

Compliant vs. Defensible

Building laboratory results that hold up — especially when there's no standard method

THE PROBLEM

A result can be perfectly compliant — and still fall apart.

✓ Accredited lab · method on scope ·
every box ticked

✗ Didn't hold when someone re-
tested it

That gap — between a result that passes and one that holds up — is defensibility.

Two different achievements

COMPLIANT

You met the requirement and can show you met it.

Verified at a point in time, against a checklist, by an assessor.

DEFENSIBLE

The result withstands challenge from someone motivated to break it — an opposing expert, a regulator, a customer's QA.

A property of the data, tested continuously by reality.

The assessment tests the first. Reality tests the second.

**Accreditation is necessary —
but it is not sufficient.**

Just because you're accredited doesn't mean your data is defensible.

Where defensibility actually lives

Not in the QMS binder — the binder proves you have procedures, not that the number is right.

1

Method validation

Documented evidence the method measures what you claim, at the levels you report — specificity, accuracy, precision, LOD/LOQ, range, robustness.

Does the method do what I say it does?

2

Measurement of uncertainty

The honest error bar — how sure am I? A number without it is a point estimate wearing the costume of a fact.

And it's the first thing a challenger attacks.

Records that reconstruct what happened + a scope claim no broader than your validation — complete the set.

THE WHOLE IDEA IN ONE LINE

Defensible =

Compliant

+

Validated

+

Uncertainty-
aware

+

Honestly
scoped

Meet the standard, prove the method works, own your uncertainty, and never claim more than you validated.

THE HARD CASE

When there's no standard method, the lab is the method's author.

Cannabis

PFAS

Novel matrices

Often there's no EPA, AOAC, or USP method to lean on.

Non-standard doesn't mean un-accreditable. It means the burden of proof shifts entirely to you — full validation, a defined scope, and characterized uncertainty. An SOP is a recipe; validation is the evidence it works.

A recipe is not evidence

AN SOP

is a recipe — the steps you follow.

VALIDATION

is the documented evidence that the recipe actually produces what you say it does.

Following a procedure is not the same as validating a method.

Build for the challenger, not the assessor.

If your data can survive someone motivated to break it, the assessment takes care of itself.

The assessor's chair meets the lab director's bench — over to you, George.