

[Organization logo]

[Organization name]

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## PROCEDURE FOR EQUIPMENT MAINTENANCE AND MEASURING EQUIPMENT

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## Change history

Date	Version	Created by	Description of change
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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 [AES4]:** Include the name of your organization.

**Commented [AES5]:** Adapt to the organization's practice.

**Commented [AES6]:** Include the name of your organization.

## 2. Reference documents

- ISO 13485:2016 standard, clauses 6.3 and 7.6
- MDR 2017/745 Annex IX – Chapter I
- Procedure for Purchasing and Evaluation of Suppliers
- Procedure for Control of Nonconforming Products
- Procedure for Corrective and Preventive Action
- Procedure for Human Resources
- [other legal and contractual requirements]

**Commented [AES7]:** Delete this if your organization does not need to be compliant with MDR.

You can find the full text of the MDR on the following link:  
<https://advisera.com/13485academy/mdr/>

**Commented [AES8]:** You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "11\_Purchasing\_and\_Evaluation\_of\_Suppliers".

**Commented [AES9]:** You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "18\_Nonconformities".

**Commented [AES10]:** You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "25\_Corrective\_and\_Preventive\_Action".

**Commented [AES11]:** You can find a template for this document in the ISO 13485 & MDR Integrated Documentation Toolkit, folder "05\_Human\_Resources".

**Commented [AES12]:** E.g., Maintenance Manager

**Commented [AES13]:** E.g., HR Manager

**Commented [AES14]:** Adapt to the organization's practice.

## 3. Equipment maintenance

### 3.1. Identifying equipment

[Job title] enters all equipment into the List of Equipment. [Job title] must ensure that inventory numbers identify all equipment.

**Commented [AES12]:** E.g., Maintenance Manager

**Commented [AES13]:** E.g., HR Manager

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### 3.2. Equipment maintenance

#### 3.2.1. Maintenance planning

According to the List of Equipment and instruction manuals from manufacturers, [job title] creates the Plan for Preventive Maintenance of Equipment.

**Commented [AES15]:** E.g., Maintenance Manager

**Commented [AES16]:** E.g., Maintenance Manager

**Commented [AES17]:** 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; an authorized service provider executes activities that the organization cannot perform.

**Commented [AES18]:** Adapt to the organization's practice.

[organization name]

Records for every preventive maintenance activity are entered into the Plan-do-Check-Act (PDCA) cycle, and confirm that the correct action was undertaken and achieved a satisfactory result. Subsequent maintenance service providers must deliver evidence of 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 are performed internally if possible; otherwise, [job title] hires an appropriate service provider.

[job title] or service provider is obliged to deliver a report about the repaired item to [job title].

Commented [AES19]: E.g., Maintenance Manager or CEO

Commented [AES20]: E.g., Maintenance Manager

Commented [AES21]: E.g., Maintenance Manager or CEO

### 3.3. Measuring equipment maintenance

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

- Monitoring involves all activities of observing and supervision in a defined period.
- Monitoring can, but does not have to, result in a measuring unit.

1. Measuring is performed to [job title], a device, or object.
2. Measuring is a part of operations aimed at determining the value of the measured object.

Commented [AES22]: Adapt to organization's practice.

[Job title] is responsible for calibration of measuring equipment and validation of monitoring equipment. It would not be necessary to calibrate monitoring equipment if it has been validated.

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#### 3.3.1. Calibration of measuring equipment

The owner of the process in which measuring equipment is used is responsible for specifying calibration intervals prior to use.

Calibration is performed by [job title or authorized laboratory] against measurable standards traceable to international or national standards. [Job title] performs adjustments or re-adjustments where necessary.

Commented [AES24]: Delete if all calibration activities are internal.

When making adjustments, [job title] will ensure processes are used to identify, and will address any non-compliance using the Procedure for Nonconforming Product. [job title] will ensure and the calibration certificate issued from outside laboratories is a positive evidence of the calibration of all measuring, monitoring, and test equipment and is capable of verifying the accuracy of the related data.

Commented [AES25]: Include the name of your organization.

If the calibration of measuring equipment is conducted in external laboratories, it is necessary to select those laboratories that are accredited for the required equipment and measurement ranges.

If the calibration of measuring equipment is conducted internally, calibration must be performed against a reference master device.

[job title] issues data about performed calibration into the Maintenance and Calibration Record according to a report from the authority that performed the calibration.

Commented [AES26]: E.g., Maintenance Manager

[organization name]

The owner of the process in which measuring equipment is used is responsible for preventing unauthorized adjustments that would invalidate the measuring results.

Each piece of measuring equipment has a unique identification number (AES27) that ensures that identification and traceability are done according to this number.

Commented [AES27]: E.g., Maintenance Manager

If it turns out that the measuring equipment is malfunctioning or out of the calibration validity, [job title] must determine in which phase of the process the malfunction occurred, in order to eliminate potential consequences.

### 3.3.2. Software validation

Commented [AES28]: Delete if not used by the organization.

[Job title] must validate software used for examinations, in order to ensure that software can respond to requests of measurement.

Commented [AES29]: One of the ways of validation of

Although software is not subjected to real-time changes, there can be unintentional changes, so it is necessary to be controlled in order to prevent unauthorized changes to software. The organization can (AES30) use (AES31) which, in that case, has the same process as setting of measuring equipment.

Commented [AES30]: For example, for protecting SCADA

### 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.

Commented [AES31]: E.g., Warehousing Manager

(AES32) must properly protect and store the measuring equipment that is not in use. This specifically refers to measuring equipment that is used as a reference value during calibration.

Commented [AES32]: E.g., Maintenance Manager

## 4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Format	Location	
List of Equipment	PR20.1	Form	Office of Measuring Equipment	Job title
Plan for Preventive Maintenance of Equipment	PR20.2	Form	Office of Measuring Equipment	Job title
Maintenance and Calibration Record	PR20.3	Form	Office of Measuring Equipment	

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[organization name]

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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 [AES36]:** Only necessary if the Procedure for Document and Record Control prescribes that paper documents must be signed.