

[Organization logo]

[Organization name]

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

PROCEDURE FOR PRODUCTION OF CHEMICAL PRODUCTS

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/>

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Commented [9100A3]: 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 chemicals 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
- [Working instruction manuals]

Commented [9100A5]: 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 [9100A6]: E.g. Production Manager

Production Plan defines the following:

- Availability of resources that define product characteristics
In cyclic production, [job title] gathers information about product characteristics from the following sources: [name the sources].

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

Commented [9100A8]: Delete if there is no cyclic production.

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

- Defining resources for production and service provision

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

for defining need for training.

Commented [9100A10]: Delete if organization doesn't perform this type of production.

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

Commented [9100A11]: E.g. Production Manager

- [redacted]

[Job title] is responsible for creation of work instructions for the following process activities:
[list the names of working instruction for each activity].

Commented [9100A12]: Working instructions are needed for

- [redacted]

[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.

Commented [9100A13]: E.g. Maintenance Operator

Commented [9100A14]: E.g. Production Manager

[redacted] such requirements.

Commented [9100A15]: E.g. Head of maintenance department

- *Conducting measuring and monitoring*

[Job title] must ensure availability of monitoring and measuring resources and define the [redacted] enter them into the Quality Plan.

Commented [9100A16]: E.g. Production Manager, Technology Engineer, etc.

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

Commented [9100A17]: Other records can be defined as addition to Quality Plan, e.g. records for monitoring temperature, pressure, humidity, etc.

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

Commented [AS910018]: E.g. Production Manager, Technology Engineer, etc.

Commented [AS910019]: E.g. pass/fail, etc.

[Job title] must ensure that when sampling is used the sampling plan is justified on the basis

Commented [AS910020]: E.g. Production Manager, Technology Engineer, etc.

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

Commented [9100A21]: E.g. Production Plan, Customer Request, Project, etc.

the Production Plan, and delivers it to [job title]. [Job title] defines which working instructions will be

Commented [9100A22]: E.g. Production Manager

product are stated in the Product Specification made by [job title].

Commented [9100A23]: Delete if clause 8.3 of AS9100 Rev D is excluded.

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

3.2. Production provision realization

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

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

Commented [9100A26]: E.g. Production Manager

reestablishment of proper working conditions. All activities, necessary work instructions and raw

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

[organization name]

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

3.2.1. Internal purchase and receipt of raw materials

According to the Production Plan and Production Registry, [job title] makes internal purchase. After
[redacted]
received quantity meets demand, [job title] sends raw materials to production.

3.2.2. Production of plastic semi-product

[Job title] receives the raw plastics in form of as granules, pellets, or powder. The raw plastic is then
[redacted]
[redacted]

3.2.3. Reacting the raw materials

Based on Product Specification, [job title] feeds the hopper with raw materials while [job title]
[redacted]
[name of document].

3.2.4. Filtration

[Job title] pours the compound into a filter in order to remove any trace levels of catalyst. If the
[redacted]
[redacted]

3.2.5. Concentration

The compound is concentrated using [redacted] [redacted] of the [redacted] [redacted] the
concentration according to the Product Specification. [Job title] is responsible for monitoring this
process.

3.2.6. Granulation

[Job title] pours the compound on the one side and the seed granules on the other side into
[redacted]
[redacted]
granules and combines them with undersized ones for use as seed.

[Job title] oversees the removal of all dust and air from the granulator by a fan into a dust scrubber,
[redacted]
[redacted]
The final product is cooled in air, [job title] weighs it and conveys to bulk storage ready for sale.

3.2.7. Packaging and storing

[redacted] Procedure for
Managing Nonconformities and Corrective Actions. Once the product is finished [job title] sends it to
warehouse for final products.

Commented [9100A28]: Adapt to organization practice.

Commented [9100A29]: Adapt to organization practice.

Commented [9100A30]: Adapt to organization practice.

Commented [9100A31]: Adapt to organization practice.

Commented [9100A32]: Adapt to organization practice.

Commented [9100A33]: Adapt to organization practice.

3.2.8. 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 configuration and the required configuration on the Record of Product-Service Configuration.

Commented [9100A34]: Or Production Registry.

3.2.9. Validation of production and service provision

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

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

Commented [9100A36]: For example laboratorial testing of the compound.

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:

- Criteria for review and approval of process
- Special working instructions
- Records needed to provide evidence of controlling parameter

Commented [AS910037]: E.g. necessary training and re-

Commented [9100A38]: This is entered in Quality Plan.

Commented [AS910039]: E.g. Statistical measurement controls, detailed implementation procedures, etc.

Commented [9100A40]: This is entered in Quality Plan.

Commented [9100A41]: This is done when previous validation didn't give expected results, or when validation needs to be done on a routine basis.

Commented [9100A42]: Adapt to organization.

[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 Special Processes on the Record of Validation of Production Process and Special Process, which

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

Commented [AS910043]: This is often called first article inspection.

3.2.10. Customer property

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

Commented [9100A44]: This can be deleted if organization doesn't use Customer Property. See Quality Manual.

[organization name]

provider property is lost, damaged, or in some other way unfit for use, [job title] notifies the property owner using Notification to Customer about Changes on His Property.

3.2.11. Control of changes

[Job title] reviews [redacted] the requirements and enters changes in the Production/Service Change Review Record.

3.2.12. 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 [redacted] Record of Product Service Conformance and approving shipment. Products that don't meet the requirements are handled according to the Procedure for Control of Non-Conforming Product and Procedure for Corrective and Preventive Actions.

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

[Job title] ensures that all documented [redacted] are present at delivery.

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

- Statutory and regulatory requirements
- [redacted]
- [redacted]
- Customer requirements
- [redacted]
- [redacted]
- Control, updating and provision of technical documentation relating to product use, maintenance, repair and overhaul
- [redacted]
- Product/customer support
- [redacted]
- [redacted]
- [redacted]
- Preparing servicing instructions
- Records about servicing activities

Commented [AS910045]: E.g. off-site work

Commented [9100A46]: Adapt to organization's needs.

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 [redacted]

[organization name]

3.3. Product preservation

[Job title] is responsible for preservation of product during production and internal transport of

Commented [9100A47]: E.g. Production Manager

During storage, [job title] is responsible for preservation of product during storage and/or assembly parts before delivery to a customer according to Warehousing Procedure.

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

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

Commented [9100A49]: E.g. Driver

3.4. Resolving non-conformities

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.

Commented [9100A50]: 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 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]

Commented [9100A52]: If the records in this column are in electronic form, write the name of the folder on Production Manager computer.

Commented [9100A53]: Adapt the information in this column to the normal practice in your company.

Commented [9100A51]: Adapt the information in this column to the normal practice in your company.

Commented [9100A54]: This document is unnecessary if organization doesn't store and work with customer property.

[organization name]

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 name/location	[job title]
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