[Organization logo]

[Organization name]

Commented [13A1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR EQUIPMENT MAINTENANCE AND MEASURING EQUIPMENT

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

Commented [13A2]: Adapt to the existing practice in organization.

Distribution list

Commented [13A3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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Change history

Date	Version	Created by	Description of change
	0.1	13485Academy	Basic document outline

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1. Purpose, scope and users

The purpose of this procedure is to describe maintaining equipment in order to provide evidence for the conformity of the product.

This procedure applies to all equipment and measuring equipment in [organization name].

Users of this document are [employees of maintenance department] of [organization name].

Commented [13A4]: Please include the name of your company.

Commented [13A5]: Adapt to organization's practice.

2. Reference documents

- ISO 13485:2016 standard, clauses 6.3 and 7.6
- ISO 9001:2015 standard, clauses 7.1.3 and 7.1.5
- Procedure for Purchasing and Evaluation of Suppliers
- Procedure for Control of Non-Conforming Product
- Procedure for Corrective and Preventive Action
- Procedure for Human Resources
- [other legal and contractual requirements]

Commented [13A6]: Delete if the organization hasn't implemented ISO 9001:2015.

Commented [13A7]: You can find a template for this document in the ISO 13485 Documentation Toolkit folder "10_Purchasing_and_Evaluation_of_Suppliers".

Commented [13A8]: You can find a template for this document in the ISO 13485 Documentation Toolkit folder "15_Nonconformities".

Commented [13A9]: You can find a template for this document in the ISO 13485 Documentation Toolkit folder "19_Corrective_and_Preventive_Action".

Commented [13A10]: You can find a template for this document in the ISO 13485 Documentation Toolkit folder "04_Human_Resources".

3. Equipment maintenance

3.1. Identifying equipment

[Job title] enters all equipment into the List of Equipment. [Job title] must ensure that inventory [illegible] must define the need for training of employees in order to ensure proper and effective handling of equipment, in accordance with the Procedure for Human Resources.

Commented [13A11]: E.g. Maintenance Manager

Commented [13A12]: E.g. HR Manager

Commented [13A13]: Adapt to organization's practice.

3.2. Equipment maintenance

3.2.1. Maintenance planning

According to the List of Equipment and instruction manuals from manufacturers, [illegible] creates the Plan for Preventive Maintenance of Equipment. In line with the plan, [illegible] creates an internal order for purchasing spare parts for maintenance activities that can be executed within the organization. For outsourced maintenance activities, [job title] hires a service provider authorized by the equipment manufacturer.

Commented [13A14]: E.g. Maintenance Manager

Commented [13A15]: E.g. Maintenance Manager

Commented [13A16]: E.g. Purchasing Manager

3.2.2. Preventive maintenance

[Employees of maintenance department] conduct all activities regarding preventive maintenance according to the Plan for Preventive Maintenance of Equipment, or authorized service provider executes activities that the organization cannot perform.

Commented [13A17]: Adapt to organization's practice.

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Records for every preventive maintenance activity are entered into the Plan for Preventive [illegible] undertaken activities to [job title].

3.2.3. Repairing equipment

Every employee who notices equipment malfunctioning is obliged to report it to [job title]. Repairs [illegible]

[illegible]

Commented [13A18]: E.g. Maintenance Manager or CEO

Commented [13A19]: E.g. Maintenance Manager

Commented [13A20]: E.g. Maintenance Manager or CEO

3.3. Measuring equipment maintenance

According to processes identified, the organization determines needs for monitoring and measuring equipment.

- [illegible]
- [illegible]
- [illegible]
- Measuring is a group of operations aimed at determining the value of the measured object.

Commented [13A21]: Adapt to organization's practice. E.g. Maintenance Manager

[Job title] is responsible for calibration of measuring equipment and validation of monitoring [illegible]

Commented [13A22]: Adapt to organization's practice. E.g. Maintenance Manager

3.3.1. Calibration of measuring equipment

The owner of the process in which measuring equipment is used is responsible for specifying [illegible]

[illegible]

Commented [13A23]: Delete if all calibration activities are outsourced.

where necessary. When making adjustments, [job title] will assess previously approved product for [illegible] and is capable of verifying the acceptability of the medical device.

If the calibration of measuring equipment is conducted in external laboratories, it is necessary to [illegible]

[illegible] against a reference master device.

[Job title] enters data about performed calibration into the Maintenance and Calibration Record [illegible]

Commented [13A24]: E.g. Maintenance Manager

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The owner of the process in which measuring equipment is used is responsible for preventing

Each piece of measuring equipment has a unique identification number. [job title] must ensure that identification and traceability are done according to this number.

If it turns out that the measuring equipment is malfunctioning, [job title] must determine in which

3.3.2. Software validation

[Job title] must validate software used for examinations, in order to ensure that software can

Although software is not subjected to real time changes, there can be unintentional changes, so it is necessary to be re-validated. In order to prevent unauthorized changes to software, the organization uses [name the types of software protection], which, in that case, have the same purpose as sealing of measuring equipment.

3.3.3. Measuring equipment storage

[Job title] is responsible for storage of measuring equipment in a way that prevents damage and deterioration during storage.

[Job title] must properly protect and label the measuring equipment that is not in use. This specifically refers to measuring equipment that is used as a reference value during calibration.

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
List of Equipment	PR.17.1	2 years	[office of Maintenance Manager]	[job title]
Plan for Preventive Maintenance of Equipment	PR.17.2	2 years	[office of Maintenance Manager]	[job title]
Maintenance and Calibration Record	PR.17.3	2 years	[office of Maintenance Manager]	[job title]

Commented [13A25]: E.g. Maintenance Manager

Commented [13A26]: Delete if not used by organization.

Commented [13A27]: One of the ways of validation of software is its validation on product whose characteristics are predetermined.

Commented [13A28]: One of the ways of validation of software is its validation on product whose characteristics are predetermined.

Commented [13A29]: For example, for protecting SCADA

Commented [13A30]: E.g. Maintenance Manager

Commented [13A31]: E.g. Warehouse Manager

Commented [13A32]: If the record is in electronic form, write the name of the folder on Maintenance Manager's computer.

Commented [13A33]: If the record is in electronic form, write the name of the folder on Maintenance Manager's computer.

Commented [13A34]: If the record is in electronic form, write the name of the folder on Maintenance Manager's computer.

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5. Appendices

- Appendix 1 – List of Equipment
- Appendix 2 – Plan for Preventive Maintenance of Equipment
- Appendix 3 – Maintenance and Calibration Record

[job title]
[name]

[signature]

Commented [13A35]: Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.

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