[Organization logo]

[Organization name]

Commented [16A1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR MANAGEMENT OF NONCONFORMITIES AND CORRECTIVE ACTIONS

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [16A2]: All fields in this document marked by square brackets [ ] must be filled in.

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Commented [16A3]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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Change history

Date	Version	Created by	Description of change
	0.1	16949Academy	Basic document outline

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1. Purpose, scope and users

The purpose of this procedure is to describe all activities related to identifying and managing non-conforming products in order to prevent its unwanted use or shipment. The procedure also defines responsibilities and authorities related to treatment of non-conforming product and ensures compliance with all customer-specified controls for nonconforming products.

This procedure is applied to all processes and/or areas (parts of organization) within the QMS (Quality Management System).

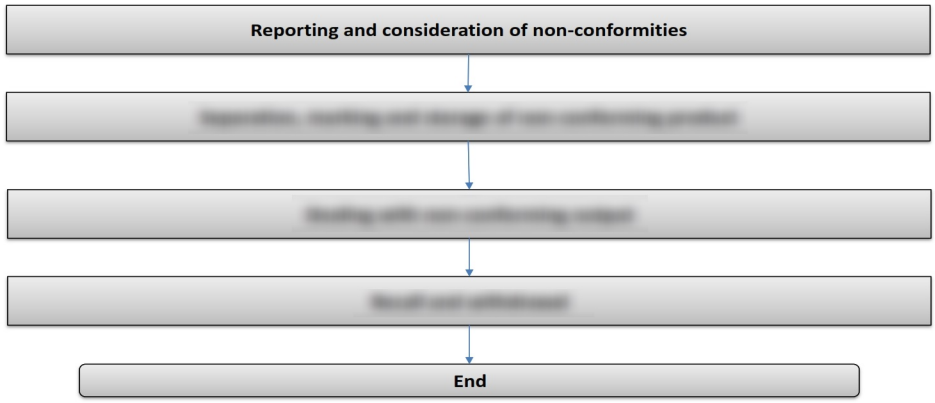
Users of this document are [members of top management] of [organization name], as well as the owner of processes in which the non-conformity occurred.

2. Reference documents

- IATF 16949:2016, clauses 8.7, 8.7.1, 8.7.1.1, 8.7.1.2.8.7.1.6, 8.7.7.1.7, 8.7.3, 10.2, 10.2.1, 10.2.2, 10.2.3
- Quality Manual

3. Managing non-conformities and corrective actions

3.1. Process flow



3.2. Nonconformities

A nonconformity is any failure to meet the requirements of the standards, internal documentation, incidents, during normal business operations, or on any other occasion.

An employee who notices a nonconformity must immediately notify [job title], who will record it in

Commented [16A4]: If you want to find out more about nonconformities, see:

- Understanding dispositions for ISO 9001 nonconforming product http://advisera.com/9001academy/blog/2014/11/18/understanding-dispositions-iso-9001-nonconforming-product/
- How to deal with nonconformities in an ISO 9001 certification audit http://advisera.com/9001academy/blog/2015/06/09/how-to-deal-with-nonconformities-in-an-iso-9001-certification-audit/

3.3. Reporting and consideration of nonconformities

The non-conformity is recorded in the Non-Conforming Product Record by [job title]. The report is

[Job title] is responsible for ensuring that all employees who deal with nonconforming and suspect products will receive specific training, and records of the training will be kept as evidence of their competence.

3.4. Separation, marking and storage of non-conforming products

[Job title] separates non-conforming product from conforming products, including suspect products. [Job title] or the shift manager for the shift where the non-conformity is found, is responsible for separation, marking and storage of non-conforming products in order to prevent misuse, unauthorized use and shipment. An employee in the place where the non-conformity is discovered marks the non-conforming product.

Non-conforming raw materials and their final products are labeled with a sign reading NON-CONFORMING PRODUCTS. They are stored in a separate space labeled as ZONE OF NON-CONFORMING PRODUCT.

After solving the nonconformity and performing all activities mentioned above, [job title] enters data about the non-conformity in the Registry of Non-Conformities and Corrective Actions.

3.5. Dealing with non-conforming outputs

[Top management] selects members of the Team for non-conforming outputs according to the process in which the non-conformity has occurred or was discovered.

The Team for non-conforming outputs reviews the non-conforming product or service in order to determine the best method for dealing with it.

Methods for dealing with non-conforming product are:

- ***Correction (Rework)*** – Performed in cases when it is possible to bring deviations from specified demands for the product to the demanded level. A work order is issued, which defines additional demands that need to be fulfilled. The corrected product is verified by (describe the method) and evidence of verification is the reported of an authorized body.
- ***Segregation, containment, return, or suspension of provision of products and services*** – Depending on the nature of the nonconformity, [job title] decides which of the listed actions will be taken.
- ***Passing or classification for other purposes*** – This is used in cases when the non-conforming product fulfills demands for the product or process in which it will be used, but this will be applied only if approved by customer.
- ***Informing the customer*** – [job title] must immediately notify customers if there is a risk of delayed deliveries, and shipment of suspect materials. This allows the customer to make arrangements for the implementation of necessary containment actions at customer sites.
- ***Obtaining authorization for acceptance under concession*** – This is performed by [job title] by approving the shipment based on written consent of customer, who agrees to receive products (including their components) which are not manufactured according to currently approved specifications. This concession will be requested in all situations where a product and process differ from what is currently approved. Concession will be requested for a limited period of time or quantity. The approved concession is described by [job title] in the Nonconformity

Commented [16A5]: Write in the person who is responsible for warehousing and storage.

Commented [16A6]: Means products with an unclear status are considered as suspect and managed as nonconforming products.

Commented [16A7]: This is usually Quality Manager.

Commented [16A8]: Choose one or more methods and adapt them to needs of organization.

Commented [16A9]: This is usually person responsible for production, e.g. chief of shift or manager of production.

Commented [16A10]: This situation is met when a product which does not met required characteristics is sent to other supply chain, for example to be sold in aftermarket.

Record, including expiration date of the concession. Following the end of the approved [redacted]

The Team for non-conforming product decides which resolution method will be used and that method is recorded in the Non-Conforming Product Record by the team leader.

3.6. Corrective actions

A corrective action may be initiated by any employee or, when appropriate, client, supplier or [redacted]

Corrective actions must be appropriate to the consequences of non-conformities that can have a negative influence on:

- Business performance of the organization
- [redacted]
- [redacted]

By reviewing corrective actions, [job title] ensures that consequences of the corrective action do not [redacted]

3.7. Implementation of corrective actions

A corrective action is implemented in the following way:

Step	[redacted]
1. [redacted]	Anyone with a role in the QMS
2. Defining the scope of non-conformity by [redacted]	Process owner together with [job title]
3. Containment actions that immediately [redacted]	[redacted]
4. Identifying cause of non-conformity	Person responsible for resolving non-conformity
5. [redacted]	[redacted]

Commented [16A11]: If you want to find out more about corrective actions, see:

Seven Steps for Corrective and Preventive Actions to support Continual Improvement
http://advisera.com/9001academy/blog/2013/10/27/seven-steps-corrective-preventive-actions-support-continual-improvement/

6. Planning corrective action	Person responsible for the area/process where the non-conformity has been identified
7. Implementing corrective action	Person responsible for the area/process where the non-conformity has been identified
8. [illegible]	[illegible]
9. [illegible]	[illegible]

Each of the above steps must be recorded in the Corrective Action Record.

3.8. Problem solving

[illegible]

- A claim is received from a customer
- Warranty failure ratio of delivered products exceeds what was agreed to by the customer
- Field failures
- [illegible]
- [illegible]
- [illegible]

Commented [16A12]: Adapt to your specific company, supply chain, customer-specific request. For customer claims it will be necessary to open an 8D analysis.

[Job title] will appoint a problem-solving leader for each specific problem. That person must follow [illegible]

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Nonconformity Record	PR.14.1	2 years	[office of [job title]]	[job title]
Registry and Status of Nonconformities and Corrective Actions	PR.14.2	2 years	[office of [job title]]	[job title]
Problem Solving 8D Template	PR.14.3	2 years	[office of [job title]]	[job title]

Commented [16A13]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Lesson Learned Template	PR.14.4	End of life + n years	[office of [job title]]	[job title]
Report of Warranty Failures	PR.14.5	End of life + n years	[office of [job title]]	[job title]
Warranty Incidents Analysis Report	PR.14.6	End of life + n years	[office of [job title]]	[job title]

Commented [16A14]: Adapt to your organization, can be for example 10 years for safety characteristics – see your customer/ OEM requirements.

5. Appendices

- Appendix 1 – Nonconformity Record
- Appendix 2 – Registry and Status of Nonconformities and Corrective Actions
- Appendix 3 – Problem Solving 8D Template
- Appendix 4 – Lesson Learned Template
- Appendix 5 – Report of Warranty Failures
- Appendix 6 – Warranty Incidents Analysis Report