



MARLOW OFFSHORE GERMANY GMBH & Co. KG

ISO 9001:2015

Control of Non-conformity & Corrective Action

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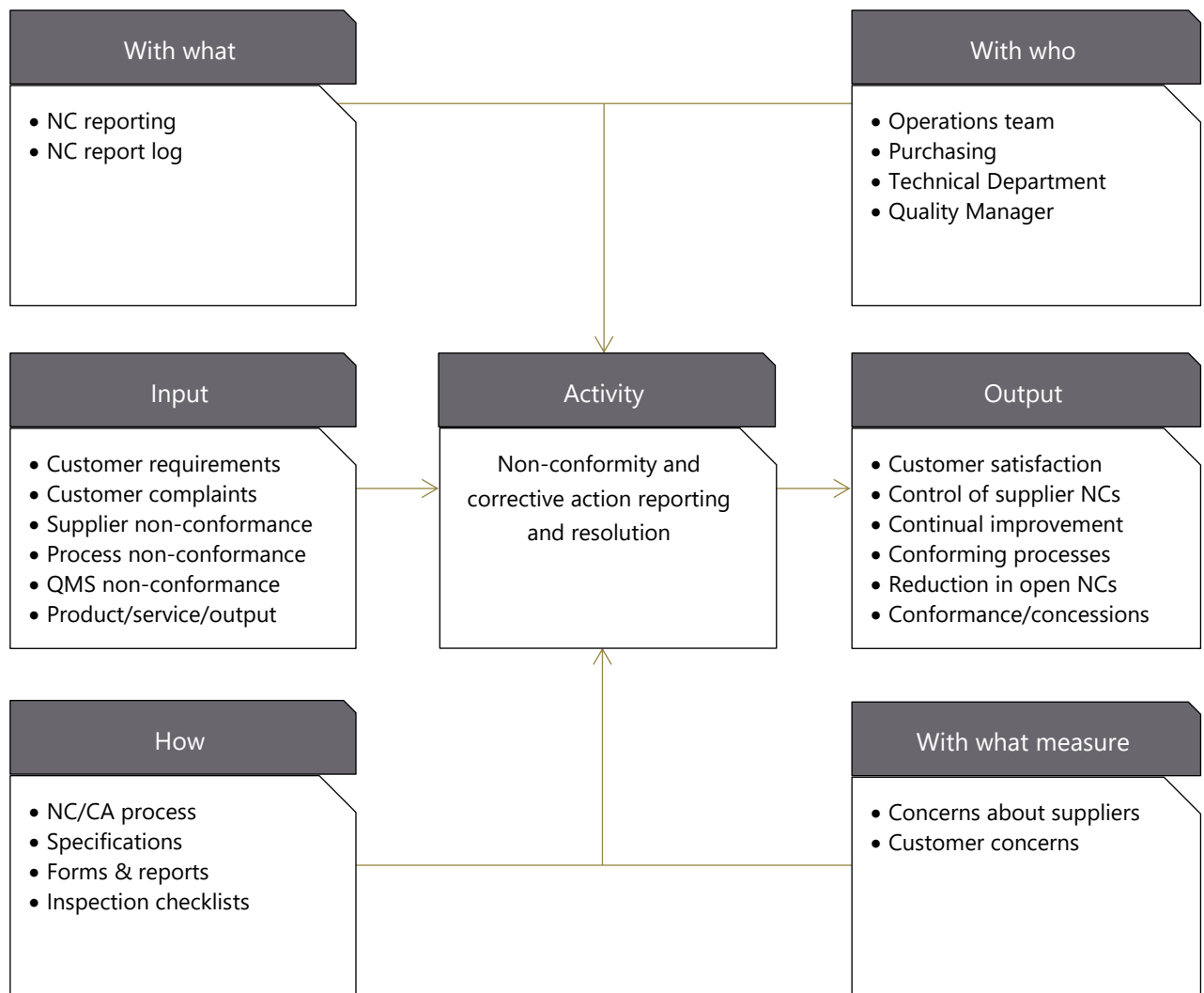
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1 Control of Non-conformity & Corrective Action

1.1 Introduction & Purpose

The purpose of this procedure is to establish the process for identifying, documenting and analyzing non-conformities and mitigating their impacts by implementing appropriate corrective actions. OOC Opielok Offshore Carriers GmbH & Co. KG quality management system is geared toward the proactive elimination of actual and potential deficiencies. Non-conformities in products, services, processes and our management system are investigated and action implemented to prevent their occurrence.

1.1.1 Process Activity Map



1.1.2 References

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2015	Quality management systems	Requirements
BS EN ISO 9004:2000	Quality management systems	Guidelines for performance improvements
BS EN ISO 19011:2011	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

Term	ISO 9000:2015 Definition
Non-conformity	Non-fulfilment of a requirement (3.6.4)
Defect	Non-conformity (3.6.9) related to an intended or specified use
Conformity	Fulfilment of a requirement (3.6.4)
Corrective action	Action to eliminate the cause of a non-conformity (3.6.9) and to prevent recurrence

1.2 Application & Scope

This procedure is applicable to all non-conforming products, services, processes and any aspect of our quality management system. Any corrective action taken to eliminate the cause of non-conformity is appropriate to the magnitude of the problem whilst also being in proportion to the risks presented by the non-conformity. Root causes of process non-conformities, including those arising from complaints are investigated and actions implemented to prevent their recurrence. This procedure applies to:

1. **Processes producing negative results and defect outputs.** Any process which does not produce an acceptable product or services should be reported by any employee through the initiation of the Corrective Action Request Form.
2. **Incoming products from suppliers or customers.** Product received from suppliers which is found to be non-conforming are identified, reported and returned to the supplier. Recurring problems with discrepant materials from a vendor are reported to the Purchasing Department.
3. **Services provided by external sources.** If a service provided from an external source does not comply with the requirements of the purchase order and/or contract, then the Corrective Action Request Form is completed and submitted.
4. **Internal issues and quality audits.** During the process of conducting internal quality audits, processes may be identified as being non-conforming. These are documented on the Internal Audit Checklist, Internal Audit Report Form, and the Corrective Action Request Form

1.3 Responsibilities

All employees are required to:

- Follow this procedure upon detecting non-conformities.
- Implement necessary actions to achieve resolution;

The Quality Manager is required to:

- Determine the root causes of non-conformities;
- Maintain a system for reporting and record keeping;
- Raise and record concessions;
- Review the effectiveness of corrective actions taken.

1.4 Control of Corrective Action

The Quality Manager reviews any issues raised by each non-conformity to identify root cause and level of action required. Repeated non-conformities of the same nature or which are significant deviations from procedures or the policies are reported to Top management for action and resolution. Corrective action is taken as a result of:

- Customer concerns, complaints;

- Non-conforming product received from suppliers;
- In-process concerns;
- Concerns about QMS stability;
- Accidents or incidents;
- Environmental incidents.

1.4.1 In-Process & QMS Non-conformities

Where problems exist in our process or in our management system, employees are authorized to report the issue to the Quality Manager via the non-conformity report or the internal audit report. The Quality Manager reviews the problem and decides whether to implement any process or system changes necessary using any specialists as required.

1.4.2 Corrective Action Impact

Where applicable any corrective action taken and controls implemented to eliminate the cause of non-conformity is applied to other similar processes and is controlled by the Quality Manager in liaison with affected process owners. Significant actions are entered onto the non-conformity log.

1.4.3 Corrective Action Review

The Quality Manager will review any issues raised and update the non-conformity report to identify root cause and level of action required. Repeated non-conformities of the same nature or significant deviations from procedures or the policies are reported to Top management for action and resolution. The Quality Manager is responsible for:

- Identifying the root cause(s) of the non-conformity;
- Identifying appropriate corrective actions (including modifying or creating new work practices);
- Planning and implementing corrective actions;
- Verifying the close-out and effectiveness of corrective actions;
- The Quality Manager verifies implementation of corrective actions;
- Where non-compliances are identified outside the audit process, the Quality Manager or designee generates a corrective action request as appropriate.

1.4.4 Implementing Containment Action

The Quality Manager should first contain the problem and then determine its root cause in order to take appropriate corrective action to prevent the problem's recurrence.

- Recording corrective actions using the forms provided;
- Performing an initial review;
- Determining causes and the need to take action;
- Implementing action where required;
- Preventing recurrence and evaluating effectiveness;
- Recording the results;
- Examine the effectiveness of corrective actions.

1.4.5 Determining the Causes

Non-conformity and opportunity for improvement may be identified by employees, customer complaints or by management system audit reports. By whichever means a non-conformance is identified, the underlying cause of the non-conformance is investigated. The Quality Manager reviews any issues raised and completes a non-conformance report to identify root cause and evaluate the level of action required. Repeated non-conformances of the same nature or significant deviations from procedures or the policies are reported to Top management for action and resolution.

1.4.6 Evaluating the Need for Action

Senior Management will be actively involved in any major corrective actions making sure that all actions agreed by any multi-functional teams are carried out fully. Major corrective actions and improvements are placed onto the continual improvement programme and reported on at Top management meetings. The eventual close-out of any significant action is presented at the management review meeting. All corrective action reports raised are categorized as having major or minor effect:

- **Major:** Where the procedure contradicts working practices and/or working practices do not reflect standard requirements or customer complaints which require additional corrective action
- **Minor:** Where the system procedure or process is not being fully adhered to, equipment breakdown or failures which do not affect operational activities. A non-conformance that does not have an immediate impact upon the stability of the management system

1.4.7 Implementing Action

Designated personnel must implement the agreed level of action within an agreed timescale. The Quality Manager will follow up all corrective actions to ensure effective and timely responses are achieved.

The Quality Manager will close out the corrective action when satisfactory resolution has been achieved and when objective evidence of close out has been obtained through inquiry or audit. Corrective action such as, implementing, modifying or enforcing procedures or controls will be taken to avoid repetition of the non-conformance where necessary.

1.4.8 Verifying the Effectiveness of Actions

The corrective action request originator verifies the effectiveness of the corrective actions taken. Where the originator is also responsible for the implementation of the corrective action, the Quality Manager provides the verification for each corrective action, and request closure. If corrective actions are determined to be ineffective, the original corrective action request is closed and a new request issued.

1.4.9 Review

Corrective actions are reviewed for long-term effects and process improvements during management reviews meetings. The Quality Manager and Top management determine if the action taken could potentially be applied to other areas of the organization.

1.5 Forms & Records

All documentation and records generated by the non-conformity and corrective action processes are retained and managed in accordance with the Control of Documented Information procedure.

Title & Description
Non-conformance Report
Corrective Action Report

1.6 Non-conformity & Corrective Action Process Map

