

[Organization logo]

[Organization name]

Commented [170251]: All fields in this document marked by square brackets [] must be filled in.

TEST AND CALIBRATION METHOD PROCEDURE

Commented [170252]: Adjust the title of this procedure if only testing or calibration is done in your organization.

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [170253]: Adapt to the existing practice in organization.

Distribution List for Paper-based Documents

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				Date	Signature

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Change History

Date	Version	Created by	Description of change
	0.1	17025Academy	Basic document outline

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[organization name]

1. Purpose, Scope and Users

The purpose of this procedure is to ensure that the correct test and calibration methods are chosen to meet customer requirements; that those methods are appropriate and [organization name] meets all of the requirements of ISO/IEC 17025:2017; and to ensure that when required, that verification and validation are applied to tests and calibrations.

Commented [170255]: It is the organizational responsibility to ensure proper selections of methods and available resources.

This procedure covers all tests and calibrations carried out in the laboratory.

Commented [170256]: Adjust the sentence if only testing or only calibration is done in your organization.

Users of this procedure are laboratory management and all laboratory personnel.

2. References

- ISO/IEC 17025:2017 clause 7.2.1, 7.2.2
- ISO/IEC Guide 99
- Quality Manual

Commented [170257]: Guide 99 provides a set of definitions and associated terms, in English and French, for a system of basic and general concepts used in metrology, together with concept diagrams to demonstrate their relations. Additional information is given in the form of examples and notes under many definitions.

3. Test and Calibration Procedure

3.1. Method Selection

[Organization name] must use appropriate methods, techniques and procedures for all laboratory

standards, manuals and reference data are kept up to date and readily available to laboratory personnel.

and it is the responsibility of [job title] to ensure that selection, verification and validation of standard methods that are carried out in order to completely satisfy customer requirements.

Commented [170259]: Laboratory or Quality manager.

[Organization name] must only use laboratory methods that meet customer requirements and are

Commented [1702510]: Following actions are completely Organizational responsibility.

[organization name]

[Job title] ensures that the laboratory uses the latest valid edition of a method unless it is not

Commented [1702511]: Laboratory or Quality manager.

process according to the Customer Service Procedure. Whenever possible, [organization name] must

Commented [1702512]: Laboratory manager or person on a position of formulating the contracts.

must ensure that periodic reviews are carried out to verify that the needs of the customer are still being met. Any change in requirements requiring modifications to the development plan, is approved and

Commented [1702513]: Laboratory or Quality manager.

3.2. Verification

[Organization name] must verify that it can properly perform methods before introducing them to

Development, Verification and Validation Register and maintained in the Method Development, Verification and Validation Record.

Commented [1702514]: Laboratory or Quality manager.

3.3. Validation

[Organization name] must validate all non-standard methods, laboratory developed methods and

include selectivity, sensitivity, measurement range, limit of detection, limit of quantification, accuracy, precision, repeatability, and evaluation of measurement uncertainty as well as robustness. The method

Commented [1702515]: Laboratory or Quality manager.

[Job title] ensures that records of all verifications and re-verifications are listed in the Test Method Development, Verification and Validation Register and maintained in the Method Development,

Commented [1702516]: Laboratory or Quality manager.

[organization name]

Verification and Validation Record. Techniques used by [organization name] for method validation can

- a. Calibration and/or evaluation of bias and precision using reference standards or
- b.
- c.
- d.
- e.
- f.

Commented [1702517]: Choose one or more validation methods that are appropriate.

If changes are made to any validated methods, the influence of such changes must be documented and,

Verification/Validation Record:

- a. The validation procedure used.
- b.
- c.
- d.
- e.

4. Managing Records Kept on the Basis of this Document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Test Method Development, Verification and Validation Register	PR.10.1	Indefinitely	[office of [job title]]	[Job Title]
Test Method Development, Verification and Validation Record	PR.10.2	Indefinitely	[office of [job title]]	[job title]

Commented [1702518]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Commented [1702519]: Laboratory or Quality manager.

5. Appendices

- Appendix 1 – Test Method Development, Verification and Validation Register
- Appendix 2 – Test Method Development, Verification and Validation Record