

[Organization logo]

[Organization name]

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

PROCEDURE FOR PRODUCTION OF RUBBER AND PLASTICS

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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Distribution list

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Change history

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

Table of contents

1. PURPOSE, SCOPE AND USERS	3
2. REFERENCE DOCUMENTS	3
3. PRODUCT REALIZATION	3
3.1. PRODUCT REALIZATION PLANNING.....	3
3.1.1. Making production plan.....	3
3.1.2. Creating work order	4
3.2. PRODUCTION OF RUBBER AND PLASTICS	4
3.2.1. Internal purchasing and receipt of raw materials	4
3.2.2. Extrusion	4
3.2.3. Calendering	5
3.2.4. Film Blowing	5
3.2.5. Injection Molding	5
3.2.6. Blow Molding	5
3.2.7. Expanded Bead Blowing.....	5
3.2.7.1. Rotational Molding	5
3.2.8. Compression Molding	5
3.2.9. Thermoforming	5
3.2.10. Identification and traceability.....	6
3.2.11. Validation of production	6
3.2.12. Customer property	6
3.2.13. Control of changes	6
3.2.14. Product release, delivery and activities after delivery	6
3.3. PRODUCT PRESERVATION	7
3.4. RESOLVING NON-CONFORMITIES.....	7
4. MANAGING RECORDS KEPT ON THE BASIS OF THIS DOCUMENT	7
5. APPENDICES	8

The procedure is applied in realization of the production process.

Commented [9A5]: Delete if organization doesn't provide services.

2. Reference documents

- Commented [9A6]:** List the names of instruction manuals used in this process.

3. Product realization

3.1. Product realization planning

3.1.1. Making production plan

Commented [9A7]: E.g. Production Manager

[Production Plan] defines the following:

- *Availability of information that defines product characteristics*

Commented [9A8]: E.g. Product Specification, law and regulatory requirements, instructions, catalogues, etc.

Commented [9A9]: Delete if there is no cyclic production.

Commented [9A10]: E.g. Customer Request, Project Task, etc.

Commented [9A11]: 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.

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

Commented [9A12]: E.g. Production Manager

- *Availability of*

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

Commented [9A13]: Working 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

Commented [9A14]: E.g. Maintenance Operator

Commented [9A15]: E.g. Production Manager

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

Commented [9A16]: E.g. Head of maintenance department

- *Measuring and monitoring resources*

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

Commented [9A17]: E.g. Production Manager, Technology Engineer, etc.

Commented [9A18]: 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 [ANSI Z39.18-2012](#), make an internal purchasing order that specifies quantities of raw material and other resources needed for production of product or [ANSI Z39.18-2012](#) [ISO 9001:2015](#), and deliver it to [ANSI Z39.18-2012](#) address. When working instructions will be applied during product realization, quality objectives, requests for product and criteria for accepting product are stated in the Product Specification made by [ANSI Z39.18-2012](#).

Commented [9A19]: E.g. Production Plan, Customer Request, Project, etc.

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

Commented [9A21]: Delete if clause 8.3 of ISO 9001:2015 is excluded.

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

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

Commented [9A24]: E.g. Production Manager

Commented [9A25]: All the steps and sub-sections can be edited or deleted in order to be aligned with the production process in the company.

Commented [9A26]: This refers to law and legal requirements.

3.2. Production of rubber and plastics

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

creation of working conditions issues, job design is integral to stop the production process until reestablishment of proper working conditions.

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

Source: *U.S. Census Bureau, Bureau of Economic Analysis, "GDP by Sector of the U.S. Economy,"* <http://www.bea.gov/gdp/gdpsectors.htm>.

3.2.2. Extrusion

Commented [9A27]: Adapt to organization practice.

[organization name]

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**

[job title] sends the plastic material to a calender. The calender consists of a series of rollers that pass the material over them to produce a smooth, uniform thickness.

3.2.4. **Film Blowing**

[job title] feeds the machine that continuously extrudes vertically a ring of semi-molten polymer in the form of a parison. The parison is then blown into a bubble by air pressure and then passes through a series of rollers to produce a uniform thickness.

3.2.5. **Injection Molding**

[job title] feeds 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 heating chamber, the material is injected into a mold cavity. The material then fills the cavity and solidifies as it cools. The finished part is then ejected from the mold.

3.2.6. **Blow Molding**

The die forms a continuous semi-molten tube of thermoplastic material. [job title] clamps a chilled die around the tube to form a parison. The parison is then blown into a bubble by air pressure and then passes through a series of rollers to produce a uniform thickness.

3.2.7. **Expanded Bead Blowing**

[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**

[job title] mounts a mold on a [machine capable of rotating on two axes simultaneously]. [job title] places plastic material in the mold and then rotates the mold around two axes to form a uniform thickness.

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 plug is pressed into the plastic to form a uniform thickness.

3.2.9. **Thermoforming**

[job title] heats films of thermoplastic to soften the film, and then the soft film is pulled by vacuum or pushed by pressure to conform to a mold or pressed with a plug into a mold. Parts are

Commented [9A28]: Adapt to organization practice.

Commented [9A29]: From 0.005 inches thick to 0.500 inches thick.

Commented [9A30]: Adapt to organization practice.

Commented [9A31]: Adapt to organization practice.

Commented [9A32]: Adapt to organization practice.

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Commented [9A36]: Adapt to organization practice.

[organization name]

[Redacted text]

Commented [9A37]: over 0.100 inches

3.2.10. Identification and traceability

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

Commented [9A38]: E.g. serial number, Working order ID, bar code, software ID, expiring date, production date, labeling, accounting documentation, etc.

Commented [9A39]: Or Production Registry.

3.2.11. Validation of production

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

- [Redacted text]
- [Redacted text]

Commented [9A40]: For example lacquer thickness of lacquered wire.

Commented [9A41]: 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
- [Redacted text]
- [Redacted text]
- [Redacted text]
- [Redacted text]

Commented [9A42]: This is entered in Quality Plan.

Commented [9A43]: This is entered in Quality Plan.

Commented [9A44]: This is done when previous validation didn't give expected results.

Commented [9A45]: Adapt to organization.

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

[Redacted text]

3.2.12. Customer property

Commented [9A46]: 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

[Redacted text]

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 responsible for determining, at appropriate stages, by which degree the product

[Redacted text]

[organization name]

[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 type of product
- The type of service
- The type of customer
- The type of environment
- The type of distribution

Commented [9A47]: 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 internal transport of product and/or assembly parts.

Commented [9A48]: This should be deleted if organization is only service oriented.

Commented [9A49]: E.g. Production Manager

Commented [9A50]: E.g. Warehousing Manager

Commented [9A51]: 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.

Commented [9A52]: E.g. Shift Leader

4. Managing records kept on the basis of this document

Record name	Code	Storage			Responsibility
		Retention time	Location	Protection	

Commented [9A54]: Adapt the information in this column to the normal practice in your company.

Commented [9A53]: Adapt the information in this column to the normal practice in your company.

[organization name]

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 [9A55]: If the record is in electronic form, write the name of the folder on Production Manager computer.

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Commented [9A57]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A58]: This document is unnecessary if organization doesn't store and work with customer property.

Commented [9A59]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A60]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A61]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A62]: If the record is in electronic form, write the name of the folder on Production Manager computer.

Commented [9A63]: 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
- Appendix 4 – Notification to a Customer about Changes on his Property

[organization name]

- Appendix 5 – Record of Traceability
- Appendix 6 – Production/Service Change Review Record
- Appendix 7 – Production Plan
- Appendix 8 – Production Registry