

TNI calibration requirements for environmental laboratories.

NELAP accreditation runs on the 2016 TNI standard, and its chemistry module sets the calibration rules your lab is audited against. DoD work adds a second, tighter layer.

SUMMARY

NELAP accreditation for environmental laboratories is based on the 2016 TNI standard, adopted by the NELAP Accreditation Council in January 2020. This paper summarizes the Volume 1, Module 4 requirements for initial calibration and continuing calibration verification, sets them beside DoD/DOE QSM 6.0 and EPA Method 8000D, and applies all three to one calibration to show how program limits change the outcome.

THE SHORT VERSION

- 01 TNI requires a relative error measure for every ICAL: RSE, or %RE at the lowest and midpoint standards.
- 02 TNI requires the measure but leaves the limit to your method or program.
- 03 One curve can pass QSM 6.0 and fail Method 8000D, so record which program's limits you applied.

TNI, NELAP and the 2016 standard.

An auditor opens the ICAL record for one analyte. The r^2 is excellent, and there is no relative error measure anywhere in the file. Under the 2016 TNI standard, that curve does not meet the rule.

The NELAC Institute (TNI) writes the consensus standard used to accredit environmental labs in the United States. Its accreditation program is NELAP, the National Environmental Laboratory Accreditation Program. State agencies that TNI recognizes grant accreditation through it ^[1]. Volume 1 is modeled on ISO/IEC 17025, so much of it will look familiar from [Insights 10](#).

The current lab standard is the 2016 edition. The NELAP Accreditation Council set its formal adoption for January 31, 2020. The 2009 edition now applies only in Kansas ^[2]^[3]. Module 2 covers general quality system rules. Module 4, Quality Systems for Chemical Testing, holds the calibration rules. It is the module to know line by line.

TNI calibration requirements for the ICAL.

Section 1.7.1.1 of Module 4 sets the ICAL rules. Four of its items are the ones most often reviewed in an audit ^[4]:

01 Minimum number of standards, 1.7.1.1(f).

Four for an average response model, five for linear and six for quadratic, unless the method asks for more.

02 The range is the standards, 1.7.1.1(g) and (h).

The lowest and highest standards bound the range for quantitative results. A result outside that range is not bracketed by the curve.

03 A measure of relative error, 1.7.1.1(k).

The lab must use one and document it. If you use percent relative error, check it at one standard at the midpoint and one at the lowest level. RSE is the alternative.

04 Second-source verification, 1.7.1.1(n).

Verify every ICAL with a standard from a second maker, or from a separate lot shown to be independently prepared.

Item (k) is the one that moves a lab past the correlation coefficient. A curve accepted on r^2 alone, with no relative error measure in the record, does not meet the standard. How good the r^2 is does not matter. [Insights 01](#) explains why the rule exists.

TNI calibration requirements for the CCV.

Section 1.7.1.2 sets the rules for the CCV, the continuing calibration verification ^[4]. A verification runs at the start and end of each analytical batch, with exceptions for certain internal standard methods.

When a verification fails, the lab takes corrective action and runs a second verification right away. If that one also fails, the lab runs a new ICAL before it analyzes new samples.

Data reported against a failed check must be qualified. The standard allows two exceptions, where the bias cannot change the conclusion. The first is a non-detect when the verification is biased high. The second is a result above a regulatory limit when it is biased low ^[4]. Every other result goes out with a qualifier.

The DoD and DOE layer.

Labs that test for the Department of Defense or Department of Energy have a second rulebook. They are also audited against the DoD/DOE Consolidated Quality Systems Manual, now version 6.0. Its Module 4 mirrors the TNI chemistry module. Its Appendix B tables add numeric limits by method type ^[5]^[6].

TNI requires the measure, and your method or program sets the limit.

For GC/MS organics, Table B-4 accepts two model types. One is an average response calibration with RSD of 20% or less. The other is a linear or quadratic fit with r^2 of at least 0.99.

Table B-4 then adds relative error limits: 20% at or near the midpoint and 50% at the low level. The RSE may not exceed 30%. Continuing verification must fall within $\pm 20\%$ of the true value, or $\pm 50\%$ for the end-of-batch check ^[6]. Where QSM 6.0 applies, these are your pass and fail lines.

Three programs, one curve.

REQUIREMENT	2016 TNI, V1M4	DOD/DOE QSM 6.0 (GC/MS ORGANICS)	EPA METHOD 8000D
Relative error measure	Required: RSE, or relative error at the lowest and midpoint standards	%RE $\leq 20\%$ at mid, $\leq 50\%$ at low; RSE $\leq 30\%$	%Error $\leq 30\%$ at every standard; RSE as the method's RSD limit or $\leq 20\%$
Second-source verification	Required for every initial calibration	Required: authoritative, independent second source	Method-specific
Calibration verification	Beginning and end of each batch, with exceptions	$\pm 20\%$ of true value; $\pm 50\%$ at end of batch	Method-specific; 8260D uses each 12-hour period, $\leq 20\%$ drift
After a failed verification	Corrective action, then an immediate second verification; if it fails, a new ICAL	Second CCV within one hour, no samples in between	Method-specific

The programs agree on what must be measured. They differ on where the line sits. Apply all three to the unweighted curve from [Insights 01](#) and the gap is plain.

PROGRAM	LOWEST STANDARD	MIDPOINT STANDARD	RSE	RESULT
DOD/DOE QSM 6.0	Low $\leq 50\%$: -36.7% PASS	Mid $\leq 20\%$: +2.5% PASS	RSE $\leq 30\%$: 17.6% PASS	PASS
EPA Method 8000D	Every level $\leq 30\%$: -36.7% FAIL	Not separately specified	RSE $\leq 20\%$: 17.6% PASS	CONDITIONAL
2016 TNI, V1M4	Measure required; limit set by the method or program	Measure required	Either measure accepted	METHOD DECIDES

Values come from the eight-level illustrative data set in Insights 01, with an unweighted linear fit. The midpoint is the 10 ppb standard. Method 8000D's 50% allowance for the lowest standard applies only for some data uses.

-36.7%

ERROR AT THE LOWEST STANDARD

Pass

UNDER QSM 6.0'S 50% LOW-LEVEL LIMIT

Fail

UNDER METHOD 8000D'S 30% LIMIT AT EVERY STANDARD

At -36.7% error at the lowest standard, the same curve passes the DoD program and fails Method 8000D's general limit. Under TNI alone, the outcome depends on the limit your method and procedures set. TNI requires the measure, and your method or program sets the limit.

So a lab that runs one method for several clients needs to know which program applies to each data set. Its calibration record must show the check against that program's limits.

A TNI audit readiness checklist.

01 Confirm the edition.

Know which edition each accrediting state applies, and whether QSM 6.0 applies to the client.

02 **Count standards against 1.7.1.1(f).**

Four, five or six by model, or more if the method requires it.

03 Record relative error for every analyte.

Use RSE, or relative error at the lowest and midpoint standards, against a documented limit.

04 **Verify every ICAL with a second source.**

Keep the lot and maker records that show independence.

05 **Bracket each batch.**

Verify at the start and end, unless the method's exception applies.

06 Handle failures the same way every time.

Take corrective action, run one second check right away, then recalibrate. Qualify any data you report.

07 Evaluate against the right program.

Where OSM 6.0 applies, test the low and mid relative error and RSE limits in its tables.

Where WLTR fits.

A multi-program lab checks the same curve against different limits for different clients. Done by hand for every analyte, this is where the relative error rule most often exists only on paper.

WLTR is calibration data integrity infrastructure for regulated analytical laboratories. For each analyte, it derives nine calibration regression models: average response factor, plus linear and quadratic fits across four weightings each. It scores every model against fifteen ICAL parameters, including RSE. All of it is computed orthogonally to the CDS, under U.S. Patent 12,038,448 B2 [P].

CALIBRATION VERIFICATION

See your ICAL evaluated against TNI, QSM 6.0 and your method's limits side by side, for every analyte.

[GET COMPLIANCE GAP ASSESSMENT](#)
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SOURCES

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