SOP Reference #: SOP-QS025

Operation/Task:	Addressing Non-Conformance			Equipment:	N/A
Owner:	Quality Manager	**Date Created:** **Revision History:**	6/30/2023 See last page	**Department:**	Quality Systems

ALERTS (see below): Critical Step ◆ Quality Check ☑ Tip ☺ Team Safety ✚

Purpose: This SOP/work instruction documents the actions and responsibilities for addressing non-conformances within the Quality Management System

	Alerts	Step Description - "What to Do"	"How to Do it"	"Why Do it"
1	◆	Non-conformance data and other input regarding performance problems are collected through many sources, including but not limited to: • **Audits** - external, customer and internal • **Data Collection** – employee time punches, purchasing coded to rework • **KPI** – performance reporting that reveals deviation from standards • **Customer Input** – information and complaints collected by sales and account personnel and reported to the quality representative • **Employees** – information collected during production time, department meetings, employee reviews, unsolicited input	There are many methods available for collecting non-conformance information. It is the responsibility of the Quality Manager to ensure that multiple avenues for communicating non-conformance information are available to everyone that participates in this activity. Audit reports are generated by the company registrar, internal auditors and customer auditors. Reports are delivered to the quality manager. Employees use data collection codes to classify the work they are performing as rework when appropriate. This is collected on a daily rework report. Database mining is reported to company management. Report generation is requested by company managers and performed by IT personnel. Customers report Supplier Corrective Action Requests (SCAR) through sales and service contacts and are reported to the quality manager. Employees observe and report non-conformance when output is not aligned with SOP requirements or when experience dictates that management is alerted. Department meetings also serve as a vehicle for reporting non-conformances and inefficiencies.	Non-conformance information has many sources and all of it must be captured for evaluation. If input is left out, lost, ignored or otherwise absent the ability to effectively address root cause is compromised.

		• **Management** – information gathered during business operation, meetings and other management activity	Observation and analysis during normal operations will reveal reportable non-conformance.	
2	◆	Recording non-conformance events	Input is gathered from all available sources. When an issue is brought to a manager's attention, an entry into the Smartsheet application is made by that manager. Non-conformance events are not limited to rework. Any incident observed that violates a process or behavior control can be entered into th The requirements for entries into Smartsheet are included on the Smartsheet page and in the QMS – Managers page on the Teams application. There are three sections to each Smart sheet entry made by three different people: The **first** section (blue header) is completed by the manager initiating the entry The **second** section (black header) is completed by the Quality Manager The **third** section (green header) is completed by the manager assigned to the entry by the Quality Manager Each entry into the application becomes a non-conformance event and a project is created for each one. Once an entry is made, a notification is sent to the Quality Manager to complete the **second** section. Completion of that section will notify the assigned manager via e-mail that they have a non-conformance event to address.	It is the goal of this process to capture all non-conforming events for evaluation and corrective action. The entry is simple in order to encourage participation. There are three sections to allow for complete information collection while not overwhelming the user with a tedious or difficult task. To act on as many non-conformances as possible.

3	◆	Process for Evaluation and Corrective Action	The Quality Manager or representative will determine where to assign each event for evaluation and corrective action. This may include combining the event with other examples of the same type or cancelling the event due to redundancy or timeliness. A notification will be automatically sent to the person/manager assigned to the event. This will come via email from the software application. Information will include (but is not limited to): 1. Date of incident 2. Job number (if applicable) 3. Description of non-conformance 4. Date the response is due	This step assigns events to appropriate managers and others to begin the process of correcting non-conformances.

			The manager receiving the request will review the information. If the manager believes the event is mis-assigned or would be better served in another department, this is the time to make a request for reassignment to the Quality Manager. Once the request is appropriately assigned, the assigned manager will take the following steps:
			
			• Understand the issue, as appropriate:
			  ○ Conduct investigation
			  ○ Interview relevant parties
			  ○ Establish facts
			• Determine root cause category:
			  ○ Process flaw
			  ▪ Current process does not account for incident
			  ▪ Current process is inadequate to address incident
			  ○ Process not performed
			  ▪ Training insufficient
			  ▪ Experience insufficient
			  ▪ Skill level not appropriate
			  ▪ Refusal to perform
			  ○ Capability or Capacity Issue
			  ▪ Resources inappropriate
			  ▪ Task beyond scope
			• Determine corrective action:
			  ○ Process change
			  ○ New process
			  ○ Training
			  ▪ Skill matrix
			  ▪ Reprimand
			  ○ Acquire resources
			  ○ No action
			• Document appropriately
			  ○ New SOP or Form
				Findings and information need to be collected and entered into the event database.
				
				See the **Required Actions** table below for event-specific recommended actions

			○ Revised SOP or Form ○ Training record Close the event by entering the “date completed” in the event line field.	
4		Review	The Quality Manager will review all closed line items and may request edits or changes to the findings and results based on the requirements of the ISO standard and the needs of the Quality Management System. This may include but is not limited to: 1. Additional documentation or documentation changes 2. Additional training 3. Smartsheet entries 4. Rework entry	To remain compliant with standard requirements
5		Reporting and Evaluation	Then Quality Manager is responsible for follow up actions resulting from the evaluation and correction steps taken. • **Audit response** – all audit findings will be documented according to the requirements of the audit author. • **Customer SCAR** – a report will be written by the quality manager and made available to the customer at their request. Corrective actions resulting from customer-reported non-conformances require documentation outside the normal QMS documentation requirements for SOP’s. Forms are usually supplied by the customer. • **Reporting** – the Quality Manager will report follow up information, statistics and evaluation information on the QMS CI board and /or during regular Management Reviews.	

6		Additional Actions and Records	Depending on the nature of the non-conformance, additional actions or documentation may be generated for fulfill ISO, customer-facing or internal requirements. This may include: **Rework Entry** – this is entered on the company intranet page and is required when a new job ticket is required to reprint resulting from a non-conformance. This entry may be made by a manager or quality manager. **CPAR** – this record is created when documentation is required for outside reporting purposes. Form CI046 is used for this record and a summary of all CPAR is generated by the Quality Manager.	Required so that accounting may track rework dollar amounts and number of jobs Customers may require written corrective action responses to their events. This is used when they do not supply their own forms or web entry pages.

Required Actions Table	
Non-conformance	**Action**
Current process does not account for incident	Update current document or create new, train revised process, create training record
Current process inadequate for incident	Update current document or create new, train revised process, create training record
Training insufficient	Update matrix or documentation, retrain or refer to HR, create training record
Experience insufficient	Update matrix requirement
Skill level not appropriate	Update training, create training record
Refusal to perform	Refer to HR
Resources lacking	Recommend requirement to Executive Committee
Task beyond scope	Recommend rule change, refer to Executive

Notes:

Documentation hierarchy:

Smartsheet Entry – performed by managers and quality manager
- Rework Entry – performed by managers and quality manager
- CPAR – performed by quality manager
- NC Record – performed by quality manager

Definitions: SCAR – supplier corrective action request. CPAR – corrective/preventive action request

Revision History	Description of Changes	Requested by	Date
Rev 0	Initial publication	Dean Milinkovich	6/30/2023