GUIDE

Read Me First - How to Use and Customise This Pack

GD-01 | Revision 1.0 | [LABORATORY NAME]

Document ID	GD-01
Document type	Guide
Organisation	[LABORATORY NAME] (replace with the legal name of the laboratory)
Revision	1.0
Status	TEMPLATE - customise before use
Effective date	[EFFECTIVE DATE]
Next review due	[REVIEW DATE] (default: 24 months from effective date, or sooner on change)
ISO/IEC 17025:2017 clauses addressed	See references section
Prepared by	[NAME, ROLE] Signature: _____ Date: _____
Reviewed by	[QUALITY MANAGER] Signature: _____ Date: _____
Approved by	[TOP MANAGEMENT / LABORATORY MANAGER] Signature: _____ Date: _____

Revision history

Rev	Date	Description of change	Author	Approved
1.0	[DATE]	Initial issue of the ValiTrac template (pack v2.0).	ValiTrac	

NOTE This document is an original template published by ValiTrac (valitrac.com) to help laboratories prepare for ISO/IEC 17025:2017 accreditation (for example by UKAS). It must be customised, technically reviewed and formally approved by the adopting laboratory before use. It does not reproduce the text of ISO/IEC 17025 or any UKAS publication, and it does not by itself confer or guarantee accreditation.

Contents

1. What this pack is

The ValiTrac ISO/IEC 17025:2017 Laboratory Documentation Pack (version 2.0, 2026-09-13) is a complete, integrated set of management system documents for a calibration laboratory preparing for accreditation to ISO/IEC 17025:2017 by UKAS or another ILAC MRA signatory accreditation body. It contains a Quality Manual, 33 procedures, 50 forms, 6 checklists, 6 guides, an uncertainty calculator workbook and a GMP validation and thermal mapping set (10 protocols and 10 forms). Every document uses the same identifiers, cross-references and terminology, so that the system reads as one system rather than a collection of templates.

The pack was written by ValiTrac (valitrac.com) as an original work. It does not reproduce the text of ISO/IEC 17025, UKAS publications, ILAC or EURAMET documents; it describes, in a laboratory's own words, how those requirements can be met. Laboratories must obtain the standard and the applicable accreditation-body publications themselves and verify the current editions.

IMPORTANT The pack is a starting point, not a finished management system. Accreditation is granted for what a laboratory actually does and can evidence, not for what its documents say. Every document must be customised to the Laboratory's real organisation, equipment, methods and scope, technically reviewed, approved, implemented and then operated long enough to generate records before an assessment.

2. Contents of the pack

Folder	Content	Documents
00-Start-Here	Start here	6
01-Quality-Manual	Quality manual	1
02-Procedures	Procedures	33
03-Forms	Forms and records	50
06-Checklists	Checklists	6
05-Validation/Protocols	Validation protocols	10
05-Validation/Forms	Validation forms	10
04-Uncertainty-Calculator	Excel workbook (GUM / M3003 budgets, decision rules, k-factor tables)	1

The full list with titles and clause references is GD-04 Master Document List; the mapping from every clause of the standard to the documents that address it is GD-03.

3. Document hierarchy and identifiers

Prefix	Type	Approval	Purpose
QM	Quality Manual	Top management	Policy and system description clause by clause
GD	Guides and policy statements	Top management / Quality Manager	Implementation guidance, matrices, policy
SOP	Procedures (management SOP-01 to 20 and 27 to 33; calibration SOP-21 to 26)	Quality Manager and Technical Manager	How each process is carried out

Prefix	Type	Approval	Purpose
FRM	Forms	Quality Manager	Templates that become records when completed
CHK	Checklists	Quality Manager	Self-assessment and review gates
VAL-P / VAL-F	Validation protocols and forms	Technical Manager / QA	GMP qualification and thermal mapping

4. Customising the documents

4.1 Find-and-replace tokens

Every document contains square-bracket tokens that must be replaced before approval. Use Word's Find and Replace (Ctrl+H) across each file, or a batch replace tool across the folder. The tokens are:

Token	Replace with
[LABORATORY NAME]	The legal name of the laboratory as it will appear on the certificate of accreditation
[ADDRESS]	The permanent facility address
[EFFECTIVE DATE]	The date the document takes effect (after training)
[REVIEW DATE]	The next review date (default 24 months)
[NAME, ROLE], [QUALITY MANAGER], [TOP MANAGEMENT / LABORATORY MANAGER], [DATE]	The actual names and dates in the approval blocks
[PATH]	The location of the controlled document folder or document management system
Square-bracket ranges and values, e.g. [-40 degC to +250 degC], [10 %rh to 95 %rh], [1 mg to 50 kg]	The Laboratory's actual ranges and CMCs (delete disciplines not offered)
Square-bracket options, e.g. [calibration / testing / calibration and testing]	Choose one and delete the others
Numbers in square brackets, e.g. [five] supervised jobs, [90 days], [two] years	The Laboratory's chosen value (the defaults are reasonable practice)

4.2 Sections to delete or adapt

- Delete the calibration procedures (SOP-21 to SOP-26), worksheets (FRM-36 to FRM-41) and scope rows for disciplines the Laboratory does not offer; remove them from GD-04, GD-03, FRM-16 and FRM-44.
- If the Laboratory does not perform sampling, state 'not applicable' in QM-01 section 7.3 and retain SOP-14 uncontrolled.
- If the Laboratory does not perform on-site work, delete SOP-32 and FRM-47 and the on-site references.
- The 'Assessment readiness notes' at the end of each procedure are written for the Laboratory's benefit; they may be deleted from the controlled version or retained (assessors generally regard them favourably).
- Replace the example uncertainty budgets in SOP-21 to SOP-26 with the Laboratory's approved budgets (FRM-26) for its actual reference standards; the examples illustrate structure and typical magnitudes only.

- Replace the roles in the responsibilities tables with the Laboratory's actual titles if different; keep the separation of Technical Manager and Quality Manager functions (they may be the same person only in a very small laboratory, with the conflict documented in FRM-32 and a second person for review).
- The VAL series is aimed at laboratories and validation teams serving GMP / GDP customers; delete it if not relevant.

4.3 Format and document control

The headers and footers contain the document ID, revision, effective-date token and page X of Y fields; update the fields after editing (Ctrl+A, F9). Long documents contain a table of contents field that must be updated in the same way. Once approved, convert the master to PDF for distribution and keep the editable file in the restricted folder (SOP-01). The footer 'Template (c) ValiTrac' line may be removed from the Laboratory's controlled versions; ValiTrac grants adopting laboratories a licence to use and modify the pack for their own management system, but not to resell or redistribute it as a template.

5. Twelve-week implementation plan

The plan below assumes a laboratory with an existing technical capability but no formal ISO/IEC 17025 system. Laboratories with an ISO 9001 system can typically compress weeks 1 to 4. Record progress in the action plan of CHK-01.

Weeks	Activities	Outputs
1-2	Appoint Technical Manager and Quality Manager; top management briefing; complete CHK-01 gap analysis honestly; decide scope (GD-05 first draft); customise QM-01, GD-06, FRM-50, FRM-32, FRM-33	Gap analysis with action plan; draft scope; organisation and policy approved
3-4	Customise and approve management procedures SOP-01 to SOP-10, SOP-27, SOP-28; set up document control (FRM-01), records (FRM-03), risk register (FRM-10); start staff induction and declarations	Management system core approved and in use; register of documents
5-6	Customise technical procedures SOP-11 to SOP-20, SOP-29 to SOP-33; build equipment register and history cards; traceability records; supplier evaluations; send reference standards for calibration where needed	Equipment, traceability and supplier control operating
7-8	Customise calibration procedures SOP-21 to SOP-26 and worksheets; prepare uncertainty budgets (FRM-26) and CMCs; verify methods (FRM-23); validate the calculator and spreadsheets (FRM-49); set QC and intermediate check plans; register for PT	Verified methods with approved budgets; scope with supported CMCs
9-10	Train and assess engineers (FRM-14, FRM-15); authorise (FRM-16); run representative jobs end to end with contract review, worksheets, CHK-03 and certificates; start control charts	Authorised personnel; job files demonstrating the system in operation
11	Full internal audit of every clause and discipline (FRM-04 to FRM-06), including vertical and witness audits; raise and action corrective actions	Audit records with findings closed or in progress
12	Management review (FRM-07); finalise CHK-02; submit application to the accreditation body with the scope; continue generating records until the assessment	Management review minutes; application submitted

6. Using the pack with ValiTrac

The procedures reference the ValiTrac Uncertainty Calculator workbook as the validated calculation tool and CHK-04 / CHK-05 mirror the review gates in the ValiTrac mapping workflow. Laboratories using the ValiTrac platform can replace the paper worksheets with the platform's technical records while retaining the same procedure structure; the document identifiers in this pack are stable so that the platform's outputs can cite them.

7. Support and feedback

Questions about the pack, corrections and suggestions are welcome through valitrac.com/contact. The pack is revised periodically; the version and date appear in every footer. Check valitrac.com/resources/iso-17025-pack for the current version.