REVISION HISTORY			
REV	**Description of Change**	**Author**	**Effective Date**
0	Initial Release	J. Hanratty	7/17/98
1	Clarifications based on 7/98 DNV Audit and 6/98 Internal Audit (see DCR 98-029). Major rewrite.	M. Hines	9/25/98
2	Clarifications based on 11/98 DNV Audit (DCR 98-058)	R. Serrano	12/18/98
3	Revised referenced AHB document (DCR 99-047)	M. Hines	10/7/99

REFERENCE DOCUMENTS	
Document Number	**Document Title**
AHB 5300.1	System Safety, Reliability and Quality Assurance Manual
53.ARC.0000	Ames Research Center Quality Manual, Section 4.4
53.ARC.0003	Acceptance and Amendment of Customer Agreements
53.ARC.0004.1	Project Management for the Design, Development, and Maintenance of Software
53.ARC.0004.3	Configuration Management
53.ARC.0006	Purchasing
53.ARC.0007	Management of Customer-Supplied Material and Supplies
53.ARC.0009.2	Management and Performance of Research
53.ARC.0009.4	Program and Project Management
53.ARC.0010	Inspection and Testing
53.ARC.0011	Control of Inspection, Measuring, and Test Equipment
53.ARC.0012	Inspection and Test Status
53.ARC.0013	Control of Nonconforming Product
53.ARC.0014	Corrective and Preventive Action
53.ARC.0016	Quality Records
53.ARC.0019	Servicing

Documents referenced in this procedure are applicable to the extent specified herein.

1. Purpose

This procedure establishes the process for the design and development of systems and hardware that are delivered to Ames Research Center (ARC) customers in accordance with the ARC Quality Manual.

2. Scope

This procedure applies to organizations that design or develop and/or deliver systems and hardware for ARC customers.

The requirements of this procedure may be tailored as appropriate based upon the size and complexity of a particular design/development effort. Any modifications of the process steps must be documented in the systems/hardware project plan. Approved systems/hardware project plans become the baseline requirements for the systems/hardware project.

Systems and hardware produced in support of research, or as part of the research, but not in and of itself a unique deliverable to the customer does not have to be designed and developed in accordance with this procedure. See 53.ARC.0009.2 for requirements governing research systems and hardware.

3. Definitions and Acronyms

3.1	Baseline Design	Design of such detail as to be able to develop the initial cost estimate and schedule, identify areas of risk, and provide a basis for the systems/hardware project plan
3.2	Concept Design	Design that is of such detail as to be able to determine the feasibility of the design/development effort and that is consistent with the systems/hardware program/project/product requirements
3.3	Customer	Any organization or individual that enters into a formal agreement with ARC for delivery of ARC products or services
3.4	Design and Development or Design/Development	Process of translating user or customer requirements into a final product

3.5	Design Verification	Activity performed at appropriate stages of the design to ensure that design-stage output meets the design-stage requirements. Verification may consist of design review, calculations, analysis, simulation, inspection, and/or testing.
3.6	Elements	These include, but are not limited to, components, sub-assemblies, and/or software that will be integrated into the final deliverable
3.7	Firmware	Hardware that contains a computer program and data that can not be changed in its user environment. The computer program and data contained in the firmware are classified as software. The circuitry containing the computer program and data is classified as hardware.
3.8	Hardware	Electronic, optical, electromechanical, structural, and mechanical devices and systems, including any embedded software
3.9	Integrate (Integration)	Process of combining software elements, hardware elements, networks, personnel, and/or procedures into an overall system
3.10	Life Cycle Cost (LCC)	The total of the direct, indirect, nonrecurring, and other related expenses incurred, or estimated to be incurred, in the design, development, verification, production, operation, maintenance, support, and retirement of a system over its planned life span
3.11	Requirements Document	Document that clearly defines the technical requirements, including performance requirements, safety requirements, constraints, acceptance criteria, and quantities
3.12	Responsible Manager	Person having the responsibility and authority to accomplish/implement a specific activity or process (includes organizational line managers, project managers, etc.)
3.13	Software	Intellectual creation comprising the programs, procedures, rules, and any associated documentation pertaining to the operation of a computer system. Software exists independent of any medium on which it may reside.

3.14	System	Combination of elements that function together to produce the capability required to meet a need. The elements may include hardware, software, equipment, personnel, and the processes and procedures needed for this purpose.
3.15	Systems/Hardware Project Manager	Individual responsible for the administration and technical direction of a systems/hardware project. Responsibilities typically include planning, organizing, directing, controlling, and managing the systems/hardware project.
3.16	Validate (Validation)	Activity normally performed on the actual hardware at the system or integrated systems level but may also be conducted at earlier stages prior to product completion. Validation may consist of examination and/or testing to produce objective evidence that the end product will accomplish its purpose.

4. Flowchart

There is no flowchart required for this document.

5. Responsibilities

5.1 **Responsible Manager** shall:

- review and approve customer requirements and the systems/hardware project plan, and
- select the systems/hardware project manager.

5.2 **Systems/Hardware Project Manager** shall:

- develop, implement, approve, and update the systems/hardware project plan,
- plan, design, implement, and manage the systems/hardware project,
- conduct design reviews,
- track systems/hardware project metrics,
- inform customer of systems/hardware project progress, and
- maintain systems/hardware project records and control the changes to those records and plans, including obtaining appropriate approvals when changes affect the overall cost, schedule, or performance of the systems/hardware project.

6. Procedure

6.1 The systems and hardware design and development process is divided into five phases:

- Planning and System Analysis
- Design
- Procurement
- Manufacturing, Fabrication, and Integration
- Test, Certification, and Activation

6.2 All systems/hardware project elements of design/development do not have to proceed in parallel through the process flow. The systems/hardware project may be divided into elements or work packages, each of which can proceed through the process flow described in the systems/hardware project plan.

6.3 Planning and System Analysis Phase

The systems/hardware planning process commences when a customer makes an inquiry or an invitation to bid for work which includes the design and development of systems or hardware by ARC. When systems/hardware are identified as being an element of the project development, section 6.3 of this procedure is used to supplement 53.ARC.0009.4 and will be followed to create a systems or hardware project plan.

6.3.1 This phase's activities will include:

6.3.1.1 Review systems/hardware project and product requirements for clarity, completeness, accuracy, and consistency.

6.3.1.2 Perform trade studies among candidate systems/hardware project concepts that consider affordability, technology, content, risk, and potential acquisition strategies.

6.3.1.3 Develop technical performance requirements and identify performance values, physical requirements, operational requirements, and resource constraints.

6.3.1.4 Identify appropriate design reviews and associated Quality Records. These Quality Records shall be documented and controlled in accordance with 53.ARC.0016.

6.3.1.5 Identify other requirements, such as safety (per AHB 5300.1), environmental, regulatory, export control, etc.

6.3.1.6 Develop a preliminary assessment of risks and risk-mitigation actions.

6.3.1.7 Develop the Life Cycle Cost estimate of the product.

6.3.1.8 The Responsible Manager or the Program/Project Manager shall perform a review of the customer agreement (in accordance with 53.ARC.0003) to ensure that:

- Systems/hardware project and product requirements are

identified,

- ARC responsibility for subcontracted work is defined,
- ARC has the capability to meet the customer requirements,
- Intellectual property rights are protected,
- A problem resolution mechanism is specified, and
- The terminology and acceptance criteria used are understood by both parties.

6.3.1.9 The systems/hardware project manager shall define how the requirements for quality will be met. This quality planning shall be consistent with all systems/hardware project constraints. The results of this planning effort shall be documented in the systems/hardware project plan.

6.3.1.10 The systems/hardware project manager shall identify and plan manufacturing, fabrication, integration, and servicing (in accordance with customer agreement requirements) processes that directly affect quality.

6.3.1.11 The systems/hardware project manager shall use ARC Quality System processes (e.g., procedures and work instructions) in the design, development, manufacture, and delivery of systems and/or hardware.

6.3.2 Requirements Review

This review shall be conducted to determine if the documented technical requirements/specifications meet all needs and requirements of the customer and are consistent with all design constraints, including budget and schedule.

6.3.3 Requirements Approval

As appropriate, the customer, the Responsible Manager, and the systems/hardware project manager shall approve and sign the requirements document, schedule, and budget. This process may be a part of or subsequent to the requirements review or a Concept Design Review.

6.3.4 Systems/hardware project planning activities are as follows:

6.3.4.1 Develop a baseline design (or designs) in accordance with the requirements/specifications of the systems/hardware project to provide a basis for the systems/hardware project plan.

6.3.4.2 The systems/hardware project plan shall document the technical and managerial approach for the systems/hardware project in accordance with the requirements of this procedure. Design

and development of software and firmware shall be performed in accordance with 53.ARC.0004.1.

6.3.4.3 The systems/hardware project plan shall document the organizational and technical interfaces between different organizations/groups that provide input into the design process. It shall also describe how this information is documented, transmitted, and regularly reviewed.

6.3.4.4 The systems/hardware project plan shall define the design input and output requirements for each phase of the systems/hardware project. It shall also identify any applicable regulatory requirements. It will describe how design outputs are verified against design-input requirements. The plan shall describe how design outputs are reviewed and approved prior to their release for further development work.

6.3.4.5 For level 2 or level 3 projects supporting ARC programs, the Program Manager and Project Manager shall approve and sign the project plan. For other projects, the project manager and the Responsible Manager shall approve and sign the project plan.

6.3.5 Concept Design Review or Preliminary Engineering Review activities are as follows:

6.3.5.1 Conduct a Concept Design Review (CoDR) for system and/or hardware design/developments. The review objective is to investigate one or more design concepts and evaluate key characteristics that would affect performance, manufacturing, or operations.

Note: These types of reviews are conducted during the planning phase or early in the design phase of a systems/hardware project.

6.3.5.2 Evaluate technical merit, budget, and schedules.

6.3.5.3 Perform an assessment of the proposed design/development to evaluate the likelihood of success for the proposed design/development effort. The assessment will include a risk assessment, safety analysis, identification of developmental technologies, and any other factors deemed critical to the particular design/development.

6.3.5.4 Select a design concept for further development.

6.3.6 Long Lead-time Procurements

Approval may be sought during the planning and system analysis phase

to initiate procurement of long lead-time items and to establish manufacturing/fabrication/integration contracts. Procurements shall be made in accordance with 53.ARC.0006.

6.4 Design Phase

6.4.1 Design to Next Level Consistent with Systems/Hardware Project Plan

The systems/hardware project shall design the products consistent with the approved systems/hardware project plan and product specifications, although systems/hardware project elements or work packages may progress through the design phase at different rates.

6.4.2 As the design evolves, the systems/hardware project plan shall be updated based on the following:

6.4.2.1 Prepare revisions to the systems/hardware project plan, as needed, to adequately deal with any issues (such as technical, risks, resource, schedule, etc.) that may have arisen in the course of the design/development process.

6.4.2.2 Ensure a revised systems/hardware project plan is approved by the same individuals or responsible organizations that performed the original approval.

6.4.2.3 Retain revisions to the systems/hardware project plan.

6.4.3 Design reviews shall be performed as follows:

6.4.3.1 Conduct design reviews at appropriate phases of the design, as defined in the systems/hardware project plan.

6.4.3.2 Include in design reviews representatives from all organizations that perform a key function in the development, implementation, or operation of the system or hardware.

6.4.4 Design verification activities shall be performed as follows:

6.4.4.1 Perform design verification to ensure that the design-stage output meets the design-stage requirements.

6.4.4.2 Perform design reviews, calculations, analyses, tests, simulations, and inspections (of prototypes and models that may have been developed) as specified in the systems/hardware project plan. These activities are done to verify that the final design can meet the customer requirements and systems/hardware project specifications.

6.4.4.3 Document and control all verification records as Quality Records in accordance with 53.ARC.0016.

6.4.5 Design Change Control

Perform design change control in accordance with 53.ARC.0004.3.

6.5 Procurement Phase

Procurement of materials and/or establishment of manufacturing contract activities shall be performed as follows:

6.5.1 Conduct materials procurement and establishment of manufacturing/fabrication contracts in accordance with 53.ARC.0006.

6.5.2 Receive, test, and/or inspect procured materials in accordance with 53.ARC.0010.

6.5.3 Where traceability is a specified requirement, implement it in accordance with systems/hardware project plan requirements.

6.6 Manufacturing, Fabrication, and Integration Phase

Manufacturing, fabrication, and integration activities will be conducted in accordance with the systems/hardware project plan.

6.6.1 Customer-supplied product shall be controlled in accordance with 53.ARC.0007.

6.6.2 System and hardware inspections and tests shall be performed in accordance with 53.ARC.0010.

6.7 Test, Certification, and Activation Phase

Test, certification, and activation phase activities are as follows:

6.7.1 Validation of Performance

6.7.1.1 Perform tests, analyses, demonstrations, and inspections to validate the integrated (or partially integrated) hardware or system in accordance with the systems/hardware project plan.

6.7.1.2 Perform validation activities to ensure that the products conform to the defined customer requirements.

Note: Validation is normally performed on the final product but may be necessary in earlier stages of product completion.

6.7.1.3 Calibrate equipment used to accept or validate customer performance requirements in accordance with 53.ARC.0011.

6.7.1.4 Conduct validation activities as specified in the systems/hardware project plan and in accordance with 53.ARC.0012.

6.7.2 Certification

Certification of systems or hardware shall only be performed when required by customer requirements. When required, certification requirements will be defined in the systems/hardware project plan.

6.7.3 Control of Nonconformance

Handle all nonconforming results from tests and validations in accordance with 53.ARC.0013.

6.7.4 Corrective and Preventive Action

Problems requiring corrective action shall be documented in accordance with 53.ARC.0014.

6.7.5 Activation

Activate systems or hardware with in-the-field training as well as preparation and implementation of maintenance and operations manuals, as required by the customer and documented in the systems/hardware project plan.

6.7.6 Final Documentation and Turnover to Customer

6.7.6.1 Prepare final documentation as specified in the systems/hardware project plan.

6.7.6.2 Formally turn over to the customer final documentation together with the completed system or hardware.

6.7.6.3 If the systems/hardware project plan includes support during operations, final close out of documentation and financial issues may be delayed until the end of the systems/hardware project.

6.7.7 Servicing

When required by customer agreement, servicing shall be performed in accordance with 53.ARC.0019 and documented in the systems/hardware project plan.

7. Metrics

There are no metrics required for this document.

8. Quality Records

The following Quality Records shall be generated and managed in accordance with 53.ARC.0016.

Required Record	Custodian
Design Review (includes list of attendees, documents reviewed and approved, and list of action items)	Systems/Hardware Project Manager
Design Verification (includes inspection or test results, reports, or project memo)	Systems/Hardware Project Manager

9. Form(s)

There are no forms required for this document.