Procedure: Corrective and Preventative Action

1. SUMMARY

1.1. In an effort to ensure continual improvement, Facilities and Services Division (F&S, or the Division) engages in corrective and preventive action to discover, investigate, and correct nonconformance’s related to F&S products, its processes, and the Division’s quality system.

1.2. For internal issues, the Division refers to this as the Corrective Action Request (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 Purchasing Critical Supplies.

2. REVISION AND APPROVAL

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<th>Rev.</th>
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<th>Nature of Changes</th>
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<td>Original issue.</td>
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3. PROCEDURE

3.1. The Corrective Action Request 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; and
- 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, F&S procedures, client requirements, or statutory/regulatory requirements.

3.3. In addition, client complaints, returns, and/or reports of non-conformances shall be handled through corrective action procedures.

3.4. F&S staff may submit suggestions for Opportunities for Improvement (OFI) to the Division through the Corrective Action Request system.
3.5. Individual product issues (incorrect or nonconforming parts, etc.) should be first written up per the procedure **Control of Nonconforming Product**. When trends are noticed within nonconforming products, then a **Corrective Action Request** may be issued to investigate the cause of the trend.

3.6. This system provides for the reporting and resolution of both corrective action requests (existing problems) and preventive action requests (potential problems.)

3.7. The **Corrective Action Request** system is comprised of two forms:

   - The **Corrective Action Request** – this is used by F&S staff to request corrective or preventive action, or to submit suggestions for improvement.
   
   - The **Corrective Action Request Log** – this is used to track CARs and to provide trend data on the CAR system for later management review.

3.8. To request corrective or preventive action, or to submit a suggestion for improvement, an F&S staff member obtains the CAR form; this may be filled out by hand, or by filling in the electronic form in MS Excel®.

3.9. The F&S staff member requesting action fills out the top portion, completing the following:

   - **CAR number**: leave blank (Official use only)
   
   - **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 F&S staff members or the Business Unit they belong to, but if a staff member is filling the CAR on behalf of someone else, indicate the original source (i.e., business unit, client, supplier, external auditor, etc.)
   
   - **Process**: indicate the process for which the issue being reported is mostly likely covered by. The F&S staff member may guess here, as the F&S Quality Manager may revise this later, as needed.
   
   - **Priority**: indicate a priority based on the following criteria:
     
     o **LOW**: Respond as availability allows; may extend deadline with permission of F&S Quality Manager.
     
     o **MEDIUM**: Respond as soon as feasible; deadline established, but may be interrupted by higher priority activities.
     
     o **HIGH**: Respond by established deadline, which may interrupt other staff working on low or medium priority activities.
     
     o **URGENT / CRITICAL**: Respond immediately with sustained effort using all available resources until resolved. F&S facing potential 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 **Internal Audits**.
3.10. The F&S staff member will then send the CAR form to the F&S Quality Manager.

3.11. The F&S Quality Manager will then begin an entry for the CAR form in the Corrective Action Request 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 Request later.

3.12. The F&S Quality Manager will assign the CAR to one or more F&S staff members 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.”

3.13. The F&S Quality Manager will assign a response date for the CAR; this can be whatever time frame the F&S Quality Manager thinks 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 F&S Quality Manager will determine this time frame with the help of the assignee.

3.14. The F&S Quality Manager will then send the CAR to the assignee.

3.15. The log will highlight when CARs are overdue, based on the assigned date. In the event of an overdue CAR, the F&S Quality Manager will either negotiate a revised date with the Assignee, or escalate the CAR to the Assignee’s manager for attention.

3.16. The Assignee shall conduct a root cause analysis 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.

3.17. 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.

3.18. 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.

3.19. For some preventive and corrective action issues, management may elect to perform a risk assessment as part of the action plan determination; see Risk and Opportunity Management.

3.20. 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.

3.21. 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 F&S Quality Manager.

3.22. The F&S Quality Manager will update the log entry for the CAR, indicating the action complete date.
3.23. The F&S Quality Manager 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?

3.24. The F&S Quality Manager will record the results of the verification activity in the log.

3.25. If the issue is satisfactorily addressed, the F&S Quality Manager may close the CAR by indicating this in the final column on the log. The CAR form is then filed.

3.26. If the F&S Quality Manager determines the issue is not properly addressed, the Corrective Action Request may be re-assigned for further action, or a new CAR filed. This is indicated in the log.

3.27. The Corrective Action Request Log generates trend reports for both corrective and preventive actions over time; these are reported during management review.