[Organization logo]

[Organization name]

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

QUALITY ASSURANCE PROCEDURE

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

Commented [170252]: Adapt to the existing practice in organization.

Distribution List for Paper-based Documents

Commented [170253]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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				Date	Signature

Change History

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

Table of Contents

1. Purpose, Scope and Users

The purpose of this procedure is to detail the activities required for [organization name] to maintain a quality assurance system that ensures valid results from all testing and calibration activities.

This procedure applies to laboratory activities to:

- ensure the functionality and integrity of the laboratory information management system (LIMS) used to collect and process data and information, whether computerized or non-computerized;
- assure quality control methods, the use of certified reference materials, participation in proficiency testing and to control and improve the quality of laboratory activities.

Users of this document are the management of the laboratory and personnel assigned to the laboratory.

2. Reference Documents

- ISO/IEC 17025:2017; Clauses 7.5, 7.7.1, 7.7.2, 7.7.3, and 7.11
- Quality Manual
- ISO/IEC 17043
- ISO Guide 33
- ISO Guide 35

3. Data and Information Management

[Job title] has full responsibility and authority for the assurance of the functionality and data integrity of the laboratory information management systems (LIMS).

[Job title] achieves this through:

- [illegible]
- [illegible] [Job title] must use Appendix 2, The Laboratory Information Management System (LIMS) Validation Register, to list the systems that are validated, and Appendix 3, The Laboratory [illegible]
- [illegible]
- [illegible] addressed through the Complaint, Nonconformity and Corrective Action Procedure.

Commented [170254]: Insert your organization/laboratory name.

Commented [170255]: Delete reference to test or calibration if one does not apply to your organization's activities.

Commented [170256]: Conformity assessment - General requirements for proficiency testing.

Commented [170257]: Reference Material - Good practice in using reference materials.

Commented [170258]: Reference Materials - General and statistical principles for certification.

Commented [17A9]: The designated person responsible for the development of the process or the laboratory manager.

Commented [17A10]: The designated person responsible for the development of the process or the laboratory manager.

Commented [17A11]: The designated person responsible for the development of the process or the laboratory manager.

Commented [17A12]: You will find this document in the ISO 17025 Toolkit folder "14_Complaint_Nonconformity_and_Corrective_Action".

[Job title] has the responsibility and the authority to decide, based on risks to data integrity, which validations are required.

Commented [17A13]: The designated person responsible for the development of the process or the laboratory manager.

4. Quality Control Methods

[Job title] must regularly monitor the validity of laboratory activities and document the results in such a way that trends are detectable and, when practicable, statistical techniques are used.

Commented [1702514]: Usually is the Quality manager, i.e. the person responsible for overall Quality Control in Laboratory.

It is the responsibility of [job title] to ensure quality assurance activities take place and the results are reported to top management.

Commented [1702515]: Usually is the Quality manager, i.e. the person responsible for overall Quality Control in Laboratory.

[Job title] must plan and review monitoring of quality control methods through the activities that may include:

Commented [1702516]: Usually is the Quality manager, i.e. the person responsible for overall Quality Control in Laboratory.

a. Regular use of reference materials or quality control materials.
b. Use of alternate instrumentation that has been calibrated to provide traceable results.
c. Functional checks of all measuring and testing equipment.
d. Use of check or working standards with control charts.
e. Intermediate checks on measuring equipment.
f. Replicate tests or calibrations using the same or different methods.
g. Retesting or recalibration of retained items.
h. Correlation of results for different characteristics of an item.
i. Review of reported results.
j. Inter-laboratory comparisons.
k. Testing of blind samples.

Commented [1702517]: List of activities is not limited to listed monitoring tools. Each organization can add additional ones, when appropriate.

[Job title] uses the results of these monitoring tools to ensure the quality, accuracy and capability of the tools, equipment and personnel conducting tests and calibrations in the laboratory.

Commented [1702518]: Usually the Quality manager, i.e. the person responsible for overall Quality Control in Laboratory.

5. Certified Reference Materials

Testing and Calibration activities may require the use of Certified Reference Materials (CRM).

[Job title] must ensure CRMs are used regularly in conjunction with the quality control methods listed in the above paragraph.

Commented [1702519]: Laboratory or Quality manager.

All CRMs purchased for and by the laboratory are accompanied by a certificate that indicates that the values listed are traceable to SI units or a national standard.

[Job title] takes care that CRMs are only purchased from sources that have direct traceability to national standards, draws attention to environmental storage requirements and observes special handling with CRMs to ensure their accuracy.

Commented [1702520]: Laboratory or Quality manager.

6. Proficiency Testing

Commented [1702521]: Participation in a Proficiency Testing scheme is a mandatory requirement of ISO/IEC 17025.

[Job title] must ensure that the laboratory is participating in proficiency testing that meets the

another laboratory. Each test and/or calibration method the laboratory performs, must be proficiency tested within a four-year cycle.

included in the Proficiency Testing Record.

In the event that a particular test or calibration is not suited to formal proficiency testing plans, [job

7. Data Analysis

[Job title] must monitor all laboratory activities and analyze all collected data to control and improve

the laboratory's specified criteria, [job title] must take corrective actions in accordance with the

8. Managing Records Kept on the Basis of this Document

Record name	Code	Storage			Responsibility
		Retention time	Location	Protection	
Proficiency Testing Record	PR.11.1	5 years	[office of [job title]]	Records are stored in file cabinet or in personal computer	[job title]

Commented [1702522]: Laboratory or Quality manager.

Commented [1702523]: Registration bodies (registrars) all have specific guidelines to meet this requirement. Check with your registrar first.

Commented [1702524]: Organization that is accredited to ISO/IEC 17025:2017.

Commented [1702525]: Laboratory or Quality manager.

Commented [1702526]: Periods vary between different registrars.

Commented [1702527]: Your registrar can provide a list of recommended laboratories.

Commented [1702528]: Must be coordinated with your registrar.

Commented [1702529]: Usually is the Quality manager, i.e. the person responsible for overall Quality Control in Laboratory.

Commented [1702530]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Commented [1702533]: Usually is the Quality Manager.

Commented [1702531]: Proficiency Testing records are provided by the participating laboratories. Format, appearance and form layout varies among different laboratories.

Commented [1702532]: Usually is the office of the Quality Manager.

				[describe name/location]	
Laboratory Information Management System (LIMS) Validation Register	PR.11.2	3 years	[office of [job title]]	Records are stored in file cabinet or in personal computer [describe name/location]	[job title]
Laboratory Information Management System (LIMS) Validation Record	PR.11.3	3 years	[office of [job title]]	Records are stored in file cabinet or in personal computer [describe name/location]	[job title]

9. Appendices

- Appendix 1 – Proficiency Testing Record
- Appendix 2 – Laboratory Information Management System (LIMS) Validation Register
- Appendix 3 – Laboratory Information Management System (LIMS) Validation Record