

## Procedure PR-PRO-006

### Corrective and Preventive Action

#### 1. SUMMARY

- 1.1. In an effort to ensure continual improvement, Pure Rail engages in corrective and preventive action to discover, investigate, and correct nonconformance's related to Pure Rail products, its processes, and the company's quality system.
- 1.2. For internal issues, the company refers to this as the Corrective Action Report (CAR) system.
- 1.3. For issues which are found to be the fault of suppliers, the Supplier Corrective Action Request (SCAR) system is used; this is defined in the procedure ***PR-PRO-018 Purchasing***.

#### 2. REVISION AND APPROVAL

Rev.	Date	Nature of Changes	Approved By
1	01/01/16	Original issue.	Kyle Devine
2	24/11/2021	Updated document number, formatting and references to relevant controlled document numbers added.	Kyle Devine

#### 3. PROCEDURE

- 3.1. The Corrective Action Report system shall be used to address all of the following:
  - Customer complaints
  - Employee reports of problems with equipment, procedures, processes, buildings, infrastructure
  - Employee suggestions for improvement
  - Resolving trends associated with product nonconformities
  - Process nonconformities
  - Audit findings (internal or external)
  - Management review action items
  - Any other reported problem or suggestion, no matter the source
- 3.2. All employees are empowered to submit a corrective or preventive action request when they discover an existing or potential nonconformity against ISO 9001 requirements, company procedures, customer requirements, or statutory/regulatory requirements.

- 3.3. In addition, customer complaints, returns, and/or reports of nonconformance's shall be handled through corrective action procedures.
- 3.4. In addition, employees may submit suggestions for improvement to the company through the Corrective Action Report system.
- 3.5. This system provides for the reporting and resolution of both corrective action requests (existing problems) and preventive action requests (potential problems.)
- 3.6. The **Corrective Action Report** system is comprised of two forms:
  - The **PR-FRM-008 Corrective Action Request** – this is used by employees to request corrective or preventive action, or to submit suggestions for improvement.
  - The **PR-REG-007 Corrective Action Register** – this is used to track CARs and to provide trend data on the CAR system for later management review.
- 3.7. To request corrective or preventive action, or to submit a suggestion for improvement, the employee obtains the **PR-FRM-008 Corrective Action Request** form; this may be filled out by hand, or by filling in the electronic form.
- 3.8. The employee requesting action fills out the top portion, completing the following:
  - **CAR number:** leave blank (this will be filled in later)
  - **Type of action requested:** select corrective when reporting existing problems, “preventive” when reporting potential problems, or “opportunity for improvement / suggestion” when the report is a pure improvement action, unrelated to any particular problem.
  - **Source:** indicate where the report originates from. In most cases, this will be from employees, but if an employee is filling the CAR on behalf of someone else, indicate the original source (i.e., customer, supplier, external auditor, etc.)
  - **Process:** indicate the process for which the issue being reported is mostly likely covered by. The employee may guess here, as the Director(s) may revise this later, as needed.
  - **Priority:** indicate a priority based on the following criteria:
    - **LOW:** Respond as availability allows; may extend deadline with permission of Director(s).
    - **MEDIUM:** Respond as soon as feasible; deadline established, but may be interrupted by higher priority activities.
    - **HIGH:** Respond by established deadline, which may interrupt other staff working low or medium priority activities.
    - **URGENT / CRITICAL:** Respond immediately with sustained effort using all available resources until resolved. Company at legal or other compliance risk.
  - **The Issue:** describe the problem being reported or the suggestion offered; be as detailed as possible. Internal audit findings must comply with the requirements put forth in the procedure **PR-PRO-014 Internal Auditing**.

- 3.9. The employee will then send the CAR form to a Director.
- 3.10. The Director(s) will then begin an entry for the CAR form in the **PR-REG-007 Corrective Action Register** (Log) by entering the information in the next available line in the log. The information entered should match that indicated on the CAR form (i.e., the process, priority, etc.) Under "Brief Description, only a short sentence describing the issue need be entered, not the entire text of the issue; this is only to help remember the nature of the Corrective Action Report later.
- 3.11. The Director(s) will assign the CAR to one or more employees who are best able to research and resolve the issue, and enter this in both the log and the CAR form under "Assigned To." This person is hereinafter referred to as the "Assignee."
- 3.12. The Director(s) will assign a response date for the CAR; this can be whatever time frame the Director(s) think is suitable for the issue being investigated. The consideration of this time frame will take into consideration the level of effort expected, costs, risks, etc.; for example, some actions may take months to correct and resolve, while others may take days or less. If necessary, the Director(s) will determine this time frame with the help of the assignee.
- 3.13. The Director(s) will then send the CAR to the assignee.
- 3.14. The log will highlight when CARs are overdue, based on the assigned date. In the event of an overdue CAR, the Director(s) will either negotiate a revised date with the Assignee, or escalate the CAR to the Assignee's manager for attention.
- 3.15. The Assignee shall conduct a root cause analysis using **PR-FRM-010b Investigation Report** form to determine the cause(s) of the problem. This exercise should be thoughtful and detailed, so as to ensure the actual root causes are identified. Failure to properly conduct root cause analysis may result in the wrong cause being acted upon, and thus the problem not being permanently resolved.
- 3.16. Root cause analysis is mandatory for corrective or preventive actions; it is not required for opportunities for improvement or suggestions since these may not be attached to any known problem; in such cases root cause analysis is optional.
- 3.17. The Assignee will then develop an action plan to address the root cause and eliminate it. By eliminating the root cause, the problem should never occur or recur.
- 3.18. For some preventive and corrective action issues, management may elect to perform a risk assessment as part of the action plan determination; see procedure **PR-PRO-020 Risk and Opportunity Management**.
- 3.19. The Assignee will then implement the plan, updating the text of the CAR as the plan progresses. During this time the plan may change, or expand, etc., so the text must be updated to reflect the actions assigned and taken.
- 3.20. Once the action is complete, and the Assignee feels the issue is resolved, he/she will sign the CAR and indicate a completion date. They shall then return the CAR to the Director(s).

- 3.21. The Director(s) will update the log entry for the CAR, indicating the action complete date.
- 3.22. The Director(s) will perform independent verification of the actions taken to ensure the actions are effective in resolving the root cause(s). This verification should examine evidence and take into consideration the following:
  - Has the action plan removed the root cause(s)?
  - Does the action appear to eliminate the original issue reported?
  - Were any related documents updated, as needed?
  - Was training conducted, if required?
  - Does the action require an update to the internal audit schedule?
  - Were all interested parties properly notified of the actions taken?
- 3.23. The Director(s) will record the results of the verification activity in the log.
- 3.24. If the issue is satisfactorily addressed, the Director(s) may close the CAR by indicating this in the final column on the log. The CAR form is then filed.
- 3.25. If the Director(s) determines the issue is not properly addressed, the Corrective Action Report may be re-assigned for further action, or a new CAR filed. This is indicated in the log.
- 3.26. The Corrective Action Report Log generates trend reports for both corrective and preventive actions over time; these are reported during management review.