[Organization logo]

[Organization name]

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

PROCEDURE FOR PRODUCTION OF RUBBER AND PLASTICS

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

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

Copy No.	Distributed to	Date	Signature	Returned	
				Date	Signature

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Change history

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

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1. Purpose, scope and users

The purpose of this procedure is to describe the process of production of rubber and plastics 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 information that defines product characteristics*

  [illegible]

  For project-based production and individual production according to customer request, [illegible]

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.

Commented [9100A10]: 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 human resources, [illegible]

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

- [illegible]

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

- *Usage of adequate equipment*

  [illegible] 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 [illegible] is responsible for complying with such requirements.

- *Measuring and monitoring resources*

  [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 [illegible] 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 [illegible]

According to [document name], [job title] makes an internal purchasing order that specifies [illegible] the Project Plan, and delivers it to [job title]. [Job title] defines which working instructions will be applied during product realization. Quality objectives, [illegible] Product Specification made by [job title].

3.2. Production of rubber and plastics

Production is executed in controlled working conditions, which implies compliance with all technical [illegible] reestablishment of proper working conditions. [Job title] ensures that products are never released

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

Commented [9100A12]: Working instructions are needed for [illegible]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Commented [9100A27]: All the steps and sub-sections can be edited or deleted in order to be aligned with the production process in the company.

Commented [9100A28]: This refers to law and legal requirements.

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for subsequent production unless all required measuring and monitoring activities are completed and conforming.

3.2.1. *Internal purchasing and receipt of raw materials*

According to the Production Plan, [job title] makes internal purchase. After receipt of demanded raw materials, [job title] inspects quantity of received raw materials and if the received quantity meets demand, [job title] sends raw materials to production.

3.2.2. *Extrusion*

Commented [9100A29]: Adapt to organization practice.

Plastic material as granules, pellets, or powder, is first loaded by [job title] into a hopper and then fed into a long heated chamber through which it is moved by the action of a continuously revolving screw.

3.2.3. *Calendering*

Commented [9100A30]: Adapt to organization practice.

[Job title] sends the film created by extrusion to further extrusion. The still warm extrudate is chilled on polished, cold rolls to create sheet according to Product Specification.

Commented [9100A31]: E.g. From 0.005 inches thick to 0.500 inches thick.

3.2.4. *Film Blowing*

Commented [9100A32]: Adapt to organization practice.

[Job title] feeds the machine that continuously extrudes vertically a ring of semi-molten polymer in an upward direction. [Job title] oversees that the tube produced is cooled by air and is nipped and wound continuously as a flattened tube.

3.2.5. *Injection Molding*

Commented [9100A33]: Adapt to organization practice.

[Job title] feds the plastic material into hopper, which feeds into an extruder. An extruder screw pushes the plastic through the heating chamber in which the material is then melted. At the end of the extruder the molten plastic is forced at high pressure into a closed cold mold. Once the plastic cools to a solid, [job title] opens the mold and the finished product is ejected. [Job title] can add special catalysts to create the thermoset plastic products during the processing, such as cured silicone rubber parts.

3.2.6. *Blow Molding*

Commented [9100A34]: Adapt to organization practice.

The die forms a continuous semi-molten tube of thermoplastic material. [Job title] clamps a chilled mold around the tube and compressed air is then blown into the tube to conform the tube to the interior of the mold and to solidify the stretched tube.

3.2.7. *Expanded Bead Blowing*

Commented [9100A35]: Adapt to organization practice.

[Job title] places measured volume of beads of plastic into a mold. The beads contain a blowing agent or gas, dissolved in the plastic.

3.2.7.1. *Rotational Molding*

Commented [9100A36]: Adapt to organization practice.

[Job title] mounts a mold on a [machine capable of rotating on two axes simultaneously]. [Job title] places solid or liquid resin within the mold and heat is applied. Rotation distributes the plastic into a

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uniform coating on the inside of the mold then the mold is cooled until the plastic part cools and hardens.

3.2.8. Compression Molding

[Job title] prepares a volume of plastic and places it into a mold cavity and then a second mold or [illegible] is applied to squeeze the plastic into the desired shape.

3.2.9. Thermoforming

[Job title] heats films of thermoplastic to soften the film, and then the soft film is pulled by vacuum [illegible] finished parts from the sheet and the scrap sheet material is recycled for manufacture of new sheet.

3.2.10. Identification and traceability

[Job title] must identify the product [illegible] according the Configuration Management practices defined in the Procedure For Production and Service Provision enter identification data in the Record of Traceability , identifying differences [illegible] configuration on the Record of Product-Service Configuration.

3.2.11. Validation of production

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

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

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:

- [illegible]
- [illegible]
- [illegible]
- Special working instructions
- [illegible]
- Records needed to provide evidence of controlling parameter
- Need for revalidation

Commented [9100A37]: Adapt to organization practice.

Commented [9100A38]: Adapt to organization practice.

Commented [9100A39]: E.g. over 0.100 inches

Commented [9100A40]: Or Production Registry.

Commented [9100A41]: For example lacquer thickness of lacquered wire.

Commented [9100A42]: E.g. Welding – techniques for testing [illegible]

Commented [AS910043]: E.g. necessary training and re-[illegible]

Commented [9100A44]: This is entered in Quality Plan.

Commented [AS910045]: E.g. Statistical measurement controls, detailed implementation procedures, etc.

Commented [9100A46]: This is entered in Quality Plan.

Commented [9100A47]: This is done when previous validation didn't give expected results, or when validation needs to be done on a routine basis.

Commented [9100A48]: Adapt to organization.

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

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

Commented [AS910049]: This is often called first article inspection.

3.2.12. Customer property

Commented [9100A50]: 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 sub-contractor [illegible] using Notification to Customer about Changes on His Property.

3.2.13. Control of changes

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

3.2.14. Product release, delivery and activities after delivery

[Job title] is [illegible] requirements are met regarding Product Specification and customer requirements. If requirements are met, [job title] confirms fulfillment of requirements by 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 [illegible]

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

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

- Statutory and regulatory requirements
- [illegible]
- [illegible]
- Customer requirements
- Customer feedback
- [illegible]

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- [illegible]
- Controls required for work undertaken external to the organization
- Product/customer support
- [illegible]
- [illegible]
- [illegible]
- Preparing servicing instructions
- Records about servicing activities

Commented [AS910051]: E.g. off-site work

Commented [9100A52]: 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 [illegible]

3.3. Product preservation

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

Commented [9100A53]: E.g. Production Manager

[illegible] and/or assembly parts before delivery to a customer according to Warehousing Procedure.

Commented [9100A54]: E.g. Warehousing Manager

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

Commented [9100A55]: E.g. Driver

3.4. Resolving non-conformities

If a non-conformity of process or product occurs, the person who discovered the non-conformity [illegible] Procedure for Management of Nonconformities and Corrective Actions.

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

Commented [9100A56]: 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]

Commented [9100A58]: If the records in this column are in electronic form, write the name of the folder on Production Manager computer.

Commented [9100A59]: Adapt the information in this column to the normal practice in your company.

Commented [9100A57]: Adapt the information in this column to the normal practice in your company.

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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.10.7	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 [9100A60]: This document is unnecessary if organization doesn't store and work with customer property.

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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

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