## 1. Supplier Corrective Action Report Guidelines

The following lists a useful set of guidelines to assist completing a supplier corrective action response for Nonconformity Reports (SCARs). These guidelines are also valuable for corrective action responses from other sources (Creation complaints, Field return defects, Customer complaints, audits etc.)

## 2. Describe the nonconformance / problem:

a. Describe the problem or reported defect in detail. Clearly define the problem and, if necessary, any specific conditions under which the problem occurs or becomes visible.

b. Obtain samples of defective products if applicable for further investigation

## 3. Team Leader / Members involved in resolving the problem:

a. Establish a team and resources.

b. List all the people involved in working on this stated problem above (name and title).

## 4. Containment Action short term:

a. Address the symptom: Identify the actions that were necessary to *immediately* cure or contain the actual non-conformance that was identified.

b. State the direct actions that were taken to ensure that the process is now being executed in conformance with supplier / customer or procedural requirements.

c. State your actions to inspect your WIP and inventory for conformance. Include the extent of your inspection and your findings of those inspections:
- *Were parts 100% inspected?*
- *What was found?*
- *XX bad out of XXX pieces?*

d. Note how the subsequent compliant parts will be identified on the packaging or label, and for how long that marking will be included – i.e. 3 shipments; 30 days; etc.

e. Describe any containment for product which would be in transit or in the supply pipeline to your customer or in your customers inventory.

f. Serious non-conformance causing risk to product or safety of the user or repeat occurrences of the same non-conformance indicate that the supplier's process is out of control. If requested by <Your Organization>, effective and timely corrective & preventative action is required and documented in the form of a SCAR. The supplier is

expected to acknowledge the receipt of a SCAR within 5 business days (e.g. email, phone call).

## 5. Root Cause Analysis:

a. Finding the actual root cause is critical to ensure that the nonconformance is prevented from recurring.

b. All defects are created by errors. The key is to identify the ORIGIN of the errors that caused or allowed the nonconformance to occur.

c. What controls of the management system were ineffective in preventing the errors that allowed the nonconformance to occur?

d. Find and verify root causes and failure analysis of the problem i.e. if a component is out of specifications, find out if the parameters setting is accurate.

e. **Use disciplined problem-solving tools to show how the root cause was determined and can be relied upon.**

f. **Examples of acceptable root cause statements might include:**
- 5-Why root cause analysis
- Process Analysis (value stream mapping, internal audits, use of process definitions, etc.)
- Cause and Effect Diagrams
- Fault Tree Analysis
- Statistical studies identifying the causes of variation (MSA, SPC, DOE, etc.)
- Brainstorming process results
- DMAIC problem solving method
- Ford 8D problem solving method

g. **Examples of unacceptable root cause statements:**
- Restating / rewording the nonconformance
- Operator failed to follow procedures (How did the management system allow this?)
- Operator error (Why did the process allow the operator to make an error?)
- Management oversight (Why did the management system allow this?)

**If there are more than one finding listed in the nonconformance statement, then there must be a root cause analysis performed and described for each finding.**

## 6. Permanent Corrective Action plan to address root cause:

a. A corrective action plan must be developed for each SCAR.

b. Corrective action must describe the formal CHANGES that were implemented to address each root cause statement.

c. A statement in a corrective action response is not evidence of formally changing the system. Changes resulting from corrective actions must be defined and documented in work instructions, or documentation.

d. Measurement of effective implementation of the changes, such as SPC data, inspection records, training records, audit records, etc. is required.

e. List the specific document names, document numbers, revision levels, pages, etc. that show where the change was defined in the management system.

f. The supplier shall analyze the problem, implement containment action(s), determine the root cause(s), define corrective and preventive actions and verify the effectiveness of those actions (Creation will review the supplier's proposed corrective and preventive plan and reserves the right to reject the plan). The supplier is expected to answer the SCAR in its entirety within **30 business days** from time notified.

g. Formal management system controls must be added or improved upon to prevent or detect the ERRORS that caused the nonconformance. **The preferred approach is to prevent errors before they occur, rather than detect and correct them after they have occurred. This is called fool-proofing, errorproofing, or Poka-yoke.**

h. **Examples of <u>acceptable</u> corrective action statements might include:**
- Automated controls were added to processes to prevent errors
- Additional manual verification points or testing operations were created at specific processes to detect the errors
- Additional internal audit requirements were established to verify conformance to process requirements

i. **Examples of <u>unacceptable</u> corrective action statements:**
- Reinforced the importance of following procedures (What improved controls were implemented to make sure people follow procedures?)
- Retrained operators (Why did the training not work the first time? Maybe even the best training will never be enough because the process needs to be error-proofed?)
- Fired the operator (What process allowed that operator to be assigned in that function?)

## 7. <u>Actions to Preventative Recurrence: how do I keep this from occurring again:</u>

a. A nonconformance could occur in similar processes or products that were not sampled. Ask the question: "Do other products require the same operation, or process, and might be affected?" The corrective action must describe an assessment of any similar processes or products. Where applicable, note any actions taken to apply the corrective actions to these.

b. Review and update procedures, work instructions, control plans, FMEAs, etc. to show any changes that were defined. Evidence of effective implementation of the changes may also be required - such as SPC data, inspection records, training records, audit records, etc.

c. State the preventative actions, along with the expected or actual date of implementation. How can you keep the described problem from ever happening again?

d. Perform Mistake Proofing or error proofing (Poke Yoke) as you develop new processes so to "design in" preventative actions.

## 8. Verifying the Effectiveness of Corrective Actions:

a. In many cases the root cause analysis does not lead to the actual root cause, nor do the corrective actions taken effectively prevent the nonconformance from recurring. Therefore, the corrective actions taken must be verified to ensure that they were effective in eliminating the root cause and preventing the nonconformance from recurring.

b. The key to verification is evidence. Gathering objective, factual evidence that the problem causes have been reduced or removed. Supporting evidence form of data or records and change management processes are encourage to be submitted together.

c. There are many methods that may be used. The method(s) to be used must be described and will be checked at the next audit.

d. **Examples of verification methods include:**

- Additional process monitoring until it is demonstrated that the process is stable and capable of consistently meeting requirements (recording and analysis of process parameters and/or product characteristics, SPC, etc.)
- Internal audits to specifically verify the effectiveness of the corrective actions
- Associated metrics showing significant improvement resulting from the corrective actions.
- Please review in detail that the corrective action plan does not create un-desired side effects or introduce new problems.

## 9. How does <Your Organization> identify products containing updates?

a. All subsequent product shipped to <Your Organization> must be labeled as 100% re inspected "CERTIFIED" for the problem that was identified in the original problem statement(s). Note in your response how that will be done, and how to identify those shipments from earlier, or "uncontained" product.

b. In certain cases, products shall need to be "witness marked" with a certain color dot or marker. If this is required, then state specifically what will be done.

Form Sample - **SUPPLIER CORRECTIVE ACTION REPORT (SCAR)**

| **Section 1: General Information (*To be filled by Helind Asia Pacific SG Pte Ltd*)** | | | |
|---|---|---|---|
| SCAR Number | | Issued To<br>(Name/ Department) | <Name – Designation)<br>Company Name |
| Date of SCAR | | Request By<br>(Name/ Department) | Personnel in <Your Organization><br>Designation |

| **Section 1: Description of Non-Conformity / Problem** |
|---|
| Describe the problem or reported defect in detail. Clearly define the problem and, if necessary, any specific conditions under which the problem occurs or becomes visible. |
| **Section 2: Investigation Team** |
| |
| **Section 3: Containment Action – Short Term (*To be filled up by Vendor*)** |
| Describe the actions that was taken immediately to cure or contain the detected non-conformity |
| **Section 4: Root Cause Analysis (*To be filled up by Vendor*)** |
| Use disciplined problem-solving tools to show how the root cause was determined and can be relied upon. |
| **Section 5: Permanent Corrective Action plan to address root cause** |
| |
| **Section 6: Report Submission** |

| Reported By | Reviewed By | Approved By |
|---|---|---|
| ---------- | ---------- | ---------- |
| Name / Designation<br>Date: | Name / Designation<br>Date: | Name / Designation<br>Date: |

**Section 7: Verification of the Effectiveness of Corrective Actions**

Describe the evidence provided from vendor planned / implemented corrective actions.

Status: ☐ Accept ☐ Reject; Please state reason(s) for rejection:

| | |
|---|---|
| Report Closed Out By<br>Name/ Designation | : |
| Date | : |