Perform Air International Inc.
Fabrication Control
Manual Section XIII
Process: XIII.01 Design Review

Revision	Revision Date	Revision Change
N/I	12/29/2023	Initial Release

1.0 Purpose:

This document defines how Perform Air International, Inc. will establish and implement systemic technical and programmatic reviews of the design and development process.

2.0 Scope:

This process applies to all new products from original concept through the design, prototype, and test phases leading to a production item. It also covers modification or customization of an existing product which are necessary to meet new customer requirements.

3.0 Responsibility:

Engineering management is responsible for the development, implementation, and control of this procedure.

Engineering management shall be responsible to ensure that design reviews are undertaken and implemented and that necessary follow up action is taken on those portions of the design which need to be changed and/or approved by the customer.

Design Reviews shall be held before the design is released for production or prototyping.

The review is to confirm that the design meets requirements and to uncover omissions, errors, or decisions that will have adverse effects on safety, reliability, performance, procedures, or costs.

4.0 Definitions:

Configuration Baseline – Hardware or system configurations which formally establishes a reference point for subsequent changes and development activities.

Critical Design Review (CDR) – Typically held upon completion of the detail design. Examines project status, schedule, detail/assembly/outline drawings, specification compliance, test plans, and technical risks of prototype and/or qualification units. All design changes resulting from the review shall be incorporated prior to releasing the design for manufacture.

Demonstration Model – Hardware that is manufactured for validation testing. This hardware is both functionally and physically representative of the end-product.

Design – Design includes the engineering, analysis, and creation of drawings to arrive at a solution which fulfills a need.

Development – Development involves fabrication of hardware, processing, assembling, and testing of prototype units. Data gathered from this activity is fed back into the original design and, if necessary, modifications made to the appropriate aspects of the process. This continues until the end-product satisfies all design criteria.

Design Review – A formal, multi-disciplinary critical study of all aspects of a design by people other than the designer. Minutes of the meeting are documented, and action items are produced which are used to improve and/or otherwise modify the design, if appropriate.

Engineering Design Review (EDR) – An internal design review held within the Engineering Department intended for prototype, development or experimental units only. The customer is typically not present.

Final Design Review (FDR) – Typically held prior to production and as far along as possible in the development/test program to ensure all information is as complete as possible. Examines project status, performance, design refinements, specification compliance, reliability, and maintainability. All design changes resulting from the review shall be incorporated prior to releasing the design for production. The customer may be present.

Preliminary Design Review (PDR) – Typically focuses on system design, the architecture of the device, features, sizing, design criteria, etc. The review also involves the detail coordination of design, performance/data requirements, and schedule. The customer may be present.

Production Process Review (PPR): Examines the production process using typical flowcharting and preliminary process Failure Mode Effects Analysis (FMEA) as tools. The key characteristics and critical processes of the device will be identified. Detail process specifications/control, quality assurance plans, and instructions will be examined and discussed. The customer may be present.

Production Readiness Review (PRR): Examines the entire product and process documentation packages including quality assurance provisions with respect to their accuracy and completeness. A final production process FMEA shall be available for review and discussion. The customer may be present.

Prototype – A working model that is functionally representative of the design. The model is used to verify that the design requirements are met through testing and subsequent evaluation of test data.

Simultaneous Engineering – A method of reducing the time taken to achieve an

engineering objective. This is accomplished by developing the resources needed to support and sustain the development of an item in parallel with the development of the item itself.

Validation – The act of validating the performance of an entity with respect to its design requirements. This activity usually occurs in the form of testing on a test bench or system which duplicates the end-user environmental parameters or is tested in the actual end-use application. The validation process typically uses end-item or production hardware.

Verification – The act of verifying the performance of an entity with respect to its design requirements. This activity usually occurs in the form of testing on a test bench or system which simulates various aspects of the end-user environment. The verification process typically uses prototype hardware.

Verification Requirements – The criteria, methods, and techniques that are put in place and are necessary to verify whether an engineered item conforms to its design requirements.

Work packages – Parcels of work that are distributed to either internal personnel or to outside suppliers to accomplish a task.

5.0 Process:

5.1 Systematic reviews address the design and encompass all aspects of the design from the highest (assembly) level down to the smallest (component) level as they pertain to the desired end result. They also serve to address the technical and programmatic issues that arise as a result of the design and development process.

Periodic reviews are critical to ensuring the success of the design on all levels and provide feedback to the designer or design team to aid in continually improving the design as necessary. PAI will define how it will conduct these reviews in accordance with the standard and sound engineering practices. Engineering Design Checklist Form 67.12 can be used throughout the design lifecycle to capture progress of a project.

5.2 Planning Design Reviews – Design reviews represent a formal mechanism for management and the customer to evaluate designs at major milestones. The purpose of these reviews is to determine whether the proposed design solution is compliant with the design requirements or should be re-evaluated and/or changed.

These reviews also ensure that the documentation necessary to proceed to the next design phase is adequate and complete.

5.3 Review Schedules and Types – depending on the complexity and/or application of the product, PAI will elect to conduct as many design reviews it deems necessary to adequately address the design evaluation throughout the design and development cycle. Major (formal) reviews will be conducted as required by PAI, contractual obligation, or customer request, and may include, but not be limited to the following:

5.3.1 EDR – the review team will be represented by Engineering Management and have the following minimum representation:

5.3.1.1 Project Engineer

5.3.1.2 Design Engineer (not associated with the design)

5.3.1.3 FAA-DER(if applicable)(Contracted)

5.3.1.4 Engineering Technician or Assembly Representative (may also be fulfilled by Engineering, Lead or Management)

5.3.1.5 Machinist or Shop representative (may also be fulfilled by Engineering, Lead or Management)

5.3.2 PDR – occurs at the conclusion of the initial design phase. This review establishes the baseline design and discusses the effort that has been performed to date which substantiate the design. The result of this review is usually a list of action items which address potential deficiencies in the design. Subsequent corrective actions may include further analyses and examination of certain aspects of the design.

5.3.3 CDR – occurs after PDR. Action items have been addressed and at the conclusion of the detailed design phase. The intent of this review is to:

5.3.3.1 Ensure that any changes that were necessary as a result of the PDR have been incorporated into the design

5.3.3.2 Discuss details of the individual components, sub-assemblies, and assembly of the product that are critical to the success of the product

5.3.3.3 Ensure that proper provisions have been made to adequately verify the performance (i.e., test)

5.3.3.4 Determine whether a clear path to a production unit is evident (i.e., can build in quantity for low cost while making appropriate level of quality)

5.3.3.5 Obtain concurrence to begin fabrication and ordering of purchased materials for a prototype model

5.3.4 Test Readiness Reviews – These reviews establish the readiness of the product prior to entering the verification, validation, or qualification test phase, if required. Any deficiencies are identified and corresponding corrective actions are agreed

upon for implementation prior to testing.

5.4 Design Review Inputs Data – An agenda and data package should be distributed to all involved in the review sufficiently in advance of the review. A design review does not necessarily require a meeting; however, a meeting is often necessary to ensure inclusion of the appropriate personnel in order to answer questions and collaborate in decision-making process.

5.5 Conducting Design Reviews – PAI will conduct design reviews with an emphasis on the following:

5.5.1 Subject the design to scrutiny by qualified personnel outside of the responsible design team for their judgement as to whether the most satisfactory design has been chosen

5.5.2 Determine if flaws in the design are revealed

5.5.3 Ensure that proper discipline is being observed by reviewing the design logic and the process by which conclusions have been reached

5.5.4 Review how and why other options may have been rejected

Reviews will be conducted by the cognizant project engineer or program manager.

5.6 Participants in the Design Review – Participants in design reviews at PAI will be determined by PAI and (if required) the Customer. Participants should be selected based on their background and experience from both technical and logistical perspectives. Participants in design reviews at sites other than PAI will be jointly determined by PAI and the customer and may include participants from the end user. A section has been included in the design and development worksheet to aid in the identification and conduct of these reviews.

5.7 Design Review Record – When required, PAI shall document formal design reviews in the form of a design review report. The following components shall serve as a guideline for generating a comprehensive design report with Form 67.19 maintained as a record.

5.7.1 Members of the review team and their roles

5.7.2 Status of corrective action items from previous reviews

5.7.3 Criteria against which the design has been reviewed

5.7.4 Documentation that describes the design and any evidence presented which demonstrates that the design meets requirements

5.7.5 List of recommendations and new corrective action items

5.7.6 Basis on which confidence has been placed in the design

5.7.7 Authorization for progression of the design to the next level

When appropriate, informal design reviews shall result in an action item list that is distributed to all attendees. The actions and corresponding results shall be maintained via Engineering Design Action Item Form 67.13 and records updated for purposes of presenting action item status at the next review meeting. The form is self- explanatory and is required to be completed by the determined closure date.

5.8 **Authorization to proceed to the next steps** – one of the outcomes of the design review is the decision as to whether the current level of the design is sufficiently mature enough to allow progression of the design to the next stage of development. Customarily, concurrence to proceed from all reviewers is preferred, although not mandatory. When customer participation is required, it is also required that the customer approves progression to the next stage. Approvals shall be documented in Design and Development Form 67.19 under "Design Reviews, Verification, Validation, and Documentation." With respect to PAI personnel, the decision to proceed to the next stage will be made by the Engineering Management, the Project Engineer, or their respective designees, as applicable.

5.9 Engineering Management is at liberty to call on other members of the Engineering Department to talk on specific items. Format of the presentations is to be straightforward.

5.9.1 Design Objective

5.9.2 Approach Taken

5.9.3 Results Achieved

5.10 During design reviews, major issues that can't be resolved may require an action item to be assigned to various individuals. Any member of the review team may assign an action item and fill out the form "Action Item" PAI Form 67.13. The design engineer is responsible for accumulating all the action items and that necessary follow-up action is taken.

5.11 When the review has been completed, the Engineer shall ensure that the findings and recommendations are reports and/or incorporated.

5.12 A follow-up design review may be required by the Engineer and/or the customer and will be scheduled as necessary.

5.13 The following items listed in section 6.0 will be added to the pertinent Engineering Project File and become part of the permanent record.

6.0 Records:

6.1 Attendance List – Form 67.11
6.2 Engineering Design Checklist – Form 67.12
6.3 Action Items – Form 67.13
6.4 Design and Development Worksheet – Form 67.19
6.5 Conformity Matrix, Specification Compliance report, or Customer Specification/Requirements, or other customer requirements (Verification Documentation)