

[Organization logo]

[Organization name]

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

PROCEDURE FOR MANUFACTURING

Commented [9A2]: If you want to find out more about product realization requirements, 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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Commented [9A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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Date	Version	Created by	Description of change
	0.1	9001Academy	Basic document outline

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1. Purpose, scope and users

The purpose of this procedure is to describe the process of production 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 manufacturing 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].

Commented [9A6]: E.g. Production Manager

[Production Plan] defines the following:

- *Availability of information that defines product characteristics*

In cyclic production, [job title] gathers information about product characteristics from the following sources: [name the sources].

Commented [9A7]: E.g. Product Specification, law and regulatory requirements, instructions, catalogues, etc.

Commented [9A8]: Delete if there is no cyclic production.

Commented [9A9]: E.g. Customer Request, Project Task, etc.

Commented [9A10]: Delete if organization doesn't perform this type of production.

- *Defining resources for production and service provision*

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

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

Commented [9A11]: E.g. Production Manager

- *Availability of [redacted]*

[Job title] is responsible for creation of [redacted]

Commented [9A12]: Work instructions are needed for more [redacted]

- *Usage of adequate equipment*

[Job title] is responsible to ensure that all equipment is [redacted]

Commented [9A13]: E.g. Maintenance Operator

Commented [9A14]: E.g. Production Manager

If requirements for equipment maintenance and working environment are specified by the customer or legal and regulatory requirements, [job title] is responsible for complying with such requirements.

Commented [9A15]: E.g. Head of maintenance department

- *Conducting measuring and monitoring*

[Job title] must ensure availability of monitoring and measuring resources and define the method of the monitoring process and product and methods of sampling and measuring and enter them into the Quality Plan.

Commented [9A16]: E.g. Production Manager, Technology Engineer, etc.

Commented [9A17]: 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 [9A18]: E.g. Production Plan, Customer Request, Project, etc.

Commented [9A19]: E.g. Production Manager

Commented [9A20]: Delete if clause 8.3 of ISO 9001:2015 is excluded.

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

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

Commented [9A23]: E.g. Production Manager

3.2. **Production provision realization**

Production is executed in controlled working conditions, which implies compliance with all technical and technological requirements defined in documents necessary for the production process. If [redacted]

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

3.2.1. *Identification and traceability*

[redacted]

Commented [9A25]: E.g. serial number, Work order ID, bar code, software ID, expiring date, production date, labeling, accounting documentation, etc.

Commented [9A26]: Or Production Registry.

3.2.2. *Validation of production and service provision*

Commented [9A27]: Delete if there are no processes that require validation; see Quality Manual.

[organization name]

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

- It is not possible to confirm by measurement that a product or service satisfies customer request

Commented [9A28]: For example lacquer thickness of lacquered wire.

Commented [9A29]: 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.

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

- Criteria for review and approval of process

Commented [9A30]: This is entered in Quality Plan.

Commented [9A31]: This is entered in Quality Plan.

Commented [9A32]: This is done when previous validation didn't give expected results.

Commented [9A33]: Adapt to organization.

[Job title] creates records needed to provide evidence that realization processes and resulting products meet predefined requests.

[Job title] enters

3.2.3. Customer property

Commented [9A34]: This can be deleted if organization doesn't use Customer Property. See Quality Manual.

[Job title] is responsible for identification, verification, and protection of customer or external

3.2.4. Control of changes

[job title] reviews and controls changes for production and service provision in order to ensure continuing conformity with the requirements and enters changes in the Production/Service Change Review Record.

3.2.5. 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

[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

[organization name]

- The potential undesired consequences associated with the products and services
- The nature, use, and intended lifetime of the products and services
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Commented [9A35]: Adapt to organization's needs.

During servicing activities, [job title] is obligated to initiate correction of non-conformance using the Procedure for Control of Non-Conforming Product for every non-conformity of product or service. If repair is executed within the warranty period, it is treated as non-conformity and dealt with as such.

3.3. Product preservation

Commented [9A36]: This should be deleted if organization is only service oriented.

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

Commented [9A37]: E.g. Production Manager

[redacted]

Commented [9A38]: E.g. Warehousing Manager

[redacted]

Commented [9A39]: 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 Control of Non-Conforming Product.

[redacted]

Commented [9A40]: E.g. Shift Leader

4. Managing records kept on the basis of this document

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	PR.10.2	2years	[office of Production	Records are stored in file	[job title]

Commented [9A42]: Adapt the information in this column to the normal practice in your company.

Commented [9A41]: Adapt the information in this column to the normal practice in your company.

Commented [9A43]: If the record is in electronic form, write the name of the folder on Production Manager computer.

[organization name]

Conformance			Manager]	cabinet [describe name/location]	
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 [9A44]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A45]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A46]: This document is unnecessary if organization doesn't store and work with customer property.

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

5. Appendices

- Appendix 1 – Product Specification
- Appendix 2 – Record of Product/Service Conformance
- Appendix 3 – Quality Plan

[organization name]

- 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