# PRODUCT SAFETY PROCEDURE

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**Commented [169492]:** If you want to find out more about product safety, see:

Ensuring product safety according to IATF 16949
https://askseer.com/16949academy/blog/2017/05/20/ensuring-product-safety-according-to-iatf-16949/

**Commented [169493]:** Adapt to the existing practice in organization.

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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
- Procedure for 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

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

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

3.2. Identification of product safety characteristics

Commented [16A6]: Delete this if the organization doesn't perform design and development of products.

Commented [16A6]: This can be a Design and Development process owner, Project Manager, etc.
When defining new product or processes to be designed and developed, [job title] must identify that can affect product safety or compliance with regulations, fit, function, performance or lifecycle of the product.

[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.

3.3. Determining and implementing product safety controls

Based on the results of DFMEA and PFMEA assessments, [job title] needs to define product safety 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

If the product safety risks cannot be mitigated by the Control Plan and additional training, [job title] will provide training to employees and suppliers to ensure their understanding and implementation of 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.

The test includes examination of the following:

- Competence and training
- 
- 
- 
- 
-
Production controls

The findings of the test are entered in the Product Safety Test Record by [job title]. If the test finds
non-conformities, the appropriate procedures are followed.

3.5. Implementation of lessons learned

Upon the examination of the product safety controls and their effectiveness, [job title] identifies the
non-conformities and updates the relevant documentation. The non-conformities are managed according to the Procedure for
Managing Nonconformities and Corrective Actions.

4. Managing records kept according to this document

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<td>Two years or the lifecycle duration of the product</td>
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5. Appendices

- Appendix 1 – Product Safety Testing Record