$\cap$	ras	ani	72	tio	n		TO
ıv	180	7 I II	L۵	uu		IU:	ίU

**Commented [9100A1]:** All fields in this document marked by square brackets [] must be filled in.

# PROCEDURE FOR PRODUCTION OF MACHINERY AND EQUIPMENT

Commented [9100A2]: If you want to find out more about production and service provision, see this 9001Academy article: Understanding Product & Service Provision in ISO 9001 http://advisera.com/9001academy/blog/2014/10/07/understanding.product-service-provision-iso-9001/

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

**Commented [9100A3]:** Adapt to the existing practice in organization.

# Distribution list

Сору	Distributed to	Date Signature	Signaturo	Returned	
No.	Distributed to		Signature	Date	Signature

**Commented [9100A4]:** This is only necessary if document is in paper form; otherwise, this table should be deleted.

©2017 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License Agreement.

# **Change history**

Date	Version	Created by	Description of change
	0.1	9100Academy	Basic document outline

# **Table of contents**

1.	PUR	POSE,	SCOPE AND USERS	.3
2.	REFE	RENC	E DOCUMENTS	.3
3.	PRO	DUCT	REALIZATION	.3
3	.1.	Prod	UCT REALIZATION PLANNING	3
	3.1.1	1.	Making production plan	3
	3.1.2		Creating work order	
3	.2.	Produ	UCTION REALIZATION	4
	3.2.1	1.	Internal purchase and receipt of raw materials	5
	3.2.2	2.	Milling	5
	3.2.3	3.	Turning	5
	3.2.4	1.	Threading	5
	3.2.5	5.	Surface cleaning	5
	3.2.6	<b>5</b> .	Finishing	6
	3.2.7	7.	Quality control	6
	3.2.8	3.	Packaging	6
	3.2.9	9.	Identification and traceability	6
	3.2.1		Validation of production and service provision	
	3.2.1	11.	Customer property	7
	3.2.1	12.	Control of changes	7
	3.2.1	13.	Product release, delivery and activities after delivery	7
3	.3.	PROD	UCT PRESERVATION	8
3	.4.	RESOL	VING NON-CONFORMITIES	8
4.	MAN	NAGIN	G RECORDS KEPT ON THE BASIS OF THIS DOCUMENT	.8
5.	APPI	ENDIC	FS	0

Procedure for Production of Machinery and Equipment

ver. [version] from [date]

Page **2** of **10** 

# 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

- AS9100 Rev D 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]

3. Product realization

# 3.1. Product realization planning

# 3.1.1. Making production plan

According to demand of products and volume of [job title] creates [Production Plan].

Availability of information that defines product characteristics

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

Defining resources for production

**Commented [9100A5]:** List the names of instruction manuals used in this process.

 $\textbf{Commented [9100A6]:} \ \ \textbf{Delete if there is no cyclic production}.$ 

**Commented [9100A7]:** E.g. Product Specification, law and regulatory requirements, instructions, catalogues, etc.

 $\begin{tabular}{ll} \textbf{Commented [9100A8]:} & \textbf{Delete if organization doesn't perform this type of production.} \end{tabular}$ 

Commented [9100A9]: E.g. Customer Request, Project Task, etc.

Procedure for Production of Machinery and Equipment

ver. [version] from [date]

Page **3** of **10** 

©2017 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License

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

[Job title] creates the Quality Plan, which defines necessary activities of verification,

Availability of work instructions

Usage of adequate equipment

[Job title] is responsible to ensure that all equipment is in operational condition and, on [job title]'s request, deliver evidence of execution of the Plan for Preventive Equipment

Maintenance and records of calibration and repairs of measuring equipment.

If requirements for equipment maintenance and working environment are specified by the

• 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.

[Job title] ensures that any documented information for monitoring and measurement

are to be retained, and any specific equipment required and instructions for use.

[Job title] must ensure that when sampling is used the sampling plan is justified on the basis of a recognized statistical principles and appropriate for use.

# 3.1.2. Creating work order

For each individual batch, [job title] creates [Work Order] which defines all activities to be executed

According to [document name], [job title] makes an internal purchasing order that specifies the Project Plan, and delivers it to [job title]. [Job title] defines which work instructions will be applied are stated in the Product Specification made by [job title].

# 3.2. Production realization

Procedure for Production of Machinery and Equipment

ver. [version] from [date]

Page **4** of **10** 

© 2017 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License Agreement. Commented [9100A10]: E.g. Production Manager

**Commented [9100A11]:** 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.

Commented [9100A12]: E.g. Maintenance Operator

Commented [9100A13]: E.g. Production Manager

Commented [9100A14]: E.g. Head of maintenance

**Commented [9100A15]:** E.g. Production Manager, Technology Engineer, etc.

**Commented [9100A16]:** Other records can be defined as addition to Quality Plan, e.g. records for monitoring temperature, pressure, humidity, etc.

**Commented [AS910017]:** E.g. Production Manager, Technology Engineer, etc.

Commented [AS910018]: E.g. pass/fail, etc.

**Commented [AS910019]:** E.g. Production Manager, Technology Engineer, etc.

**Commented [9100A20]:** E.g. Production Plan, Customer Request, Project, etc.

Commented [9100A21]: E.g. Production Manager

**Commented [9100A22]:** Delete if clause 8.3 of AS9100 Rev D is excluded.

Commented [9100A23]: E.g. Warehouse Manager

Commented [9100A24]: E.g. Production Manager

Commented [9100A25]: E.g. Production Manager

**Commented [9100A26]:** All the steps and sub-section can be edited or deleted in order to be aligned with the production process in the company.

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

Commented [9100A27]: This refers to law and legal

materials are entered in Production Registry by [job title]. [Job title] ensures that products are never completed and conforming.

#### 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

Commented [9100A28]: 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 milling machine. Then, [job title] loads workpiece into milling machine and controls the milling process.

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

discarded after the production.

Commented [9100A29]: Adapt to organization practice.

# 3.2.3. Turning

[Job title] sets up the turning machine, plans the tool movements (whether performed manually or into turning machine and controls the turning process.

Commented [9100A30]: Adapt to organization practice.

### 3.2.4. Threading

[Job title] prepares threading machine and sets it up according to the Product Specification. Once the

Commented [9100A31]: Adapt to organization practice.

# 3.2.5. Surface cleaning

To remove this [job title] cleans the surface by blasting. This means a granular media will be media may be blown with compressed air, or may be hurled using a shot wheel.

Numerous materials may be used as media, including steel, iron, other metal alloys, aluminum

Commented [9100A32]: Adapt to organization practice.

Procedure for Production of Machinery and Equipment

ver. [version] from [date]

Page **5** of **10** 

©2017 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License Agreement.

to develop the color and reflectance of the cast surface. Shot peening may be used by [job title] to further work-harden and finish the surface.

#### 3.2.6. Finishing

Removing the remaining gate material, called a gate stub, is done by [job title] using a grinder or

#### 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

products and are handled according to the Procedure for Managing Nonconformities and Corrective Actions.

#### 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

configuration management practices defined in the Procedure for Production and Service Provision enter identification data in the Record of Traceability, identifying differences between the actual Record of Product-Service Configuration.

# 3.2.10. Validation of production and service provision

[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

Processes that fall under at least one of above conditions are defined as Special Processes and the results of their validation are recorded on the Record of Validation of Product Process and Special Process.

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

- Equipment, facilities, and personnel approval and qualification needed for process

Procedure for Production of Machinery and Equipment

ver. [version] from [date]

Page 6 of 10

© 2017 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License

Commented [9100A33]: Adapt to organization practice.

Commented [9100A34]: Or Production Registry.

Commented [9100A35]: Delete if there are no processes that require validation; see Quality Manual.

Commented [9100A36]: For example lacquer thickness of

Commented [9100A37]: E.g. Welding – techniques for testing

Commented [AS910038]: E.g. necessary training and re-

Special work instructions

•

Records needed to provide evidence of controlling parameter

•

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

[Job title] enters data about validation in the Production Plan, which demonstrates the capability of

Processes on the Record of Validation of Production Process and Special Process, which demonstrates the capability of the process to accomplish planned results.

[Job title] obtains data from a representative item from the first production run of a new batch to

original results.

#### 3.2.11. Customer property

[Job title] is responsible for identification, verification, and protection of customer or sub-contractor

owner using Notification to Customer about Changes on His Property.

# 3.2.12. 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.

### 3.2.13. 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 signing Record of Product Service

Conformance and approving shipment. Products that don't meet the requirements are handled according to the Procedure for Managing Nonconformities and Corrective Actions.

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

[Job title] ensures that all documented information required to accompany the products and services are present at delivery.

Procedure for Production of Machinery and ver. [version] from [date] Page **7** of **10**Equipment

©2017 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License

Commented [9100A39]: This is entered in Quality Plan.

**Commented [AS910040]:** E.g. Statistical measurement controls, detailed implementation procedures, etc.

Commented [9100A41]: This is entered in Quality Plan.

**Commented [9100A42]:** This is done when previous validation didn't give expected results, or when validation needs to be done on a routine basis.

Commented [9100A43]: Adapt to organization.

**Commented [AS910044]:** This is often called first article inspection.

**Commented [9100A45]:** This can be deleted if organization doesn't use Customer Property. See Quality Manual.

- Statutory and regulatory requirements
- •
- Customer requirementsCustomer feedback
- .
- •
- Controls required for work undertaken external to the organization
- Product/customer support
- The same of the same of the same of
- •
- •
- Preparing servicing instructions
- Records about servicing activities

During servicing activities, [job title] is obligated to initiate correction of non-conformance using the Procedure for Management of Nonconformities and Corrective Actions for every non-conformity of

### 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.

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

# 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 Management of Nonconformities and Corrective Actions.

production process and acts according to the Procedure for Management of Nonconformities and Corrective Actions, but can't change technological parameters.

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

Record name	Code	Storage	Responsibility
Procedure for Production of Machinery and		ver. [version] from [date]	Page <b>8</b> of <b>10</b>
Equipment			

©2017 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License

Commented [AS910046]: E.g. off-site work

Commented [9100A47]: Adapt to organization's needs.

Commented [9100A48]: E.g. Production Manager

Commented [9100A49]: E.g. Warehousing Manager

Commented [9100A50]: E.g. Driver

Commented [9100A51]: E.g. Shift Leader

		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	2 years	[office of Production Manager ]	Records are stored in file cabinet [describe name/location]	[job title]
Quality Plan	PR.10.3	2 years	[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	2 years	[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]
Record of Validation of Product Process and Special Process	PR.10.9	2 years	[office of Production Manager ]	Records are stored in file cabinet [describe name/location	[job title]
Record of Product- Service Configuration	PR.10.10	2 years	[office of Production Manager ]	Records are stored in file cabinet [describe name/location	[job title]
Production Plan	PR.10.17	2 years	[office of Production Manager]	Records are stored in file cabinet [describe	[job title]

Procedure for Production of Machinery and Equipment

ver. [version] from [date]

Page **9** of **10** 

©2017 This template may be used by clients of Advisera Expert Solutions Ltd. www.advisera.com in accordance with the License

Commented [9100A53]: If the records in this column are in electronic form, write the name of the folder on Production Manager computer.

**Commented [9100A54]:** Adapt the information in this column to the normal practice in your company.

**Commented [9100A52]:** Adapt the information in this column to the normal practice in your company.

**Commented [9100A55]:** This document is unnecessary if organization doesn't store and work with customer property.

				name/location	
Production Registry	PR.10.18	2 years	[office of Production Manager]	Records are stored in file cabinet [describe name/location	[job title]

# 5. Appendices

- 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 9 Record of Validation of Product Process and Special Process
- Appendix 10 Record of Product-Service Configuration
- Appendix 17 Production Plan
- Appendix 18 Production Registry