Nonconformity Management

Bizagi Suite
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Nonconformity Management

Version: 1.0

Author: Bizagi Process Modeler.

Description

Companies nowadays face new challenges in order to improve the quality of their products and services provided. However, the term *quality* can have different interpretations depending on the person or company that is evaluating it, for that reason it is very important to have a standard for the requirements that the company wishes to meet.

International Organization for Standardization (ISO) has created a set of standards and procedures (ISO 9000, ISO 9001) to represent an international consensus on good quality management practices.
ISO 9000 describes the fundamentals of a quality management system including the eight management principles. ISO 9001 deals with the requirements that organizations must meet to fulfill quality standards.

A key point in a Quality Management System is the solution of nonconformities. A nonconformity is presented when a requirement is not fulfilled. Failing to correct a nonconformity or the continued presence of one, results in costs associated to re-work, replacement, loss of customers, and even the loss of quality certification, to name a few.

Considering the development and efficiency of companies, bizagi offers a new process that helps to manage nonconformities in a quick and efficient manner.

The Nonconformity Management template offers a fast and flexible tool that allows the person responsible for the solution of the nonconformity to easily allocate tasks, from the NC detention going through the root cause analysis and finishing with the elimination of the causes.

The process provides the possibility to execute an immediate solution to correct the nonconformity in the short term. It is also possible to create a Corrective Action to attack the root cause of the problem and avoid future recurrences.

Additionally, the template includes a small process that creates a Preventive Action in order to eliminate potential causes of nonconformities.

Finally Bizagi offers the possibility to control and monitor the performance of the process, through indicators that can be created using Query Forms, bizagi’s tools like BAM and sensors.

Scope

Bizagi’s Nonconformity Management Template is designed to correct and eliminate the root causes of nonconformities. The user can execute an immediate solution or create a corrective action in order to eliminate the causes of it. Also the process includes the possibility of executing a preventive action to avoid potential nonconformities.
Objectives

The process covers:

- Implementing an immediate solution for the nonconformity
- Performing a Corrective Action to eliminate the root causes of the Nonconformity.
- Executing a flexible Action Plan to assign responsibilities to different people.
- Performing a Preventive Action to eliminate the root causes of a potential Nonconformity.

Definitions

- Nonconformity: A nonconformity is presented when a requirement is not fulfilled.
- Corrective Action: A procedure to eliminate the causes of a detected nonconformity.
- Preventive Action: A procedure to eliminate the causes of a potential nonconformity.
- QMS: Quality Management System is a group of activities and procedures to direct and control in an efficient and proactive manner the development of your business processes.
- Product: Throughout the document the word PRODUCT is used to indicate a product or service.
- Correction: To correct or to eliminate a nonconformity.
Process Elements

☐ Report Nonconformity

Description

According to the ISO 9000 standard, a nonconformity is presented when a requirement is not fulfilled. Nonconformity can be detected in different ways. For example during an audit, a customer complaint, or during quality inspections.

If nonconformity is found, the auditor or the person who reports it, must include information about the nonconformity such as description, requirement against the nonconformity that has been detected, the area that has to correct it, etc. The information should be sufficiently detailed, to enable the process owner to find and confirm the nonconformity.

If there is no real evidence about the nonconformity, there is no nonconformity.

Performers

Auditor

Activities

<table>
<thead>
<tr>
<th>Description</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set the Case Creator as the Auditor</td>
<td>On Enter</td>
</tr>
<tr>
<td>Set date as Today</td>
<td></td>
</tr>
</tbody>
</table>
Form

Identify NC Causes and Action Plan

Description

A Quality Management System (QMS) requires a fully documented process. For that reason it is necessary to document the nonconformity according to the QMS procedures.

If the nonconformity is accepted by the area, the process owner must include the root cause and the action plan to eliminate it.

If the nonconformity needs immediate treatment, this must be included.

Performers

Process Owner

Activities

<table>
<thead>
<tr>
<th>Description</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set Immediate action option to &quot;No&quot;</td>
<td>On Enter</td>
</tr>
<tr>
<td>Set the Boolean Nonconformity to null</td>
<td>On Enter</td>
</tr>
<tr>
<td>Set the attribute First Time to one</td>
<td>On Exit</td>
</tr>
</tbody>
</table>
Nonconformity Accepted?

Description

The gateway evaluates if the nonconformity was rejected or accepted.
Gateways

- No: If the nonconformity was rejected by the process owner, the process continues to the Analyze Rejection of NC task.
- Yes: If the nonconformity was accepted by the process owner, the process continues to the next validation.

💎 Immediate Improvement Action Required?

Description
The gateway opens the flow of the process depending on the action plan.

Gateways

- Yes: If the solution of the nonconformity can be immediate, the process continues to the next gateway Follow Action?
- No: If the solution of the nonconformity requires a Corrective Action, the process continues to the sub process Corrective Action.

💎 Follow Action?

Description
The correction of a nonconformity can include some activities that can be performed immediately, for that reason the gateway validates the next activity to be performed.

Gateways

- Correction: If the nonconformity can be corrected, the process continues to the Correction task.
- Concession: If the nonconformity can be accepted only this time, the process continues to the Concession Product/Service sub-process, where the customer (Internal or external) may give his approval.
• Rejection: If the products or the services related to the nonconformity need to be rejected, the process continues with the Reject Product/Service task.

**Correction**

Description

A nonconformity can be corrected by executing different activities, for example a rework, reclassification or the replacement of the nonconforming product. The activity is performed by the person assigned by the process owner.

Performers

Analyst

Form

<table>
<thead>
<tr>
<th>Nonconformity Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detention Date: 11/28/2012</td>
</tr>
<tr>
<td>Auditor: Marketing Manager</td>
</tr>
<tr>
<td>Process: Purchases</td>
</tr>
<tr>
<td>Area: Area</td>
</tr>
<tr>
<td>Process Owner Name: Marketing Manager</td>
</tr>
<tr>
<td>Nonconformity Description: Nonconformity Description</td>
</tr>
<tr>
<td>Nonconformity Accepted: Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nonconformity Root Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Root Causes</td>
</tr>
<tr>
<td>Description</td>
</tr>
<tr>
<td>Root causes 1</td>
</tr>
<tr>
<td>Root causes 2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immediate Action Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Action: Correction</td>
</tr>
<tr>
<td>Responsible: Marketing Manager</td>
</tr>
<tr>
<td>Immediate Action Plan: Immediate Action Plan</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Execute ActionPlan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Action Executed:</td>
</tr>
<tr>
<td>Correction Comments:</td>
</tr>
</tbody>
</table>
Correction Report

Description
The auditor and the process owner are informed about the Product or Service Correction.

Script
Correction of Product or Service

<NonconformityManagement.Auditor.fullName> has identified the following nonconformity:

<NonconformityManagement.NonconformityType.Name>
<NonconformityManagement.NonconformityDescription>

The process owner identified the following root causes:

Table: Root Causes

The solution to the problem requires the implementation of the following activities:

<NonconformityManagement.ImmediateAction.ImmediateAction.Description>,
<NonconformityManagement.ImmediateAction.ImmediateActionPlan>

The solution was:

<NonconformityManagement.ImmediateAction.CorrectionComments>

Thank you
QMS Team

Concession Product/Service

Description
If the nonconformity can be accepted only this time, the process continues to the Concession Product/Service sub-process, where the customer (Internal or external) may give their approval.
Concession Approved by client?

Description

If the correction of a nonconformity includes the concession of the defective product, it is necessary to validate if the client agrees with the concession.

Gateways

- Yes: If the client accepts the concession, the process continues to the next task, Verify Result of Immediate Action.
- No: If the client rejects the concession, the process returns to the Action Plan task.

Reject Product

Description

If the product or service with the nonconformity needs to be rejected in order to continue the process, the Reject Product/Service task is performed.

If the rejection of the product needs special treatment, such as reorder a new one, or open a Corrective Action, it must be indicated.

Performers

Analyst
Rejection Report

Description

The auditor and the process owner are informed about the Product or Service rejection

Script

Rejection of Nonconformity

<NonconformityManagement.Auditor.fullName> has identified the following nonconformity:

<NonconformityManagement.NonconformityType.Name>.
<NonconformityManagement.NonconformityDescription>
The process owner identified the following root causes:

Table: Root Causes

The solution requires the rejection of the products

Thank you

QMS Team

Corrective Action

Description

A corrective action is performed to eliminate the root cause of the nonconformity. The process owner creates an Action Plan to eliminate the cause. He or she assigns a person responsible for executing each task. Finally the Auditor verifies the effectiveness of the Action Plan.

Verify Result of Immediate Action

Description

The auditor should confirm the effectiveness of the solution or correction of the nonconformity, it is important to check that the requirements are fulfilled.

Activities

<table>
<thead>
<tr>
<th>Description</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set the Effective Action attribute to null</td>
<td>On Enter</td>
</tr>
</tbody>
</table>
Immediate Action Effective?

Description

The gateway validates the auditor’s decision

Gateways

- No: If the nonconformity was not corrected by the immediate action, the process returns to the Action Plan in order to make a new plan to correct it.
• Yes: If the nonconformity was corrected by the immediate action, the process continues to the task “Close Nonconformity”.

### Close NC

**Description**

After correcting a NC it is necessary to close the nonconformity.

**Activities**

<table>
<thead>
<tr>
<th>Description</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Close the Nonconformity</td>
<td>On Exit</td>
</tr>
</tbody>
</table>

**Script**

Closure of Nonconformity

The following nonconformity

<NonconformityManagement.NonconformityDescription>

Reported on <NonconformityManagement.DetentionDate> by <NonconformityManagement.Auditor.fullName>

was closed on <NonconformityManagement.ClosingDate>

QMS Team

### Analyze Rejection of NC

**Description**

When the nonconformity is rejected by the area, the process needs the QMS evaluation. The process continues to the Analysis task where the QMS Analyst decides what the following action should be. It is possible to redirect the nonconformity to a different area or to close it.
Performers
Analyst
Form

NC continues?
The gateway validates the QMS Analyst decision

Gateways

- Redirect: If the QMS analyst redirects the nonconformity, the process continues to the task Identify Causes NC and Action Plan task is executed by the process owner of the redirected process.

- No: If the QMS Analyst closes the nonconformity the process continues to the Close Nonconformity task.
Close Nonconformity

Description
If the Analyst closes the nonconformity, the auditor and the process owner must be informed.

Script
Cancellation of Nonconformity
The following nonconformity has been canceled:
<NonconformityManagement.NonconformityType.Name>
<NonconformityManagement.NonconformityDescription>
Reason:
<NonconformityManagement.QMSConcept>
Thank you
QMS Team
**Product Concession**

Version: 1.0

Author: Bizagi Process Modeler

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**Process Elements**

☐ **Concession**

**Description**

A concession is an authorization to accept a nonconformity. It is not to be regarded as a precedent. The information about the concession must be included, for example the reason for the concession, and if the client’s approval is required.

**Performers**

Analyst
**Client Approval Required?**

**Description**

The gateway is validated if the concession requires the client’s approval.

**Gateways**

- **Yes**: If the client must approve the concession, the process continues to the Client Approval task.
- **No**: If the client approval is not necessary, the process continues to the Notify Concession activity.
Client Approval

Description
The client approves the concession.

Performers
Client

Form

Approved by Client?

Description
The gateway validates the client’s decision.
Gateways

- Yes: If the concession was approved by the client, the process continues to the Notify Concession activity.
- No: If the concession was not approved by the client, the process returns to the Action plan task in the parent process.

Notify Concession

Description

It is necessary to notify the process owner, the auditor and the client about the concession.

Script

Notification of Nonconformity

<NonconformityManagement.Auditor.fullName> has identified the following nonconformity:

<NonconformityManagement.NonconformityType.Name>
<NonconformityManagement.NonconformityDescription>

The process owner identifies the following root causes:

Table with Root Causes

The solution requires the implementation of the following activities:

<NonconformityManagement.ImmediateAction.ImmediateAction.Description>,
<NonconformityManagement.ImmediateAction.ImmediateActionPlan>

The implementation was:

<NonconformityManagement.ImmediateAction.ConcessionComments>

Thanks

QMS Team
Corrective Action

Version: 1.0

Author: Bizagi Process Modeler

Process Elements

☐ Identify NC Causes and Action Plan

Description

A Corrective Action is performed in order to correct the root causes of a nonconformity. It is necessary to identify the root causes and analyze them carefully. The level of complexity of the corrective action depends on the severity of the nonconformity. The process owner must propose an action plan to eliminate the causes of the nonconformity.

Performers

Process Owner
Activities

<table>
<thead>
<tr>
<th>Description</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set the Correct attribute to true or false according to the process data</td>
<td>On Exit</td>
</tr>
</tbody>
</table>

Form

Send Action Plan

Description

The action plan must be sent to all those involved.

Script

Nonconformity Action Plan

The nonconformity:
<CorrectiveAction.idNonconformity.NonconformityDescription> has new Root causes

Table: Root Causes

The following is the new action plan to correct the nonconformity:

Table: Action Plan

Thank you

QMS Team

Execute Action Plan

Description

It is necessary to execute the plan that was created in the Action Plan task. The process owner must verify the completion of each task.

Verify Action Plan Effectiveness

Description

The auditor should confirm the effectiveness of the solution of the nonconformity, it is important to check that the requirement is fulfilled.

Performers

Auditor

Activities

<table>
<thead>
<tr>
<th>Description</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set the CorrectiveActionCorrect attribute to null</td>
<td>On Enter</td>
</tr>
<tr>
<td>Increase the First Time attribute.</td>
<td>On Exit</td>
</tr>
</tbody>
</table>
Form

Corrective Action Effective?

Description
The gateway validates the auditor’s decision.

Gateways

- Yes: If the nonconformity was corrected by the Corrective Action, the process continues to the final activity Close CA.

- No: If the nonconformity was not corrected by the Corrective Action, it is necessary to review the root causes and modify the action plan.
## Close Corrective Action

### Description

After correcting an NC thought, it is necessary to close the Corrective Action.

### Activities

<table>
<thead>
<tr>
<th>Description</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Close the Corrective Action</td>
<td>On Exit</td>
</tr>
</tbody>
</table>

### Script

**Closure of Corrective Action**

The following nonconformity: 
<NonconformityManagement.NonconformityDescription> was detected on <NonconformityManagement.DetentionDate> by <NonconformityManagement.Auditor.fullName> was closed on <NonconformityManagement.ClosingDate>

Thank you

QMS Team
Execute Action Plan

Version: 1.0

Author: Bizagi Process Modeler

Process Elements

☐ Execute Activity

Description

The person assigned by the process owner must execute the activity proposed in the Action Plan.

Performers

Analyst
Form

Nonconformity Description

- Detention Date: 11/26/2012
- Auditor: Marketing Manager
- Process: Accounts payable
- Area: Area
- Process Owner Name: Marketing Manager
- Nonconformity Description: Nonconformity Description
- Nonconformity Accepted: Yes

Nonconformity Root Causes

<table>
<thead>
<tr>
<th>Root Causes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Root cause 1</td>
<td></td>
</tr>
<tr>
<td>Root cause 2</td>
<td></td>
</tr>
</tbody>
</table>

Action Plan

- Responsible: Marketing Manager
- Dead Line: 11/29/2012
- Activity: Activity 1
- Activity Result: 
- Activity File: 

☑ Verify Activity

Description

The process owner must verify if the proposed activity was executed correctly.

Performers

Process Owner
Form

![Form Image]

**Activity Effective?**

**Description**
The gateway validates if the activity was correct.

**Gateways**

- **No**: If there is a need to correct something, the process returns to the Execute Activity.
- **Yes**: If the activity was successfully performed the sub process ends.
Preventive Action

Version: 1.0

Author: Bizagi Process Modeler

The Preventive Action Process is an additional process that helps to eliminate the root causes of potential nonconformities. The Auditor must open a new Preventive Action Case only if a potential nonconformity is found.

Process Elements

☑ Report Nonconformity

Description

If a potential nonconformity is found, the auditor or the person who found it, must include the information about the potential nonconformity, such as description of it, requirement against the potential nonconformity is detected, the area that has to correct the potential nonconformity, etc. The information should be sufficiently detailed, to enable the process owner to find and confirm the potential nonconformity.
Performers
Auditor

Activities

<table>
<thead>
<tr>
<th>Description</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set Auditor as the case creator</td>
<td>On Enter</td>
</tr>
<tr>
<td>Set date as Today</td>
<td></td>
</tr>
</tbody>
</table>

Form

☐ **Identify**  NC Potential Causes and Action Plan

Description

A Preventive Action is performed in order to eliminate the causes of a potential nonconformity. It is necessary to know the root causes through the data analysis and create an action plan in order to eliminate them.

Performers
Process Owner
Send Action Plan

Description
The action plan must be sent to all people involved.

Script
NC Action Plan
The nonconformity:
<NonconformityManagement.NonconformityDescription>
has new root causes
The following is the new action plan to correct the nonconformity:
Table with action plan
Thank you
QMS Team
Execute Action Plan

Description

It is necessary to execute the plan that was created in the Action Plan task. The process owner must verify the completion of each task.

Verify Action Plan Effectiveness

Description

The auditor should confirm the effectiveness of the solution of the potential nonconformity, it is important to check that the requirement is fulfilled.

Performers

Auditor

Form
Preventive Action Effective?

Description
The gateway validates the auditor's decision

Gateways

- Yes: If the potential nonconformity was corrected by the Preventive Action the process continues to the final activity Close PA.

- No: If the potential nonconformity was not corrected, the process returns to the Action Plan task.
**Close Preventive Action**

Description

After eliminating the possible causes for a nonconformity, it is necessary to close the preventive action that was opened by the QMS area.

Activities

<table>
<thead>
<tr>
<th>Description</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Close Preventive Action</td>
<td>On Exit</td>
</tr>
</tbody>
</table>

Script

Notification of Preventive Action Closure

The following nonconformity: \(<CorrectiveAction.idNonconformity.NonconformityDescription>\) was detected on \(<CorrectiveAction.idNonconformity.DetentionDate>\) by \(<CorrectiveAction.idNonconformity.Auditor.fullName>\). The Preventive Action was closed on \(<CorrectiveAction.idNonconformity.ClosingDate>\).

Thank you

QMS Team
Performers

Process Owner (Role)

The persons who is responsible for the process.

Auditor (Role)

The person who monitors, assesses, and analyzes organizational risk and the organization’s controls.

Analyst QMS (Role)

The person who provides leadership during system analysis, design, configuration, implementation and support for the Quality Management business process and application needs.