

[Organization logo]

[Organization name]

Commented [9A1]: All fields in this document marked by square brackets [] must be filled in.

PROCEDURE FOR PRODUCTION OF MACHINERY AND EQUIPMENT

Commented [9A2]: If you want to find out more about the product realization process, see:

- article: ISO 9001:2015 clause 8.5 Product realization – Practical examples for compliance

<http://advisera.com/9001academy/blog/2015/11/03/iso-90012015-clause-8-5-product-realization-practical-examples-for-compliance/>

- free online course: ISO 9001 Foundations Course

<http://training.advisera.com/course/iso-90012015-foundations-course/>

Commented [9A3]: Adapt to the existing practice in organization.

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1. Purpose, scope and users

The purpose of this procedure is to describe the process of production of machinery and equipment according to demanded quantity and deadlines, in line with the request for product quality, according to customer request.

The procedure is applied in realization of the production process.

Users of this document are persons responsible for the process of production in [organization name].

2. Reference documents

- ISO 9001:2015 standard clauses 8.5; 8.6
- Procedure for Document and Record Control
- Procedure for Competence, Training and Awareness
- Procedure for Purchasing and Evaluation of Suppliers
- Procedure for Design and Development
- Warehousing Procedure
- Procedure for Management of Nonconformities and Corrective Actions
- Procedure for Equipment Maintenance and Measuring Equipment
- [Work instruction manuals]

Commented [9A5]: List the names of instruction manuals used in this process.

3. Product realization

3.1. Product realization planning

3.1.1. Making production plan

According to demand of products and volume of production in previous period, [CEO] together with [job title] creates [Production Plan].

[Production Plan] defines the following:

- *Availability of information that defines product characteristics*

[Redacted text]

Commented [9A6]: E.g. Product Specification, law and regulatory requirements, instructions, catalogues, etc.

Commented [9A7]: Delete if there is no cyclic production.

Commented [9A8]: E.g. Customer Request, Project Task, etc.

Commented [9A9]: Delete if organization doesn't perform this type of production.

- *Defining resources for production*

[job title] defines all resources needed for production, including human resources,

[Redacted text]

[Job title] creates the Quality Plan, which defines necessary activities of verification, monitoring, measuring, controlling and testing the product.

Commented [9A10]: E.g. Production Manager

- **Availability of [redacted]**

[Job title] is responsible for [redacted]

Commented [9A11]: Work instructions are needed for more complex activities that have precisely defined order of execution operations and/or appropriate measuring is needed. They can be in form of Quality Plans, Flowcharts, drawings, etc.

- **Usage of [redacted]**

[Job title] is responsible to ensure that all equipment is in operational condition and, on [job title] is responsible to ensure that all equipment is in operational condition and, on [redacted]

Commented [9A12]: E.g. Maintenance Operator

Commented [9A13]: E.g. Production Manager

[redacted]

Commented [9A14]: E.g. Head of maintenance department

- **Conducting measuring and monitoring**

[Job title] must ensure availability of monitoring and measuring resources and define the [redacted]

Commented [9A15]: E.g. Production Manager, Technology Engineer, etc.

Commented [9A16]: Other records can be defined as addition to Quality Plan, e.g. records for monitoring temperature, pressure, humidity, etc.

3.1.2. **Creating work order**

For each individual batch, [job title] creates [Work Order] which defines all activities to be executed during production, responsibility for each activity, deadline, as well as raw materials needed.

According to [document name], [job title] makes an internal purchasing order that specifies [redacted]

Commented [9A17]: E.g. Production Plan, Customer Request, Project, etc.

Commented [9A18]: E.g. Production Manager

Commented [9A19]: Delete if clause 8.3 of ISO 9001:2015 is excluded.

Commented [9A20]: E.g. Warehouse Manager

Commented [9A21]: E.g. Production Manager

Commented [9A22]: E.g. Production Manager

Commented [9A23]: All the steps and sub-section can be edited or deleted in order to be aligned with the production process in the company.

Commented [9A24]: This refers to law and legal requirements.

3.2. **Production realization**

Production is executed in controlled working conditions, which implies compliance with all technical [redacted]

3.2.1. **Internal purchase and receipt of raw materials**

According to the Production Plan, [job title] makes internal purchase. After receipt of demanded raw [redacted]

Commented [9A25]: Adapt to organization practice.

3.2.2. Milling

In order to produce a given quantity of parts [job title] sets up the milling machine, plans the tool movements (whether performed manually or by computer), and reads the Program Specification for the milling machine. This job title will complete the milling machine and control the milling process.

Commented [9A26]: Adapt to organization practice.

If defined by Product Specification, the secondary processes may be used to improve the surface finish of the part. The scrap material, in the form of small material chips cut from the workpiece, is collected and sent to the scrap bin in the center of the mill, or the scrap is removed manually. Scrap material may be used to produce the rough material, which can be collected and recycled after the process.

3.2.3. Turning

[job title] sets up the turning machine, plans the tool movements (whether performed manually or by computer), and reads the Program Specification for the turning machine. This job title will complete the turning machine and control the turning process.

Commented [9A27]: Adapt to organization practice.

3.2.4. Threading

[job title] sets up the threading machine and sets up according to the Product Specification. This job title will complete the threading machine and control the threading process.

Commented [9A28]: Adapt to organization practice.

3.2.5. Surface cleaning

To remove this [job title] cleans the surface by blasting. This means a [job title] will use the blasting media to clean the surface of the workpiece. The media may be steel shot, aluminum oxide, or any other media used for blasting.

Commented [9A29]: Adapt to organization practice.

Numerous materials may be used as media, including steel, iron, other metal alloys, aluminum oxide, glass beads, walnut shells, and many others. The media used for blasting is selected based on the surface finish and tolerance of the part surface. The blasting media is used to clean the surface and remove the remaining gate material.

3.2.6. Finishing

Removing the remaining gate material, called a gate stub, is done by [job title] using a grinder or sander. This job title will use the grinder or sander to remove the gate stub material from the surface of the workpiece.

Commented [9A30]: Adapt to organization practice.

3.2.7. Quality control

After production, [job title] samples the products and conducts inspection to determine whether the produced parts meet product requirements defined in Product Specification. If the products pass the inspection, the job title will complete the inspection process and control the inspection process.

3.2.8. Packaging

[job title] receives final products and sends them to packaging which is done by [describe the process].

3.2.9. Identification and traceability

[Job title] must identify the product through the entire production process and define methods of identification and enter them in the Production Registry.

3.2.10. Validation of production and service provision

[Job title] must conduct validation of all processes of production and service provision where:

- [redacted]
- [redacted]

Where appropriate, as part of validation, [job title] must determine:

- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[Job title] creates records needed to [redacted]

[Job title] enters [redacted]

3.2.11. Customer property

[Job title] is responsible for identification, verification, and protection of customer or sub-contractor property that is given for use or implementation in a product or service. If customer or external

[redacted]

3.2.12. Control of changes

[job title] reviews and controls changes for production and service provision in order to ensure

[redacted]

3.2.13. Product release, delivery and activities after delivery

[Job title] is responsible for determining, at appropriate stages, by which degree the product requirements are met regarding Product Specification and customer requirements. If requirements

Commented [9A31]: E.g. serial number, Work order ID, bar code, software ID, expiring date, production date, labeling, accounting documentation, etc.

Commented [9A32]: Delete if there are no processes that require validation; see Quality Manual.

Commented [9A33]: For example lacquer thickness of lacquered wire.

Commented [9A34]: E.g. Welding – techniques for testing welding compactness don't give information about its strength, or when service provision is instant and prevents subsequent testing.

Commented [9A35]: This is entered in Quality Plan.

Commented [9A36]: This is entered in Quality Plan.

Commented [9A37]: This is done when previous validation didn't give expected results.

Commented [9A38]: Adapt to organization.

Commented [9A39]: This can be deleted if organization doesn't use Customer Property. See Quality Manual.

[organization name]

are met, [job title] confirms fulfillment of requirements by signing Record of Product Service

[job title] ensures that the release of products and services to the customer will not proceed until

[Job title] defines the extent of post-delivery activities that are required, considering:

- Statutory and regulatory requirements
- The potential undesired consequences associated with the products and services
- The nature, use, and intended lifetime of the products and services
- Customer requirements
- Customer feedback
- The organization's policies
- The organization's procedures and standards
- The organization's resources
- The organization's capabilities

Commented [9A40]: Adapt to organization's needs.

During servicing activities, [job title] is obligated to initiate correction of non-conformance using the

3.3. Product preservation

[Job title] is responsible for preservation of product during production and service provision and internal transport of product and/or assembly parts.

Commented [9A41]: This should be deleted if organization is only service oriented.

Commented [9A42]: E.g. Production Manager

[Job title] is responsible for preservation of product during production and service provision and internal transport of product and/or assembly parts.

Commented [9A43]: E.g. Warehousing Manager

[Job title] is responsible for preservation of product during transport.

Commented [9A44]: E.g. Driver

3.4. Resolving non-conformities

If a non-conformity of process or product occurs, the person who discovered the non-conformity notifies [job title], who acts according to the Procedure for Managing Nonconformities and Corrective Actions.

[Job title] is responsible for resolving non-conformities and initiating corrective actions according to the Procedure for Managing Nonconformities and Corrective Actions, and for using technology resources.

Commented [9A45]: E.g. Shift Leader

4. Managing records kept on the basis of this document

[organization name]

Record name	Code	Storage			Responsibility
		Retention time	Location	Protection	
Product Specification	PR.10.1	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Record of Product/Service Conformance	PR.10.2	2years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Quality Plan	PR.10.3	2years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Notification to a Customer about Changes on his Property	PR.10.4	2years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Record of Traceability	PR.10.5	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Production/Service Change Review Record	PR.10.6	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Production Plan	PR.10.7	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]
Production Registry	PR.10.8	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location]	[job title]

Commented [9A47]: Adapt the information in this column to the normal practice in your company.

Commented [9A46]: Adapt the information in this column to the normal practice in your company.

Commented [9A48]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A49]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A50]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A51]: This document is unnecessary if organization doesn't store and work with customer property.

Commented [9A52]: If the record is in electronic form, write the name of the folder on Production Manager computer.

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5. Appendices

[organization name]

- Appendix 1 – Product Specification
- Appendix 2 – Record of Product/Service Conformance
- Appendix 3 – Quality Plan
- Appendix 4 – Notification to a Customer about Changes on his Property
- Appendix 5 – Record of Traceability
- Appendix 6 – Production/Service Change Review Record
- Appendix 7 – Production Plan
- Appendix 8 – Production Registry