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ISO/IEC 17025:2017 • PRACTICAL GUIDE

Guide to Interlaboratory Comparison For ISO/IEC 17025

A practical alternative to proficiency testing: run the comparison, calculate the E_n number, and package the evidence your assessor expects.

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About This Guide

This guide shows you how to verify a testing or calibration method through an interlaboratory comparison when proficiency testing is not an option, and how to document the result so an assessor accepts it without follow-up questions.

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How to Use This Guide

- Read the early sections to understand what the standard asks for and how the E_n number decides pass or fail.
- Follow the seven-step framework to run your own comparison.
- Use the worked examples as models for a calibration laboratory and a testing laboratory.
- Work through the checklist before you hand your evidence package to the assessor.

Verify before you rely on it
Clause references point to ISO/IEC 17025:2017. Confirm every clause number and any coverage-factor requirement against your own controlled copy of the standard before use.

Contents

SECTION ONE

Executive Summary

You just expanded your scope, and your assessor wants proof that your results hold up. You look for a proficiency testing round, and no suitable one exists. An interlaboratory comparison solves that problem. You measure the same item another accredited laboratory already measured, then compare the two results with a formula that accounts for both laboratories' uncertainty.

ISO/IEC 17025:2017, Clause 7.7 asks you to ensure the validity of your results. Proficiency testing is one accepted route, but it is not the only one. An interlaboratory comparison satisfies the same requirement, which gives you a defensible option when a proficiency testing scheme falls short on availability, cost, or range.

This guide walks you through the whole sequence. You pick a device with a current certificate, measure it yourself, line up the shared points, and calculate the normalized error, written E_n, at each point. Any point with an absolute E_n of 1 or less passes. You then attach both certificates, add a short cover report, and hand the assessor a clean package.

Key takeaway. When proficiency testing is not available, an interlaboratory comparison under Clause 7.7 gives you real evidence of competence. The E_n number turns two sets of results and their uncertainties into a single pass-or-fail decision.

SECTION TWO

Purpose and Scope

Purpose

This guide helps you run an interlaboratory comparison, calculate the E_n number, and assemble evidence that stands up during an assessment. It explains why the standard asks for the comparison, when the method fits, and how to document it so an assessor can follow your reasoning without asking you to fill gaps.

Intended Audience

The primary audience is small laboratories and organizations new to ISO/IEC 17025 who need interim verification of a method. Quality managers and experienced practitioners will also find a concise reference for the E_n calculation and the evidence layout. The guide assumes you already hold, or are pursuing, accreditation and that you understand expanded uncertainty at a working level.

Scope

Included	Running a comparison for calibration or testing, calculating normalized error, handling mismatched points, and building the assessor's evidence package.
Excluded	Full derivation of measurement uncertainty budgets, selection of a specific proficiency testing provider, and any organization-specific procedure text.
Dependencies	A current calibration certificate or reference result from an accredited laboratory, your own stated expanded uncertainty, and approval of your monitoring plan by your accreditation body.

Get the plan approved first

Accreditation bodies such as A2LA, ANAB, PJLA, or NVLAP generally expect proficiency testing as the first course of action. If you plan to rely on an interlaboratory comparison, state your reason and secure approval before you treat the comparison as evidence.

SECTION THREE

Key Concepts and Definitions

These terms carry precise meanings in an assessment. Use them consistently, and your evidence reads as the work of a laboratory that knows the standard.

Term	Working definition	Reference
Interlaboratory comparison (ILC)	Organizing, performing, and evaluating measurements on the same or similar items by two or more laboratories under predetermined conditions.	Clause 7.7
Proficiency testing (PT)	Evaluation of laboratory performance against set criteria through interlaboratory comparisons run by an external scheme provider.	Clause 7.7
Device under test (DUT)	The shared artifact or sample both laboratories measure, such as a mass standard or a portion of one water sample.	—
Expanded uncertainty (U)	The standard uncertainty multiplied by a coverage factor to give an interval expected to contain the true value at a stated level of confidence.	GUM
Coverage factor (k)	The multiplier applied to standard uncertainty. Laboratories commonly report at k = 2, roughly 95 percent confidence.	GUM
E_n (normalized error)	An agreement statistic that compares the difference between two results against their combined expanded uncertainty. A value of 1 or less indicates agreement.	ISO 13528

Terminology note

Keep accreditation and certification distinct. Laboratories earn **accreditation** to ISO/IEC 17025 through a body such as A2LA or ANAB. Organizations earn **certification** to ISO 9001 through a certification body. The two are not interchangeable.

SECTION FOUR

Core Guidance

4.1 Why ISO/IEC 17025 asks you to compare your results

Clause 7.7 asks you to ensure the validity of your results. The standard sets this expectation because accredited laboratories should agree with one another when they use the same method for the same measurement. That agreement protects the customer. A customer who buys an accredited result can trust that the laboratory produced evidence for its validity, not just a number on a certificate.

Many laboratories reach first for proficiency testing to meet this requirement, and that is often the right move. Sometimes, though, a suitable scheme does not exist, or it does not cover your range. An interlaboratory comparison fills that gap and still meets the clause.

4.2 When to choose a comparison instead of proficiency testing

An interlaboratory comparison fits several situations well:

- You added a parameter and need interim verification before the next proficiency testing round.
- No proficiency testing scheme is available for the measurement.
- Proficiency testing exists but costs more than the verification justifies.
- The available scheme does not cover the full range of your scope, so a comparison serves the measurement better.

4.3 The En number, explained

The normalized error tells you whether two results agree once you account for their uncertainties. The formula is straightforward:

$$En = \frac{x_1 - x_2}{\sqrt{{U_1}^2 + {U_2}^2}}$$

x_1, x_2	The measurement results from laboratory 1 and laboratory 2 at the same point.
U_1, U_2	The expanded uncertainty each laboratory reports at that point.

The numerator captures the raw difference between the laboratories. The denominator captures how much difference their combined uncertainty already allows. Divide one by the other, and the result comes out unitless. Calculate an E_n value for every nominal or measurement point you want to compare.

That structure explains the acceptance rule. When the difference stays smaller than the combined uncertainty, E_n lands between minus one and plus one, and the point passes. When the difference outgrows the uncertainty, E_n climbs past 1, and the point fails. The statistic rewards agreement, and it forgives small gaps that your stated uncertainty already predicts.

> **Two details protect your math**
> First, use expanded uncertainties, not standard uncertainties, on both sides. Second, confirm both laboratories report at the same coverage factor before you compare. If you mix a $k = 2$ value with a $k = 1$ value, the E_n number may misstate how close the results are. When the other laboratory uses a different coverage factor, expand your own uncertainty to match it.

SECTION FIVE

Implementation Framework

The workflow stays the same across most measurement disciplines. This sequence uses a balance, since a mass example shows the method clearly, and the same seven steps carry over to any method.

1. **Pick your device (DUT).** Choose an item with a recent calibration certificate from an accredited laboratory. A scale you already own works well, because you hold its certificate from a prior calibration provider.
2. **Measure the same item yourself.** Run your own calibration on that device. Capture your as-found and as-left data at each nominal point you plan to compare.
3. **Line up the shared points.** Place both laboratories' readings side by side, matched by nominal value, such as 50 g, 100 g, and 200 g.
4. **Record each expanded uncertainty.** Pull the expanded uncertainty for each laboratory at each point, and note the coverage factor.
5. **Calculate the normalized error.** Compute the E_n number for every matched point.
6. **Check compliance for each point.** Accept the point when the absolute value of E_n stays at or below 1.
7. **Build the comparison report.** One column holds your readings, the next holds the other laboratory's readings, and the following columns hold each uncertainty and the resulting E_n. That layout reads cleanly, and it maps onto what your assessor wants to see.

The framework as a repeatable cycle

1 · Define	2 · Assess	3 · Implement	4 · Verify	5 · Improve
State the method and the points to verify.	Gather results, uncertainties, and coverage factors.	Calculate E_n at each matched point.	Apply the rule and mark pass or fail.	Investigate any failure and refine.

Handling gaps and mismatched points

Laboratories rarely run the exact same nominal points. Never force an E_n number where one side has no reading. Leave the cell blank and drop that row, or keep the row with a note that reads, "No comparison data available at this nominal value." The rule is simple: never invent a reading and never let a blank field feed a broken calculation.

SECTION SIX

Worked Examples and the Evidence Package

Worked example: mass calibration

Suppose your laboratory reads 99.9998 g at the 100 g point with an expanded uncertainty of 0.20 mg. The comparison laboratory reads 99.9999 g with an expanded uncertainty of 0.05 mg. The difference is 0.1 mg. The combined uncertainty is $\sqrt{(0.20^2 + 0.05^2)}$, roughly 0.21 mg, so E_n comes out near 0.5. That point passes with room to spare. The table below carries the same calculation across three nominal points.

Worked E_n Calculation Example

Comparison of laboratory results at the 50 g, 100 g, and 200 g measurement points

Nominal	Your Lab Result	Your Lab Expanded Uncertainty	Comparison Lab Result	Comparison Lab Expanded Uncertainty
50 g	49.9999 g	0.15 mg	50.0000 g	0.05 mg
100 g	99.9998 g	0.20 mg	99.9999 g	0.05 mg
200 g	200.0003 g	0.25 mg	200.0001 g	0.10 mg

Nominal	Difference	Combined Uncertainty	E_n Value	Evaluation
50 g	0.10 mg	$\sqrt{(0.15^2 + 0.05^2)}$ **0.158 mg**	**0.63**	**PASS**
100 g	0.10 mg	$\sqrt{(0.20^2 + 0.05^2)}$ **0.206 mg**	**0.49**	**PASS**
200 g	0.20 mg	$\sqrt{(0.25^2 + 0.10^2)}$ **0.269 mg**	**0.74**	**PASS**

The absolute E_n value is less than 1 at all three measurement points. Therefore, each comparison result is considered satisfactory.

Figure 1. A worked En calculation for a mass comparison, applying the rule at 50 g, 100 g, and 200 g.

Worked example: a testing laboratory

Testing laboratories run comparisons too. Instead of calibrating a shared artifact, each laboratory tests the same sample for one or more analytes. Here, two laboratories receive portions of one water sample and use ion chromatography with conductivity detection to determine fluoride, chloride, and bromide. They then compare their reported results and expanded uncertainties with the same normalized error.

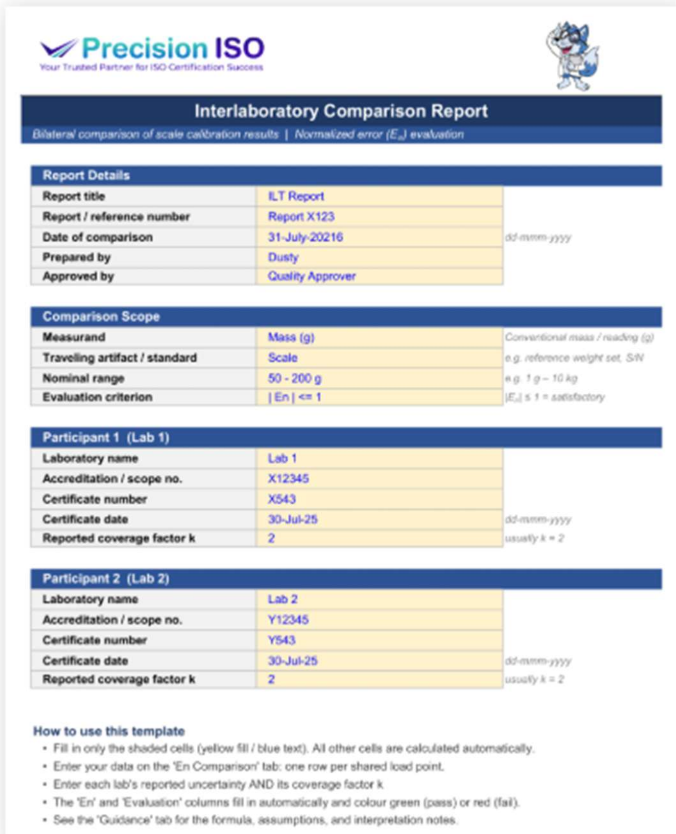
Analyte	Lab 1 result	Lab 1 U	Lab 2 result	Lab 2 U	Difference	Combined U	E_n	Evaluation
Fluoride	1.02	0.06	0.99	0.05	0.03	0.078	**0.38**	**Satisfactory**
Chloride	25.4	0.80	25.0	0.70	0.40	1.063	**0.38**	**Satisfactory**
Bromide	0.48	0.04	0.50	0.05	−0.02	0.064	**−0.31**	**Satisfactory**

Figure 2. A testing-laboratory comparison across three analytes. Every point returns an absolute E_n well under 1, so each result agrees within the combined uncertainty.

What the evidence package looks like

Your evidence package matters as much as your results. Assemble it so the assessor follows it without questions. A complete comparison report holds a cover page that states the reason for the comparison, the date, and both laboratories' details; a data summary that lists each point, both readings and uncertainties, the E_n value, and a pass-or-fail status; and the two calibration certificates attached as evidence.

Example Cover Page



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Interlaboratory Comparison Report

Bilateral comparison of scale calibration results | Normalized error (E_n) evaluation

Report Details		
Report title	ILT Report	
Report / reference number	Report X123	
Date of comparison	31-July-20216	dd-mmm-yyyy
Prepared by	Dusty	
Approved by	Quality Approver	

Comparison Scope		
Measurand	Mass (g)	Conventional mass / reading (g)
Traveling artifact / standard	Scale	e.g. reference weight set, S/N
Nominal range	50 - 200 g	e.g. 1 g – 10 kg
Evaluation criterion	| En | <= 1	$\|E_n\| \le 1$ = satisfactory

Participant 1 (Lab 1)		
Laboratory name	Lab 1	
Accreditation / scope no.	X12345	
Certificate number	X543	
Certificate date	30-Jul-25	dd-mmm-yyyy
Reported coverage factor k	2	usually k = 2

Participant 2 (Lab 2)		
Laboratory name	Lab 2	
Accreditation / scope no.	Y12345	
Certificate number	Y543	
Certificate date	30-Jul-25	dd-mmm-yyyy
Reported coverage factor k	2	usually k = 2

How to use this template

- Fill in only the shaded cells (yellow fill / blue text). All other cells are calculated automatically.
- Enter your data on the 'En Comparison' tab: one row per shared load point.
- Enter each lab's reported uncertainty AND its coverage factor k.
- The 'En' and 'Evaluation' columns fill in automatically and colour green (pass) or red (fail).
- See the 'Guidance' tab for the formula, assumptions, and interpretation notes.

Figure 3. Example cover page: the report's reason, dates, and both participating laboratories.

Example Data Page

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E_n Comparison Worksheet

Enter shared load points below. Shaded columns are inputs; the remaining values calculate automatically.

Interlaboratory comparison of mass calibration results using normalized error.

#	Nominal load (g)	Lab 1 value (g)	Lab 1 U reported (g)	Lab 1 k	Lab 1 U (k=2) (g)	Lab 2 value (g)	Lab 2 U reported (g)
ex	10.00000	10.00210	0.01500	2.0	0.0150	10.00060	0.00800
1	50.00000	50.00010	0.00020	2.0	0.0002	50.00020	0.00030
2	100.00000	100.00000	0.00010	2.0	0.0001	99.99990	0.00001
3	200.00000	200.00001	0.00010	2.0	0.0001	200.00000	0.00002
4							
5							
6							
7							
8							

Figure 4. Example data page: shared load points, inputs, and the calculated En values.

SECTION SEVEN

Checklist and Action Plan

Work through this checklist before you treat a comparison as evidence.

- ☐ Confirm your accreditation body approved an interlaboratory comparison for this measurement.
- ☐ Select a device or sample with a current certificate from an accredited laboratory.
- ☐ Measure the same item and capture data at each nominal point you plan to compare.
- ☐ Match both laboratories’ readings by nominal value.
- ☐ Record each expanded uncertainty and confirm both use the same coverage factor.
- ☐ Calculate E_n at every matched point.
- ☐ Mark each point pass or fail against the acceptance rule.
- ☐ Note any mismatched points honestly rather than forcing a value.
- ☐ Investigate and document any point that fails.
- ☐ Assemble the cover page, the data summary, and both certificates into one report.

Priority actions

First: before you measure

Secure your accreditation body’s approval and choose a device whose certificate covers the points in your scope. This one step prevents the most common reason a comparison gets rejected.

Next: during the comparison

Standardize the coverage factor across both laboratories, and calculate E_n the same way at every point so the worksheet reads consistently.

Ongoing: build the habit

Keep a reusable worksheet that carries the E_n calculation and the comparison layout, so each new verification turns into a report your assessor recognizes as sound.

SECTION EIGHT

References and Resources

References

1. ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories, Clause 7.7 (Ensuring the validity of results). Verify clause numbers against your controlled copy.
2. JCGM 100:2008, Evaluation of measurement data: Guide to the expression of uncertainty in measurement (GUM), for expanded uncertainty and coverage factor.
3. ISO 13528, Statistical methods for use in proficiency testing by interlaboratory comparison, for the normalized error statistic. Confirm the exact definition and any coverage-factor requirement before you rely on it.

Related Precision ISO Resources

- Uncertainty budget development, built to carry into your E_n worksheet.
- SOP-008 Reporting Results template, for consistent result and uncertainty reporting.
- Choosing an ISO/IEC 17025 accredited laboratory, a companion guide for selecting a comparison partner.

Precision ISO supports laboratories and quality teams across pharmaceutical, medical device, aerospace, and calibration environments. We help organizations evaluate calibration vendors, review scopes of accreditation, build internal qualification procedures, and prepare for ISO/IEC 17025 and ISO 9001 assessments. Whether you are selecting an outside laboratory for the first time or rebuilding your supplier qualification process, our engagements give you a clear, defensible path forward.

Practical systems. Defensible evidence. Fewer audit surprises.

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