

[Organization logo]

[Organization name]

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PRODUCT SAFETY PROCEDURE

Commented [16A2]: If you want to find out more about product safety, see:
Ensuring product safety according to IATF 16949
<https://advisera.com/16949academy/blog/2017/09/20/ensuring-product-safety-according-to-iatf-16949/>

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Table of contents

1. PURPOSE, SCOPE AND USERS	3
2. REFERENCE DOCUMENTS	3
3. PRODUCT SAFETY PROCESS	3
3.1. IDENTIFICATION OF PRODUCT SAFETY REQUIREMENTS	3
3.2. IDENTIFICATION OF PRODUCT SAFETY CHARACTERISTICS	3
3.3. DETERMINING AND IMPLEMENTING PRODUCT SAFETY CONTROLS	4
3.4. PRODUCT SAFETY TESTING	4
3.5. IMPLEMENTATION OF LESSONS LEARNED	5
4. MANAGING RECORDS KEPT ACCORDING TO THIS DOCUMENT	5
5. APPENDICES	5

1. Purpose, scope and users

The purpose of this procedure is to define processes for the management of product safety-related products and manufacturing processes in order to ensure the product performs according to its designated purpose without causing harm or damages.

The procedure is applied to all processes that have or can potentially have product safety-related issues.

Users of this document are the process owners of [organization name] within the scope of the QMS (Quality Management System).

2. Reference documents

- IATF 16949:2015, clause 4.4.1.2
- Quality Manual
- Procedure for Determining Context of the Organization and Interested Parties
- Procedure for Competence Training and Awareness
- Procedure for FMEA Risks Assessment
- Procedure for Design and Development
- Production Part Approval Process Procedure
- Procedure for Purchasing and Evaluation of Suppliers
- Procedure for Production and Service Provision
- Procedure for Management of Nonconformities and Corrective Actions

3. Product safety process

3.1. Identification of product safety requirements

When determining statutory and legal requirements as part of the identification of interested parties

and their needs and expectations, all the needs and expectations of interested parties (customers, suppliers, regulatory bodies) related to the product safety according to the Procedure for Determining Context of the Organization and Interested Parties and other than the list of Interested Parties and

Requirements.

In case of development of new products or new production processes, [job title] needs to identify all

product safety requirements and regulatory requirements and other than a Product Safety according to Procedure for Design and Development.

[Job title] is responsible for defining a method of notification to the customer about the product

safety-related characteristics of the product.

3.2. Identification of product safety characteristics

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[organization name]

When defining new product or processes to be designed and developed, [job title] must identify product safety-related characteristics of the products by including product safety characteristics in PFMEA (Production Failure Mode Effect Analysis) assessment, according to the Procedure for PFMEA Risk Assessment. This will identify and mitigate product safety-related risks during the entire lifecycle of the product.

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[Job title] needs to identify product safety-related characteristics of the products by including product safety characteristics in PFMEA (Production Failure Mode Effect Analysis) assessment, according to the Procedure for PFMEA Risk Assessment. This will identify and mitigate product safety-related risks during the production process.

3.3. Determining and implementing product safety controls

Based on the results of DFMEA and PFMEA assessments, [job title] needs to define product safety controls to address product safety-related risks at the point of manufacturing. Product safety-related controls are implemented in the Control Plan by job title and are approved by job title. Within the Control Plan, [job title] defines reaction plans and escalation processes when the acceptance criteria for the product or manufacturing process are not met.

In addition to the information provided in the Control Plan, [job title] defines the need for training to be provided to personnel involved in product safety-related product and associated manufacturing processes, according to Procedure for Competence, Training and Awareness.

If the product safety risks cannot be mitigated by the Control Plan and additional training, [job title] defines measures to manage the risks in the product lifecycle of the process, according to the Procedure for Design and Development.

Job title ensures that the requirements related to product safety are transferred throughout the supply chain, including the customer designated sources and the supplier controls, according to the Procedure for Purchasing and Evaluation of Suppliers.

3.4. Product safety testing

[Job title] conducts examination of product safety-related procedures and records it once every year to ensure that proper product safety is being implemented.

The test includes examination of the following:

- Competence and training
- [redacted]
- [redacted]
- [redacted]
- [redacted]
- [redacted]

[organization name]

- Production controls

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The findings of the test are entered in the Product Safety Test Record by [job title]. If the test finds that the product safety controls are effective, [job title] updates control files and control plans.

3.5. Implementation of lessons learned

Upon the examination of the product safety controls and their effectiveness, [job title] identifies the root causes as well as failure and nonconformities, and enters the information in control control records.

Identified nonconformities related to product safety are managed according to the Procedure for Managing Nonconformities and Corrective Actions.

4. Managing records kept according to this document

Record name	Code	Storage			Responsibility
		Retention time	Location	Protection	
Product Safety Testing Record	PR.07.1	Two years or the lifecycle duration of the product	[office of [job title]]	Records are stored in file cabinet [describe name/location]	[job title]

5. Appendices

- Appendix 1 – Product Safety Testing Record