[Organization logo]

[Organization name]

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

PROCEDURE FOR MANAGEMENT OF NONCONFORMITIES AND CORRECTIVE ACTIONS

Commented [9A2]: If you want to find out more about ISO 9001:2015 visit our free online course ISO 9001 Foundations Course http://training.advisera.com/course/iso-90012015-foundations-course/

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

Commented [9A3]: Adapt to the existing practice in organization.

Distribution list

Commented [9A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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				Date	Signature

Change history

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

Table of contents

1. Purpose, scope and users

The purpose of this procedure is to describe all activities related to identifying and managing non-conforming product in order to prevent its unwanted use or shipment and to define responsibilities and authorities related to treatment of non-conforming product.

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

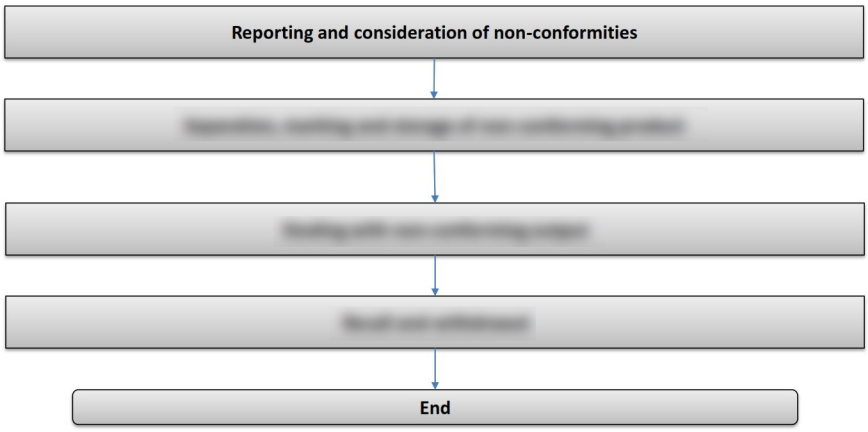
Users of this document are [members of top management] of [organization name], as well as the owner of processes in which the non-conformity occurred.

2. Reference documents

- ISO 9001:2015, clauses 8.7; 10.2
- 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, regulations, contractual and other planned arrangements of the QMS. Nonconformities can be

3.3. Reporting and consideration of nonconformities

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

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

[Job title] separates non-conforming product from conforming products. Responsible for separation, marking and storage of non-conforming products in order to prevent misuse and unauthorized use

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 depending on the

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

Methods for dealing with non-conforming product are:

- ***Correction (Rework)*** – is performed in cases when it is
- ***Segregation, containment, return, or suspension of provision of products and services*** – [job title] decides which of the listed actions will

Commented [9A5]: 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/

Commented [9A6]: Write in the person who is responsible for warehousing and storage.

Commented [9A7]: This is usually Quality Manager.

Commented [9A8]: Choose one or more methods and adapt them to needs of organization.

Commented [9A9]: This is usually person responsible for production, e.g. chief of shift or manager of production.

- ***Reusing or classification for other purposes*** – is used in cases when the [illegible]
- ***Informing the customer*** – [job title] decides what will be communicated to the customers if [illegible]
- ***Obtaining authorization for acceptance under concession*** – is performed by [job title] by approving the shipment based on consent of the user or the decision of a relevant authority [illegible]

Commented [9A10]: This can be laboratory for microbiological or technical testing.

The Team for non-conforming product decides which method for resolving non-conforming product will [illegible]

3.6. Corrective actions

Commented [9A11]: 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/

A corrective action may be initiated by any employee or (where appropriate) client, supplier or [illegible]

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

- [illegible]
- [illegible]
- [illegible]

By reviewing corrective actions, [job title] ensures that consequences of the corrective action don't have a negative influence on other parts of the system.

3.7. Implementation of corrective actions

A corrective action is implemented in the following way:

Step	***Person responsible for*** [illegible]
1. Identifying, reviewing and analysis of non-conformity	Anyone with a role in the QMS
2. [illegible]	[illegible]
3. [illegible]	[illegible]
4. Identifying cause of non-conformity	Person responsible for resolving non-conformity

5. Deciding if it is needed to initiate corrective action depending on complexity of non-conformity	Person responsible for resolving non-conformity
6. [illegible]	[illegible]
7. [illegible]	[illegible]
8. [illegible]	[illegible]
9. Updating risks and opportunities determined during planning, if necessary	Top management

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

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Non-Conformity Record	PR.12.1	2 years	[office of [job title]]	[job title]
Corrective Action Record	PR.12.2	2 years	[office of [job title]]	[job title]
Registry and Status of Nonconformities and Corrective Actions	PR.12.3	2 years	[office of [job title]]	[job title]

Commented [9A12]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Commented [9A13]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

5. Appendices

- Appendix 1 – Non-Conformity Record
- Appendix 2 – Corrective Action Record
- Appendix 3 – Registry and Status of Nonconformities and Corrective Actions