RM producers; covers all RMs, with added requirements for CRMs. A new edition is under development [9]	Producer
ISO 33401:2024	Contents of certificates, product information sheets and labels (formerly ISO Guide 31)	Certificate
ISO 33405:2024	Characterization, homogeneity, stability, uncertainty of certified values, traceability (formerly ISO Guide 35)	Studies
ISO 33403:2024	Requirements and recommendations for RM use (formerly ISO Guide 33)	Users
ISO/TR 33402	Good practice in RM preparation; replaced ISO Guide 80 for in-house QC materials	Preparation
ISO/IEC 17025:2017	Competence of testing and calibration labs; often applies to the labs that characterize	Labs
ILAC P10	Accreditation policy on metrological traceability of measurement results	Traceability
VIM and GUM	Free JCGM vocabulary of metrology and guide to expressing uncertainty	Vocabulary

Paraphrased, not quoted. ISO standards are sold by ISO and national bodies; this guide describes their scope from ISO's public abstracts. Your quality manual, not this guide, is the reference for how you meet them [1][2][3][5].

WHERE V5 FITS

V5 keeps procedures, methods and specifications as controlled documents with revision history, and links each lot record to the revisions it used. V5 does not interpret ISO requirements or make a management system conform.

PREPARE / 01

Starting materials, held until accepted.

Neat analytes, solvents, matrices and containers carry evidence the final value depends on: identity, purity or composition, and the supplier's documentation. ISO 17034 expects producers to control purchased materials and services [1].

MATERIAL LOT (WORKED EXAMPLE)	EVIDENCE	ISSUE TO PREPARATION?
Neat analyte NA-551	Identity confirmed; purity per supplier certificate reviewed	YES
Solvent SV-1180	Grade and lot accepted	YES
Ampoules AM-3012	Cleaned lot; inspection recorded	YES
Solvent SV-1192	Identity test awaited	HOLD
Neat analyte NA-560	Certificate does not match specification	NO

Purity is an input

For a gravimetric standard the neat material's purity value and its uncertainty feed the final value. Record which purity value, from which certificate or in-house assignment, was used.

Supplier evidence

Review supplier certificates against your specification, and decide whether identity or purity must be confirmed in house. Record the decision per lot.

Storage from day one

Capture storage conditions, retest or expiry dates and container details at receipt, because stability and labels depend on them.

PRACTICE: KEEP THE CERTIFICATE WITH THE LOT

Attach the supplier's certificate to the material lot, not to a shared folder. When an auditor asks which purity value a standard used, the answer should be one click from the lot.

WHERE V5 FITS

V5 receiving records supplier and internal lots, holds each lot as pending until released, attaches supplier certificates and issues only released lots. AI certificate extraction can draft values from supplier PDFs for a person to check. Acceptance criteria stay yours.

PREPARE / 02

Prepare by weight, record the balance.

Many solution standards are prepared gravimetrically: masses of analyte and solvent determine the nominal concentration. The record must show which balance, its status on the day, and every weight as read.

STEP (WORKED EXAMPLE, RM-2207)	TARGET	ACTUAL	TOLERANCE	IN LIMIT?
Neat analyte NA-551	100.00 mg	100.12 mg	±0.50 mg	YES
Solvent SV-1180 (to mass)	998.0 g	998.3 g	±1.0 g	YES
Balance AB-02 daily check	100 g check weight	100.0002 g	Your limit	YES
Balance AB-05 (micro)	Calibration due	Expired 2026-09-30	Blocked	NO

WORKED EXAMPLE: THE WRONG BALANCE

The analyst picks up micro-balance AB-05 for the neat addition. Its calibration expired the day before, so the weighing step does not accept it. The analyst moves to AB-02, which passed its daily check that morning, and the record shows both the attempt and the balance actually used.

Readings, not retyping

Capture weights from the connected balance where possible; where a value is typed, record who and why, as your procedure requires.

Corrections stay yours

Air buoyancy correction, purity correction and the concentration calculation belong to your validated method and tool. Record the inputs and the result.

Version the preparation

The preparation procedure is a controlled document; the lot record shows which revision was followed.

WHERE V5 FITS

V5 weigh and dispense steps check the scanned lot and the balance, read connected scales, flag out-of-limit entries and can gate devices whose calibration is out of date. V5 does not calculate certified concentrations, buoyancy corrections or uncertainty.

PREPARE / 03

Number every unit, account for every one.

A lot becomes hundreds or thousands of ampoules or vials. Homogeneity sampling, stability pulls, customer shipments and any later notice all depend on knowing which units exist and where they went.

UNITS (LOT RM-2207)	COUNT	NOTES
Filled	1,200	RM-2207-0001 to -1200
Rejected at inspection	14	Fill height, seal defect; reasons recorded
Homogeneity samples	10	Drawn per your plan across the fill
Stability reserve	60	Held for the monitoring schedule
Available for release	1,116	Pending certificate approval



WHERE V5 FITS

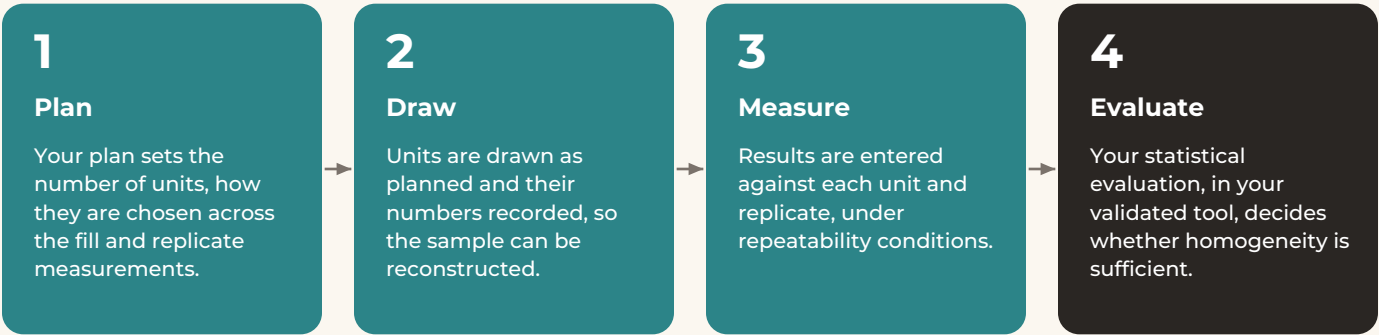
V5 records fill and inspection steps, counts filled, rejected, sampled and released units per lot and keeps unit ranges with the lot. Your sampling plan decides which units are drawn for studies; V5 records the selection and the results.

Sources: [1], [3] (linked on pages 21–22)

STUDY / 01

Show the lot is homogeneous enough.

ISO 33405 describes approaches to assessing between-unit and, where relevant, within-unit homogeneity, including designs that draw on prior experience. The producer chooses the design; the record must show what was done [3].



RECORD FIELD	WORKED EXAMPLE
Units drawn	0007, 0131, 0249, 0377, 0498, 0612, 0745, 0861, 0990, 1188
Replicates per unit	3, run in random order
Method	Method A, revision 6
Results	Entered for all 30 measurements
Evaluation	Performed in your validated tool; result attached
Decision	Recorded by the metrologist

WHERE V5 FITS

V5 laboratory sample plans can carry your homogeneity design, record which units were drawn and the results against each, and attach your evaluation. V5 does not perform ANOVA or decide whether between-unit variation is acceptable.

Sources: [3] (linked on pages 21–22)

STUDY / 02

Assign the value with your own method.

ISO 33405 describes several characterization approaches: a single method in one laboratory, several methods, or an interlaboratory study, each with its own evidence. The certified value and its uncertainty come from your evaluation [3].



- Approach on record**
Record which approach was used and why; for example, whether a CRM of the same kind was available to validate a single method.
- Results with context**
Keep each result with its method revision, instrument, calibration status and analyst, so the value can be reconstructed.
- Uncertainty is yours**
The uncertainty budget combines characterization, homogeneity and stability contributions. It is built in your validated tool.

INPUT (WORKED EXAMPLE)	HOW IT REACHES THE RECORD	CALCULATED IN
Gravimetric value	From preparation record	Your tool
Method A result	Entered by lab	Your tool
Method B result	Entered by lab	Your tool
Certified value and expanded uncertainty	Entered by metrologist	Your tool
Traceability statement	Written by your team	Your procedure

WHERE V5 FITS
V5 keeps characterization results with method revisions, instruments and analysts, and stores the certified value and uncertainty your metrologist enters. V5 does not combine uncertainty components, establish metrological traceability or choose the certified value.

STUDY / 03

Stability before and after release.

ISO 33405 covers short-term stability for transport conditions, long-term stability for storage, and greater attention to post-certification monitoring. Each pull and result belongs with the lot it supports [3].

STUDY (WORKED EXAMPLE)	SCHEDULE	STATUS	CURRENT?
Transport study, elevated temperature	Weeks 0, 1, 2, 4	Complete	YES
Long-term, stated storage	Months 0, 6, 12, 24	Month 6 done	PENDING
Post-certification monitoring	Every 12 months	Scheduled	PENDING
Customer repeated-use note	From your study	On certificate	YES

Transport conditions

Short-term data support the shipping conditions you choose. Record the conditions studied, not only the result.

Validity period

Long-term data support the period of validity stated on the certificate; monitoring confirms it while units are in the field.

Opened units

Where users take repeated portions from one unit, ISO 33405 now gives guidance for user storage and repeated sampling [3].

SCHEDULES, NOT REMINDERS

A stability pull that is missed is evidence that is missing. Keep the schedule in the system that holds the lot, so a late pull is visible to quality, not only to the analyst.

WHERE V5 FITS

V5 stability management schedules pulls, records results against your specification and escalates out-of-specification results. Study design, trend evaluation and the validity period you state are decided by your team.

CERTIFY / 01

What the certificate and label must carry.

ISO 33401 lists mandatory, recommended and optional content for RM certificates and product information sheets, and minimum content for the label on each unit. Here are its topics in plain words [2].

CERTIFICATE TOPIC (PARAPHRASED)	SOURCE IN V5	WHO DECIDES
Producer and document identity	Template	Your team
Material name, lot and description	Lot record	Your team
Property of interest and intended use	Product master	Your team
Certified or indicative values with uncertainty	Entered values	Your metrologist
Metrological traceability statement	Entered text	Your metrologist
Instructions for storage, handling and use	Product master	Your team
Period of validity or expiry	Lot record	Your team
Approval by a named person	E-signature	Your reviewer

Every part identified

ISO 33401 no longer needs page numbers but expects each part of a document to be identifiable as part of the whole, which suits digital certificates [4].

Label minimum

Each unit's label carries at least the information that links it to its certificate, such as name, lot and producer; check the standard for the full list [2].

WHERE V5 FITS

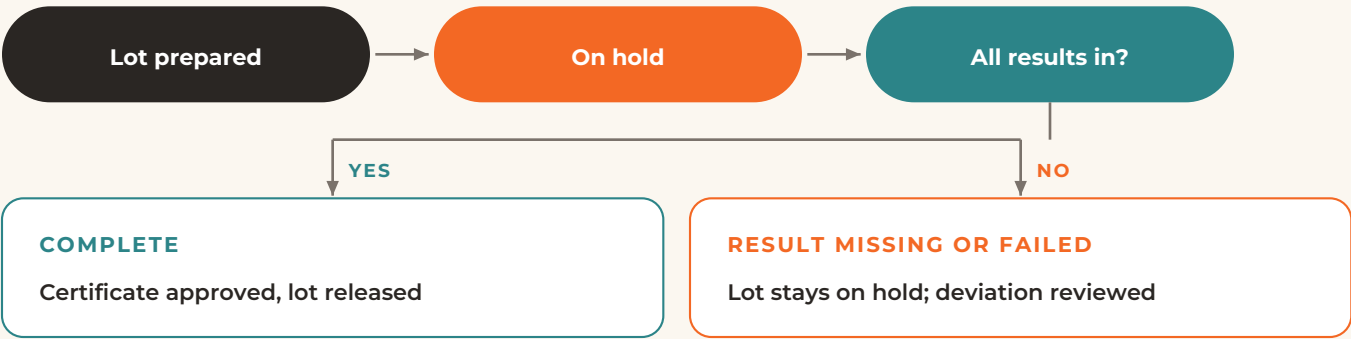
V5 prints certificates and labels from your approved templates, using the lot record and the values your people enter, and keeps a revision history of every certificate issued. V5 does not write traceability statements or decide which values are certified.

Sources: [2], [4] (linked on pages 21–22)

CERTIFY / 02

Approve the certificate, then release.

ISO 17034 expects the producer to authorize the release of an RM and its documents. Make that a recorded decision by a named person, made with every planned result in view [1].



WHAT THE REVIEWER SEES IN ONE PLACE

Inputs

Released starting materials, preparation weights, balances and their calibration status.

Studies

Homogeneity, characterization and stability results, with any pending result shown as pending.

Documents

Certificate values entered by the metrologist, label check and unit reconciliation.

Separate the roles. Many producers keep the person who prepares the certificate distinct from the person who approves it. Your procedure decides; the record should show both names.

WHERE V5 FITS

V5's QC release queue shows each lot's results, deviations and reconciliation in one view, and a named reviewer records the decision with an electronic signature. V5 never approves a certificate or releases a lot automatically.

Sources: [1] (linked on pages 21–22)

SUSTAIN / 01

When a monitoring result moves.

A worked example. Twelve months after release, a monitoring result for lot RM-2207 trends towards the edge of its certified range. The question is how fast you can decide and reach every holder.

Result entered	Month 12 monitoring result recorded against the lot
Out of trend	Escalated by your configured rule; deviation DV-3105 opened
Investigate	Re-test retained units; review storage and method records
Decide	Your metrologist decides: confirm, revise validity or withdraw
Notify	Customers holding RM-2207 units listed from shipment records

Revised certificates are new documents. If a value or validity period changes, issue a revised certificate that identifies what changed and keep the earlier version on record, so customers can match results to the certificate they used [2].

WHERE V5 FITS

V5 escalates out-of-specification results, links deviations and CAPA to the lot, keeps every certificate revision, and lists customers who received units of a lot. Whether to revise, withdraw or notify is your decision.

Sources: [2], [3] (linked on pages 21–22)

From one neat lot to every customer.

If a starting material is questioned, the first job is to find every lot made from it and every customer who holds units. Unit ranges make that answer precise.

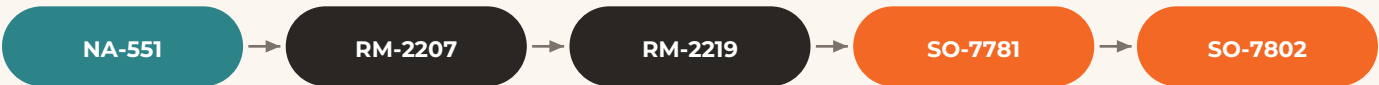


Trace forward

From neat analyte NA-551: lots RM-2207 and RM-2219, their unit ranges, orders and customers, with dates.

Trace back

From a customer's unit number to its lot, preparation, starting materials and the certificate revision they received.



WORKED EXAMPLE: ONE NEAT LOT, TWO STANDARD LOTS, TWO ORDERS

LOT	UNITS SHIPPED	ORDER	CUSTOMER
RM-2207	Units 0001-0240	SO-7781	Laboratory A, 240 units
RM-2219	Units 0001-0060	SO-7802	Laboratory C, 60 units
In stock	876 + 1,104 units	None	Held; can be blocked at once

WHERE V5 FITS

V5 traces from a starting-material lot to finished lots, orders and customers and back, and the customer portal can give customers their certificates where enabled. Notices and their content stay with your people.

Sources: [1] (linked on pages 21–22)

SUSTAIN / 03

Complaints, nonconforming work and corrective action.

ISO 17034, like ISO/IEC 17025, expects a producer to handle complaints, control nonconforming work and take corrective action, with records. These are management system requirements, paraphrased here [1][5].

01**Complaint received**

Record the customer, unit number, lot and what they observed, and acknowledge it as your procedure requires.

02**Is the work nonconforming?**

Decide whether the lot, a study or a document departs from requirements, and the effect on issued certificates.

03**Contain**

Hold remaining units, stop shipments and, where needed, inform affected customers.

04**Correct and prevent**

Find the cause, act on it and check the action worked; link it all to the lot.

Look for patterns. One complaint about a unit may be handling; three about one lot is a signal. Keep complaints linked to lots so trends are visible without a spreadsheet.

WHERE V5 FITS

V5 records complaints against lots and unit numbers, routes investigations, holds stock and tracks CAPA to verified closure. Whether work is nonconforming and what customers are told stays with your people.

Sources: [1], [5] (linked on pages 21–22)

SUSTAIN / 04

Your software holds the evidence.

ISO 17034 and ISO/IEC 17025 expect control of records and of the data and software used to produce results. Customers in regulated industries may also ask how your electronic records and signatures are controlled [1][5][10].

01 Define intended use
What each system does in your process: preparation records, results, certificates, or calculations.

02 Validate calculations
Spreadsheets and tools that compute values and uncertainty need their own validation, separate from the production record.

03 Control changes
Assess each change, including supplier releases, and revalidate as needed.

04 Keep records retrievable
Lot records, certificates and their revisions stay readable for as long as your procedures require.

WHO DOES WHAT

You, the producer, decide the intended use, validate the system for it, including performance qualification, and decide when a change needs revalidation. **A supplier** can provide documentation and, where agreed, installation and operational qualification support. In V5's case, IQ/OQ and validation support are part of the Enterprise plan, scoped in the accepted quote or statement of work.

WHERE V5 FITS

V5 keeps an audit trail of record and configuration changes and releases software in versions. It is not validated for your use until you validate it, and it does not replace the validated tools you use for value assignment and uncertainty.

Sources: [1], [5], [10] (linked on pages 21–22)

APPLY / 01

Where V5 fits, and where it does not.

A plain map from each stage to the V5 capability that keeps its record, and the decision that stays with you. Capabilities are from the V5 product reference reviewed 1 October 2026 and depend on plan and configuration.

STAGE	V5 KEEPS THE RECORD	YOUR PEOPLE DECIDE
Starting materials	Receiving, lot status, certificates	Acceptance, purity value
Gravimetric preparation	Weigh steps, connected balances	Concentration, corrections
Balances and instruments	Calibration records, gating	Calibration intervals
Fill and units	Counts, unit ranges, rejects	Sampling plans
Homogeneity	Sample plans, results, attachments	Statistics, acceptance
Characterization	Results with method and instrument	Value, uncertainty
Stability	Schedules, results, escalation	Study design, validity
Certificate	Templates, revisions, e-signature	Content, approval
Customers	Orders, unit trace, portal	Notices
Complaints	Records, CAPA, holds	Nonconformity decisions
Software	Versioned releases, audit trail	Validation, incl. PQ

Not offered: certification of materials, value assignment, uncertainty or traceability calculations, homogeneity statistics, or accreditation. If you need a specialist calculation inside the system, ask for it to be confirmed in scope before you buy. **Coming soon:** AI forecasting and process anomaly detection. **Plan-dependent:** IQ/OQ and validation support are Enterprise only.

WHERE V5 FITS

Nothing in V5 certifies a material, assigns a value, approves a certificate or releases a lot. It keeps the evidence connected so the qualified people who make those decisions can see it.

WORKSHEET 01

Certificate readiness for one lot.

Use with a real (or test) lot record. Tick what the record shows today without asking anyone.

	SHOWN	PARTLY	NOT SHOWN
Starting materials released Each lot accepted, with its certificate attached	☐	☐	☐
Purity value source Which purity value and uncertainty was used, and from where	☐	☐	☐
Preparation weights Every weight, balance and calibration status recorded	☐	☐	☐
Unit reconciliation Filled, rejected, sampled, reserved and available accounted	☐	☐	☐
Homogeneity Units drawn, results and your evaluation attached	☐	☐	☐
Characterization Results with method revision, instrument and analyst	☐	☐	☐
Stability Transport and long-term data supporting stated validity	☐	☐	☐
Certificate values Value, uncertainty and traceability entered by a named person	☐	☐	☐
Approval Who approved, when, with what evidence	☐	☐	☐
Customers Shipments linked to lots and unit ranges	☐	☐	☐

NOTES AND OWNERS

WORKSHEET 02

Questions for any software demo.

Ask the vendor to show, not tell, using test data. Record what you saw.

	SHOWN	PARTLY	NOT SHOWN
Pending material Try to issue a starting material awaiting identity testing.	☐	☐	☐
Expired calibration Try to weigh on a balance whose calibration has lapsed.	☐	☐	☐
Out of tolerance Enter a weight outside tolerance; show the hold.	☐	☐	☐
Unit ranges Show filled, rejected and sampled units for one lot.	☐	☐	☐
Missing result Try to approve a certificate with a result pending.	☐	☐	☐
Certificate revision Revise a certificate; show both versions on record.	☐	☐	☐
Trace From one neat lot, list lots, orders and customers, timed.	☐	☐	☐
Calibration look-back Fail a balance calibration; list lots prepared on it.	☐	☐	☐
Customer access Show what a customer sees for their certificates.	☐	☐	☐
Audit trail Show who changed a value, when and why.	☐	☐	☐

NOTES AND OWNERS

APPLY / 02

A fair evaluation in four weeks.

A practical way to test any system with your own people and one real product, without touching live records.

WEEK 1

Agree one product and the five questions that matter most. Load its preparation, methods, specs and certificate template.

WEEK 2

Run a lot end to end with test data: receipt, weighing, fill, studies, certificate review, labels and an order.

WEEK 3

Break it on purpose: pending material, lapsed balance, out-of-tolerance weight, missing result, revised certificate.

WEEK 4

Run a timed customer trace from one neat lot. Review with quality, lab, production and IT; plan validation.

Rules for the evaluation. Use test data only. Keep your validated calculation tools and current records live until a validated change is approved. Record what was shown, not what was promised.

ASK V5

“We produce [certified reference materials / analytical standards] in [number] product lines. Our hardest moment is [e.g. certificate review]. Which workflows should we evaluate first?”

Start a 7-day free trial, no card required, or ask V5 on v5ultimate.com.

WHERE V5 FITS

Try V5 with your own product in a trial workspace using test data. The assistant answers questions about features and plans; it does not give accreditation or metrology advice.

SOURCES

Keep the evidence close.

Sources behind this guide, checked 3 October 2026. Click a title to open the publisher's page.

- | | | |
|-----|---|------------------------------------|
| [1] | <u>ISO 17034:2016 Competence of reference material producers</u> | INTERNATIONAL STANDARD (PURCHASED) |
| | https://www.iso.org/standard/29357.html | |
| [2] | <u>ISO 33401:2024 Certificates, labels and accompanying documents</u> | INTERNATIONAL STANDARD (PURCHASED) |
| | https://www.iso.org/standard/84222.html | |
| [3] | <u>ISO 33405:2024 Characterization, homogeneity and stability</u> | INTERNATIONAL STANDARD (PURCHASED) |
| | https://www.iso.org/standard/84226.html | |
| [4] | <u>ISO/TC 334 published reference material standards</u> | ISO COMMITTEE INFORMATION |
| | https://committee.iso.org/sites/tc334/home/projects/published/overview---publis... | |
| [5] | <u>ISO/IEC 17025:2017 Competence of testing and calibration labs</u> | INTERNATIONAL STANDARD (PURCHASED) |
| | https://www.iso.org/standard/66912.html | |
| [6] | <u>JCGM publications: International vocabulary of metrology (VIM) and the GUM</u> | FREE INTERNATIONAL GUIDANCE |
| | https://www.bipm.org/en/committees/jc/jcgm/publications | |
| [7] | <u>ILAC policy series, including ILAC P10 on metrological traceability</u> | ACCREDITATION POLICY |
| | https://ilac.org/publications-and-resources/ilac-policy-series/ | |
| [8] | <u>NIST Standard Reference Materials programme</u> | NATIONAL METROLOGY INFORMATION |
| | https://www.nist.gov/srm | |

SOURCES

Sources, continued.

[9] [ISO 17034 revision project \(new edition under development\)](https://www.iso.org/standard/93583.html)

[ISO PROJECT PAGE](#)

<https://www.iso.org/standard/93583.html>

[10] [U.S. eCFR, 21 CFR Part 11: electronic records and electronic signatures](https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11)

[BINDING U.S. REGULATION](#)

<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-11>

How to read the status labels. ISO standards are purchased documents and are paraphrased here from ISO's public abstracts, never quoted. JCGM documents are free. Accreditation policy applies through your accreditation body. Part 11 applies only where U.S. FDA record requirements reach your records or your customers' use of them.

SCOPE AND LIMITS

This guide is practical orientation for evaluating reference material and analytical standard production operations and software. It is not accreditation, metrology or legal advice and does not list every requirement that applies to you. Standards were checked against ISO's public pages on 3 October 2026; a new edition of ISO 17034 is under development, so confirm the current editions before relying on them. V5 capability statements reflect the V5 product reference reviewed on 1 October 2026 and depend on plan, configuration, devices and permissions. AI forecasting and anomaly detection are coming soon. V5 does not certify materials, assign certified values, calculate measurement uncertainty or metrological traceability, perform homogeneity statistics, approve certificates or confer accreditation; it is not validated for your use until you validate it. Photography is illustrative; lots, values and results are worked examples, not customer data.



Every gram weighed. Every certificate reviewed.

[See reference material workflows at v5ultimate.com](https://v5ultimate.com) · International edition · October 2026