Perform Air International, Inc.
Quality Control Manual
Section II
Procedure: II.09 Corrective and Preventive Action Procedure

Revision	Revision Date	Revision Change
N/I	02/08/10	Initial Release/Re-release
1	12/31/10	Addition of 4.8 - definition clarification. Revision of 6.5 – removal of location.
2	09/28/12	Expanded 1.0 Purpose, 2.0 Scope and 3.0 Responsibility to include continuous improvement concept. In 4.6 corrected effect to affect. Added 4.9 to definitions. To 5.1.1 and 5.2.2 included health and safety/hazard concern, minor he/she correction. Removed 5.1.2 entirely (moved intent of this paragraph to paragraph 3.0 Responsibility) Removed 5.3 Hazardous Notification with intent added above to 5.1.1 and 5.2.2. Added 5.3 Observations. Removed 6.5 and 6.6 from Records, added Diamond Excellence Award.
3	07/01/13	Pagination of 3.1 thru 3.4 for consistency of format. Revision to procedure for clarification of responsibility and grammar.
4	10/31/13	Revision to 3.2, 3.3, 4.5, 4.6, 4.7, 5.1.1, 5.1.1.2, 5.1.1.3, 5.1.1.4, 5.1.1.5.1, 5.1.1.6, 5.2.2, 5.3.2, 5.3.3, 6.1 and 6.3 for grammar and clarification of procedure. Addition to 6.7 and 6.8 Records.
5	12/01/14	Revision to 5.1.1.1. Addition of 5.1.1.5.1, 5.1.1.5.2, 5.2.2.1 and 5.2.2.2.
6	07/31/17	Revision to 3.2 (removal of text), 3.4, 4.1, 5.1.1, 5.1.1.2, 5.1.1.4, 5.1.1.5, 5.1.1.5.2 and 5.2.2.2 for grammar and responsibility change. Addition of 5.4for clarification.
7	02/28/18	Revision to 5.1.1.1
8	01/31/19	Revision to 5.1.1.1.1, 5.4 and 5.4.1 for clarification. Removal of 6.5 and 6.6 resulting in repagination.
9	*06/27/25*	*Revision to 5.1.1.2, 5.1.1.4, 6.6 (now 6.5): Removed 6.4 Root Cause Analysis Chart*

1.0 Purpose:

To eliminate actual and potential system and safety deficiencies, and to ensure via a root cause analysis that the deficiency does not recur. To establish a means for all employees the Corrective and Preventive Action (CAPA) methodology to continuously improve the quality of product, processes, workplace, and environment.

2.0 Scope:

Any actual and potential system and safety deficiencies can be discovered via complaints, non-conforming product, internal/external audits, data analysis, observation, or other concerns in support of the Perform Air International Inc. Mission Statement to provide the highest quality product to our customers.

3.0 Responsibility:

3.1 The maintenance of this procedure is the responsibility of the Quality Assurance Manager.

3.2 The Quality Assurance Manager is responsible for ensuring compliance with the provisions of this procedure. Deficiencies identified by employees and/or external auditors will result in a Corrective Action request(s) being issued.

3.3 It is the responsibility of all employees to initiate Corrective/Preventive Actions or Observations whenever deficiencies, the potential for deficiencies, or PAI System improvements are identified.

3.4 It is the department manager's responsibility to verify the response made by their direct reports is adequate to prevent recurrence of any stated problems.

3.5 The Management Representative is responsible for reviewing completed CAPA's that have been sent for verification and providing data analysis of the CAPA system. Through analysis, the Management Representative will determine if similar non-conformities exist or could potentially occur.

4.0 Definitions:

4.1 **CAPA –** The Corrective and Preventive Action system utilized within Perform Air International Inc.

4.2 **Corrective Action–** A reactive response to a problem that has already occurred (i.e., discovered via complaint, damaged part, internal audit findings, etc.).

4.3 **Preventive Action-** Proactive response to a problem which has not yet occurred (i.e., discovered via data analysis such as future procedural improvements to reduce production costs, etc.).

4.4 **Root Cause-** The "real" reason an actual or potential problem has/will occur. Note: this is rarely "human error" but rather, conditions leading to "human errors."

4.5 **Critical Priority-** A Corrective Action relative to the health and safety of employees, a maintenance function which could cause non-compliance to an applicable standard Perform Air International Inc. complies with, or a requirement.

4.6 **Urgent Priority-** A Corrective/Preventive Action relative to a requirement that requires investigation quickly but does not directly affect compliance to applicable standard, or employee health or safety.

4.7 **Routine Priority-** Any Corrective/Preventive Action that does not meet the requirements of Critical or Urgent priority.

4.8 **Non-Conformance-** Process or procedural errors of commission/omission as indicated by Internal Audits.

4.9 **Observation-** Insightful process in support of the systematic effort of continuous improvement to product, process, documentation, or environment.

5.0 Procedure:

5.1 **Corrective Action**:

5.1.1 Perform Air International Inc. will effectively handle complaints, product and environmental non-conformances, as well as health and safety/hazard concerns by means of analyzing causes of deficiencies, analyzing processes, applying controls to ensure that Corrective Actions are taken, and performing audits to ensure that Corrective Actions are effective.

5.1.1.1 The corrective/preventive action system utilizes a priority system. The priority choices, and required response times are as follows:

Critical:	1-day investigation/response required
Urgent:	5-day investigation/response required
Routine:	30-day investigation/response required

Extension may be granted on responses categorized as Routine if extenuating circumstances exist. This extension will be requested through the Management Representative and granted by executive management. This extension will be recorded in the verification section of the CAPA system by the Management Representative and will include justification and the revised due date. Extended period will be equal to the original response time (i.e., 30-day extension for Routine CAPA).

5.1.1.2 Any employee may initiate the investigation of a non-conformance via the CAPA system. The Corrective Action, once issued, is electronically sent to *Department Manager* who has responsibility for the area of concern. The Quality Assurance Manager is advised via electronic mail of each newly issued Corrective Action request.

5.1.1.3 Any supplier who is determined to be responsible for the root cause of a Corrective Action will receive a Corrective Action request. This is a flow down of the Corrective Action system and is designed to assist the supplier in system improvement.

5.1.1.3.1 All Diamond Excellence Award vendors must respond to the Corrective Action request to remain a preferred status.

5.1.1.4 Each *department manager* ensures investigation and documentation of the Corrective Action by use of the Root Cause Analysis *selections provided in the electronic system*. The Root Cause Analysis *selections are* encompassed within the CAPA system. It allows each *manager* to select the correct root cause via a drop-down classification field. The Immediate Solution and Long-Term Corrective Action areas allow the *manager* to provide information on immediate correction and further prevention. Once completed, *managers* forward the response to their *next level supervisor* for review. If acceptable, the manager forwards the response to the Management Representative. Note: *Director Level* personnel are not required to forward their responses to their Executive *Vice president* for review. Once completed, management will send the response to the Management Representative for verification.

5.1.1.5 The Management Representative reviews the documented response. If acceptable, he/she approves the action, enters the verification, and closes out the non-conformance. If unacceptable, it is returned to the applicable individual for root cause identification. The resubmission will be reviewed again via the same process.

5.1.1.5.1 All Corrective Actions must be researched and verified within 90 days of Corrective Action response.

5.1.1.5.2 If more than 90 days are required for verification of response, executive approval is required and will be documented in the verification section of the CAPA system.

5.1.1.6 Once the Corrective Action is verified, the form is closed out and the documentation is electronically retained for review in the next scheduled management review.

5.2 Preventive Action:

5.2.1 Perform Air International Inc. uses the appropriate sources of information to ensure that Preventive Action is taken.

5.2.2 In the event that an employee identifies an area that he/she feels could be a potential non-conformance or a health and safety/hazard concern, the employee is encouraged to issue a Preventive Action. The Preventive Action is created in the same method as a Corrective Action and is sent electronically to the individual responsible for the area in question.

5.2.2.1 All Preventive Actions must be researched and verified within 90 days of Preventive Action response.

5.2.2.2 If more than 90 days are required for verification of response, executive approval is required and will be documented in the verification section of the CAPA system.

5.2.3 Once the Preventive Action is verified, the form is closed out and the documentation is electronically retained for review in the next scheduled management review.

5.3 Observations

5.3.1 In the event that any employee identifies an area that he/she feels could help or bring improvement to the product itself, a tool, the process, documented procedure or a health and safety enhancement, the employee is encouraged to issue an Observation.

5.3.2 Much in the same manner as a Corrective or Preventive Action, an Observation can be issued by any employee to the area manager for consideration and follow up.

5.3.3 Once the Observation is verified, the form is closed out and the documentation is electronically retained for review in the next scheduled management review.

5.4 Extrinsic Audits *and Customer Complaints*

5.4.1 Any non-conformance or observation that has resulted from an extrinsic audit *or a customer complaint* will be documented via the CAPA system. Upon receipt of the extrinsic audit report, the Quality Assurance Manager will issue the Corrective or Preventive Actions and/or Observations to the appropriate department manager.

5.4.2 All audits will be answered in the required response time and will require approval from the Accountable Manager prior to submittal to the extrinsic auditor.

6.0 Records:

6.1 CAPA (Electronically Stored in CAPA System)
6.2 Management Review Records
6.3 Internal Audit Reports
6.4 External Audit Reports
6.5 Audit Assessment Form *63.03*