[Organization logo]

[Organization name]

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

## **EQUIPMENT AND CALIBRATION PROCEDURE**

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

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

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# **Change History**

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

## **Table of Contents**

1.	PUR	POSE, SCOPE AND USERS	.3		
	REFERENCE DOCUMENTS				
3.	EQU	IPMENT	.3		
	3.1.	GENERAL EQUIPMENT	1		
		EQUIPMENT CALIBRATION			
	3.3.	EQUIPMENT HANDLING	4		
4.	MET	ROLOGICAL TRACEABILITY	.5		
5.	MAN	NAGING RECORDS KEPT ON THE BASIS OF THIS DOCUMENT	.5		
		FNDICFS			

#### 1. Purpose, Scope and Users

The purpose of this procedure is to describe the process of for handling, transport, storage, use and planned maintenance of equipment in order to ensure proper functioning, to prevent contamination or deterioration and to maintain metrological traceability.

This procedure applies to all equipment of every type and class that are used in the laboratory.

Users of this procedure are managers, supervisors and technicians working as employers in the laboratory or other personnel associated with the laboratory.

#### 2. Reference Documents

- ISO/IEC 17025:2017; clauses 6.4 and 6.5, Annex A
- JCGM 200:2012 (information)
- ISO/IEC Guide 99 (information)
- ISO Guide 33
- ISO Guide 80
- Quality Manual
- **Evaluation of Measurement Uncertainty Procedure**

#### 3. Equipment

### 3.1. General Equipment

Equipment purchased by [Organization's name] is capable of achieving the measurement accuracy and measurement uncertainty required to provide valid results.

laboratory's activities and its results in the List of Laboratory Equipment. Those records include the following:

- 1. The identity of the equipment, including software and firmware if available.
- 2. The manufacturer's name, type identification, serial number or other unique identification.
- 3
- 4. 5.
- 6.
- 7.
- **Equipment and Calibration Procedure**

ver. [version] from [date]

Page 3 of 6

Commented [170254]: International vocabulary of metrology Basic and general concepts and associated terms (VIM) I used as information about understanding of terms and some definitions.

The HTML version of JCGM 200, on which ISO/IEC Guide 99:2007 is based, can be found at  $\underline{\text{http://www.iso.org/sites/JCGM/VIM-}}$ introduction.htm.

Commented [170255]: ISO/IEC 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

Commented [170256]: ISO Guide 33:2015 describes good

Commented [170257]: ISO Guide 80 outlines the essential

Commented [17A8]: You will find this document in the ISO

Commented [17A9]: You will find this document in the ISO 17025 Toolkit folder
"15\_Evaluation\_of\_Measurement\_Uncertainty".

Commented [1702510]: Quality manager or Laboratory

Commented [1702511]: Adapt to organization's needs.

[organization name] When intermediate checks are necessary, meaning the period between calibrations, in order to maintain confidence in the performance of the equipment, [job title] decides about and takes care Commented [1702512]: Person designated by quality or laboratory manager Commented [17A13]: Person designated by quality or Practical measures are taken to prevent unintended adjustments to equipment that would invalidate measurement results. 3.2. **Equipment Calibration** When measurement accuracy and measurement uncertainty affect the validity of the reported Commented [1702514]: Laboratory or quality manager. traceability of the measurement results. This includes reviewing the calibration frequency and **Commented [1702515]:** Use the label, code or otherwise identification as a status of calibration. All calibrated equipment is recorded on the List of Calibrated Equipment. A record of all calibrations is maintained in the Calibration Record. When performing calibrations in-house on the organization's own equipment [job title] evaluates the Commented [1702516]: Laboratory or quality manager. measurement uncertainty for all those calibrations as prescribed in the Evaluation of Measurement Uncertainty Procedure. 3.3. **Equipment Handling** [Job title] ensures that all equipment is handled in such a way as to prevent damage to the Commented [1702517]: Laboratory employees, laboratory technicians equipment or adversely affect its calibration status. Proper handling of equipment applies to Commented [1702518]: Laboratory employees, laboratory

equipment will be recorded in the Equipment Maintenance Record.

**Equipment and Calibration Procedure** 

ver. [version] from [date]

Page 4 of 6

Commented [1702519]: Laboratory or Quality manager.

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If equipment has been subjected to overloading, mishandling or gives questionable results, [job title]

#### 4. Metrological Traceability

[Job title] establishes and maintains metrological traceability of measurement results by means of a

[Job title] accomplishes this through:

 the use of calibration services that are fully accredited to the ISO/IEC 17025:2017 international standard, or

.

•

[Job title] ensures all measurement results are traceable to the International System of Units (SI). If

## 5. Managing Records Kept on the Basis of this Document

		Storage		
Record name	Code	Retention time	Location	Responsibility
List of Laboratory Equipment	PR.08.1	7 years	[office of [job title]]	[job title]
Calibrated Equipment Record	PR.08.2	7 years	[office of [job title]]	[job title]
Calibration Record	PR.08.3	7 years	[office of [job title]]	[job title]
Equipment Maintenance Record	PR.08.4	7 years	[office of [job title]]	[job title]

#### 6. Appendices

- Appendix 1 List of Laboratory Equipment
- Appendix 2 Calibrated Equipment Record
- Appendix 3 Calibration Record

**Equipment and Calibration Procedure** 

ver. [version] from [date]

Page 5 of 6

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Commented [1702520]: Quality manager or Laboratory manager.

**Commented [1702521]:** Quality Manager or Laboratory Manager.

**Commented [1702522]:** Quality Manager or Laboratory Manager.

**Commented [1702523]:** See the possibilities in 6.5.2 of ISO/IEC

**Commented [1702524]:** Quality manager or rarely laboratory manager.

**Commented [1702525]:** See the possibilities in 6.5.3 of ISO/IEC 17025.

**Commented [1702526]:** e. g. Joint Committee for Traceability and Laboratory Medicine (JCTLM).

**Commented [1702527]:** Laboratory manager or Quality manager.

**Commented [1702529]:** If the record is in electronic form, write the name of the folder on Laboratory Manager's or Quality Manager's computer.

**Commented [1702528]:** It's suggested retention time, you can adapt it to the organization needs or national requirements.

[organization name]	
Appendix 4 – Equipment Maintenance Record	