1.0 PURPOSE

- To control the design and development of new products.
- To define the process for new product development from initial investigation through completion, and to assign responsibilities for product design and design verification and validation activities.
- To establish a standard format for all engineering drawings and subsequent engineering documentation as referenced in MIL-STD-100 and superseding ASME/SAE/ANSI and ASTM standards. This extends to MIL-DTL-31000 Technical Data Packages, General, Specification for; MIL-STD-973 Configuration Management and MIL-HDBK-831 Preparation of Test Reports.
- Supplements QAP 4.0 – Design Control

2.0 SCOPE

This procedure applies to new product as well as changes and improvements of existing product.

3.0 DEFINITIONS AND ACRONYMS

ECR/ECN/ECO – Engineering Change Request/Engineering Change Notice/Engineering Change Order.

PRT – Product Review Team controls all aspects of proposed product through design and development to production and delivery planning and implementation.

4.0 RESPONSIBILITIES

Sales & Marketing - Responsible for initiating the basis for the development of the project plan and initial master schedule.

Engineering Department - Responsible for all stages of concept development, product review, product verification, and providing requirements for product validation including chair of the PRT.

Project Management - via customer request provides initial product requirements, performance target values, and market utility assessments.

Manufacturing - ensures the availability of products and services required for the manufacturing and testing of the product.

Human Resources - ensure that sufficient-qualified personnel are available and suitable for the production of the product, and that an appropriate training program is instituted.

Quality Department – ensures that the facilities, instrumentation, machinery, equipment, and services are available for the efficient production of the product.

Purchasing – orchestrates the purchasing activities and controls monetary expenditures related to the product development.

(PRT) Product Review Team - with appropriate authority and request support from additional functions as needed, coordinates:

- the design and production of sketches, drawings, and layouts

- the building and testing of models, prototypes, and pilots, including the acquisition of materials
- the collection and recording of test data
- any modifications to the product specification, if necessary
- the review of requirements for completeness and clarity

At all stages of development, the Product Review Team may determine whether to modify the product specification or change the design of the product based on test results.

5.0 PROCEDURE

5.1 Investigation

Awareness of new products needed may come from various sources (i.e., customers, employees, competitors, etc...).

New product ideas are analyzed to determine that there is sufficient business justification to pursue. This is done by the Product Review Team and senior Management.

The Product Review Team is chaired by the most senior-qualified representative (normally Engineering) and meets at predetermined intervals as defined and established by the PRT.

5.2 Requirements Documentation (Inputs)

Sales & Marketing initiates PRT Meeting via electronic means, i.e. email to present the new proposed product design concept and a preliminary implementation plan and an initial development schedule which includes at a minimum in baseline form (Not fully detailed):

- functional and performance requirements,
- applicable statutory and regulatory requirements,
- where applicable, information derived from previous similar designs, and
- other requirements essential for design and development.

The inputs are reviewed for adequacy. Requirements are complete, unambiguous and not in conflict with each other.

5.3 Develop Project Plan

Using an industry standard format, the Engineering Department creates a project plan and initial master schedule that details target dates, and responsibilities required in designing and development of the product. Note: Use of any software that is capable of producing Gantt Charts will produce the required results.

The Engineering Department is responsible for the initial product design to ensuring the specifications detailed in the product requirement sheet are incorporated.

If applicable, a prototype may be created for review.

5.4 Product Review

Design reviews by the PRT are planned at the end of each phase and at important milestones in the design process, and can be called by any member of the PRT on an as need basis.

The purpose and objectives of design reviews are to evaluate the design as it evolves to ensure it meets the design input requirements.

5.5 Product Verification

A final review to determine if the product meets the requirements of the product specification is held by the PRT.

Design verifications are carried out at various phases of the design to ensure that the product design outputs meets the design input requirements as approved previously.

Records of these verifications are the approval and release signatures on design output documents.

When the design does not meet requirements and must be modified or corrected, the necessary actions required to correct the problem are documented and their implementation is recorded.

5.6 Product Validation

Design validation activities are planned and scheduled in the project plan and initial master schedule. All planned design validation activities will be completed with satisfactory results prior to any delivery of the product where practical.

Design validation is completed by following the steps as outlined in the project plan and initial master schedule. This validation will ensure that the resulting design is capable of meeting the requirements, as defined.

Results of design validation activities are documented in the on line Master Job File.

When the design does not meet requirements and must be modified or corrected, the necessary actions required to correct the problem are documented and their implementation recorded in the Master Job Folder.

Once validated, the product is released into production.

5.7 Changes to Product Design

Any changes made prior to implementation are controlled through the Design Change process.

After the design is released to production, any design changes are controlled through the Design Change process.

Documentation processing is best illustrated in the QAM, page 14, 4.10 Configuration Management, Documentation Flow/Product Realization Interface.

5.8 Quality Records

Record Name	Record Location	Record Access	Disposal Method	Retention Time
Design Review Records	Master Job Folder	All Employees	Archival	Per QAP 5.0 - Document and Data Control
Design Verification Records	Master Job File located in the Master Job Folder	All Employees	Archival	Per QAP 5.0 - Document and Data Control
Design Validation Records	Master Job File located in the Master Job Folder	All Employees	Archival	Per QAP 5.0 - Document and Data Control

6.0 CHANGE LOG

NOTE: A physical change log is not required as an on-line electronic document control system is utilized.

Document Revision Date	Description of Change	Approval(s)
xx/xx/xx	Initial Release	

7.0 RELATED-REFERENCED DOCUMENTS

QAM – Quality Assurance Manual
QAP 3.0 - Contract Review
QAP 4.0 - Design Control
QAP 5.0 - Document and Data Control
QAP 6.0 - Purchasing
QAP 11.0 - Inspection, Measuring, and Test Equipment Document and Data Control
QAP 16.0 - Quality Records
QAP 18.0 – Training
WI-1.0 Master Job Folder Setup
WI-11.0 Approved Supplier List
MIL-STD-100 – Engineering Drawing Standards as reference
MIL-DTL-31000 Technical Data Packages, General, Specification for as reference
MIL-STD-973 Configuration Management as reference
MIL-HDBK-831 Preparation of Test Reports as reference
Reference to *Best Practices in Mechanical Engineering*

Additional Reference Document and Industry Standards Template

APPENDIX A - PRT/DESIGN CRITERIA AND CONSIDERATIONS

APPENDIX A
PRT/DESIGN CRITERIA AND CONSIDERATIONS

A. Drawing Media (Choose all that apply)

(1) Non-digital (Specify_____)
(2) Digital Data (Specify_____)
(3) Other (Specify_____)

B. Drawing Format (Choose One)

(1) Contractor
(2) Government (forms supplied by the Government)
(3) Government (forms supplied by the Contractor)

C. Drawing Sheet Size (and Format) (Choose One)

(1) ASME Y14.1
(2) ASME Y14.1M

D. Drawing Reference to MIL-STD-100 (4.1.1) (Choose all that apply)

(1) Reference to MIL-STD-100 will not appear on drawing
(2) Reference to MIL-STD-100 will be made on drawing
(3) Reference to MIL-STD-100 to include applicable revision level
(4) Reference to MIL-STD-100 to include applicable revision level and notices

E. Application Data (Choose all that apply)

(1) Contractor option
(2) Required
    (a) On drawing
    (b) By reference. Specify_____
    (c) Contractor option
(3) General use or multi-use notations
    (a) allowed
    (b) not allowed

F. Drawing Detail (ASME Y14.24M) (Choose all that apply)

(1) Monodetail
(2) Multidetail
(3) Tabulated

G. Dimensioning and Tolerancing (Choose all that apply)

(1) Metric
(2) Decimal-inch
(3) Application of ASME Y14.5M
    (a) Specific issue (revision) required (Specify issue_____)
    (b) Issue in effect (Specify issue _____)

H. Drawing Notes (Choose One)

(1) On drawing
(2) By reference. Specify_____
(3) Contractors option

I. Types of Drawings (ASME Y14.24M and Chapter 200) (Choose one)

(1) Contractor selects
(2) Government selects

J. Maintenance of Multi-Sheet Drawings (ASME Y14.35M)

(Choose all that apply)
- (1) Drawing revision level (DOD preferred)
- (2) All sheets same revision level
- (3) Sheet revision level

K. Redrawn Drawings (redrawing without change) (ASME Y14.35M) (Choose one)
- (1) Advance revision level
- (2) Revision level is not advanced

L. Maintenance of Revision History (Choose all that apply)
- (1) Contractor option
- (2) Optional methods
  - (a) Remove one or more revision record as required
  - (b) Remove all previous revision history
  - (c) Remove all revision history but retain line entry for revision authorization and date of revision
  - (d) Remove all except revision preceding current
  - (e) Maintain revision history in its entirety

M.Adding Sheets (ASME Y14.35M) (Choose all that apply)
- (1) Contractor option
- (2) Optional methods
  - (a) Renumber sheet using consecutive whole numbers
  - (b) Number added sheets in decimal-number sequence
  - (c) Number added sheets in alpha-numeric sequence

N. Deleting Sheets (ASME Y14.35M) (Choose all that apply)
- (1) Contractor option
- (2) Optional methods
  - (a) Renumber all affected remaining sheets
  - (b) Affected remaining sheets not renumbered (revision status of sheets block is updated with notations such as CANC or DEL)

O. Markings on Engineering Drawings (Choose one)
- (1) Special items and processes apply
  - (a) Applicable symbols (Specify_____)
  - (b)Applicable special notes (Specify_____)
- (2) Special items and processes do not apply

P. Associated Lists (ASME Y14.34M) (Choose all that apply)
- (1) Non-digital (Specify_____)
- (2) Digital Data (Specify_____)
- (3) Other (Specify_____)

Q. Types of Associated Lists (ASME Y14.34M) (Choose all that apply)
- (1) Parts Lists
  - (a) Integral
  - (b) Separate
  - (c) Contractors option
- (2) Data Lists
- (3) Index Lists
- (4) Other (Specify_____)

R. Angle of Projection (ASME Y14.3M) (Choose one)

(1) 3rd Angle
(2) 1st Angle

S. Language (Choose one)
(1) English required
(2) Other (as specified)