[Organization logo]

[Organization name]

Commented [AS91001]: 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 [AS91002]: Adapt to the existing practice in organization.

Distribution list

Commented [AS91003]: 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	9100Academy	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 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 also describes the activities for corrective action that is taken to eliminate the causes of nonconformities and prevent recurrence.

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

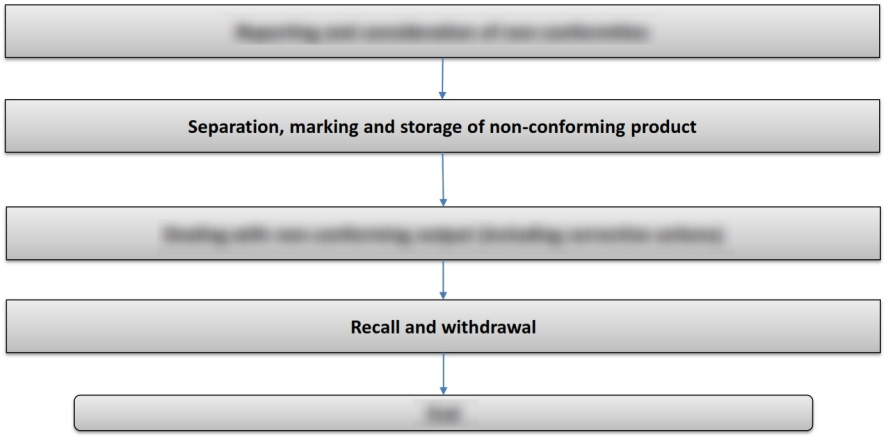
Users of this document are [members of top management] of [organization name], as well as the owner of processes in which the non-conformity occurred.

2. Reference documents

- AS9100 Rev D, 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 identified during an internal or external audit, based on results of the management review, after incidents, during normal business operations, or on any other occasion and can include nonconforming products and services produced internally or from an external provider.

An employee who notices a nonconformity must immediately notify [job title], who will record it in the Nonconforming Product Record and take action to control it, contain it, and correct it, and to deal with its consequences. If a nonconformity is discovered after delivery, [job title] must evaluate its impacts to delivered products and services and ensure that proper actions are taken to control and correct it, as well as deal with the consequences.

Commented [AS91004]: If you want to find out more about nonconformities, see these useful blogs from the 9001Academy:
- 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 considered by [job title], who gives guidelines for isolation of the non-conformed product. If [job title] cannot independently resolve the incurred non-conformity, he notifies [job title]. If nonconformity affects delivered products [job title] must ensure timely reporting to customers and interested parties.

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 unauthorised use and shipment is [job title] or chief of shift in which the non-conformity is discovered. An employee in the work place where the non-conformity is discovered marks the non-conforming product.

Non-conforming raw materials and the final products are labeled with a sign reading NON-CONFORMING PRODUCTS, and they are stored in a separated 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 depending on the process in which the non-conformity has occurred or was discovered. The team for non-conforming products must be approved by top management, and have knowledge of the product or service as well as the customer requirements pertaining to the nonconformity.

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 possible to bring deviations from specified demands for the product to the demanded level. For procedure for correction, the work order is issued, which defines additional demands that need to be fulfilled. The corrected product is verified [describe the method] and evidence of verification is the report of an authorized body.
- ***Segregation, containment, return, or suspension of provision (scrap) of products and services*** – [job title] decides which of the listed actions will be taken, considering the nature of the nonconformity. [job title] ensures that product dispositioned as scrap is to be permanently and conspicuously marked or controlled until physically made unusable.
- ***Reusing or classification for other purposes*** – is used in cases when the non-conforming product fulfills demands for the product or process in which it will be used.
- ***Informing the customer*** – [job title] decides what will be communicated to the customers if the nonconformity is detected after delivery of products and during and after provision of services in order to avoid further adverse effects of the nonconformity.
- ***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 and customer if necessary. [job title] describes the concession obtained in Nonconformity Record.

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

Commented [AS91005]: Write in the person who is responsible for warehousing and storage.

Commented [AS91006]: This is usually Quality Manager.

Commented [AS91007]: Choose one or more methods and adapt them to needs of organization.

Commented [AS91008]: This is usually person responsible for production, e.g. chief of shift or manager of production.

Commented [AS91009]: This can be laboratory for microbiological or technical testing.

3.6. Corrective actions

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:

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

By reviewing corrective actions, [job title] ensures that consequences of the corrective action don't [illegible] are not achieved [job title] takes action to address the delay.

Commented [AS910010]: 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/

Commented [AS910011]: Actions can include applying additional resources, including people, to the team to increase the speed of the corrective action response.

3.7. Implementation of corrective actions

A corrective action is implemented in the following way:

Step	*Person responsible for implementation*
1. Identifying, reviewing and analysis of non-conformity	Anyone with a role in the QMS
2. [illegible]	[illegible]
3. Containment actions that immediately correct non-conformity or prevent recurrence	[illegible]
4. [illegible]	[illegible]
5. Deciding if it is needed to initiate corrective action depending on complexity of non-conformity (including flow down to external provider if the cause originates there)	[illegible]
6. [illegible]	[illegible]

Commented [AS910012]: Human factor causes include [illegible]

Commented [AS910013]: Flow down is a situation that occurs [illegible]

7. Implementing corrective action	Person responsible for the area/process where the non-conformity has been identified
8. [illegible]	[illegible]
9. Updating risks and opportunities determined during planning, if necessary	Top management

[illegible] 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 [AS910014]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

Commented [AS910015]: 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