


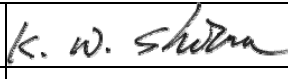
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Note : Highlighted sections are only applied to tasks associated with Electric Div'

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Revision History

Rev. No	Date	Description	Remark
0	2017.07.14	New establish for Separation of Nuclear / General Procedure	

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1.0 Purpose

This procedure is intended to establish and maintain procedures for product design and development, management, and validation to meet specified product requirements.

2.0 Responsibilities

2.1 Engineering Dept General manager (Design Team Manager) is responsible for:

- (1) review and approval of design plan
- (2) review of customer documents (Design Specification)
- (3) review and approval of the design input data and output data
- (4) assigning a reviewer (verifier), if necessary,
- (5) control of overall design activities
- (6) qualify for design personnel (preparer, reviewer, approver)
- (7) final approval of final design

3.2 A design engineer designated by the Engineering Dept General manager (Design Team Manager) is responsible for:

- (1) preparation, maintenance of a design plan
- (2) preparation design input data
- (3) preparation of test procedures for design verification
- (4) preparation of design outputs
- (5) Review design output document, request verification and check result
- (6) Distribution management of corresponding design output document

3.0 Qualification of Design personnel

Qualification standards and accreditation procedures for designers are in

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accordance with "QAP-18.2 Human resource control Procedures".

4.0 Design and development Work Procedure

4.1 Design and development Plan

4.1.1 A Design Plan shall be established when product design or development is required.


4.1.2 The Engineering Dept General manager (design team leader) reviews the development submission or project information, designates the design person, and directs the design plan.

4.1.3 The design engineer shall prepare a design plan (QAP-3.2-01) based on the design input data, and the design plan shall include at least the following items.

- 1) Design input data (design and development, customer, legal requirements)
- 2) Design method
- 3) Design and development phase, schedule
- 4) Design review, verification and validation method
- 5) Design Interfaces
- 6) Design output data
- 7) Duties and Responsibilities
- 8) Requirements for final review of design

4.1.4 Designers should consider the following when design planning.

- 1) Nature, duration and complexity of design and development activities
- 2) Need for internal and external resources for product design and development
- 3) The need for customer involvement in design and development
- 4) Requirements for supply after design and development

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5) the level of management expected by customers and other stakeholders in the design and development process;

4.1.5 The design plan is written by the design engineer and reviewed and approved by the Engineering dept General Manager (design team Manager).

4.1.6 The design plan established by the design person is consulted with the relevant team when necessary and approved by Engineering dept General Manager (design team Manager).

4.1.7 The person in charge should update the design plan as the design work progresses, and manage the revision of the design plan in the same way as the original plan.

4.1.8 Design Interface Control (Exhibit3 QAP-3.2-03)

4.1.8.1 External interface


1) All external information related to drafting, mold making, testing, research and development, outsourcing, certification, consulting, etc. should be assigned to a person in charge of external linkage and be transferred to design and development personnel.

2) Design information transmitted through the external interface shall be controlled by Engineering Dept General manager. Where additional requirements are appropriate for a specific project, these shall be established on the Design Plan..

4.1.8.2 Internal Interface

1) The internal interface between the Engineering Dept and other Depts shall be identified and established on the Design Plan.

2) The Engineering Dept General manager is responsible for assuring that

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the requirements of para.4.5.2.3 are implemented. Design related responsibilities of other Depts shall be identified.

3) In design and development, the **Engineering dept(design team)**, the QM department, the production team, and the sales team should review the progress and document the information, if necessary, through the design and development meetings.

4.2 Design input


4.2.1 The design person in charge of the design understands the design input requirements, including the following, and obtains the design input (ex. 4 QAP-3.2-04) after review and approval by the Engineering dept General Manager (**design team Manager**).

4.2.1 The followings shall be considered as design inputs:

- (1) Customer's Purchase Specification (Owner's Design Specification)
- (2) Applicable Code and Standard(including API specification)
- (3) Application environment and operating conditions
- (4) Applicable calculation
- (5) historical performance and other information derived from previous similar designs
- (6) Result of Risk assessment
- (7) legal requirements

4.2.2 Design Inputs Sheet (Exhibit4 QAP-3.2-04) shall be reviewed by the designated reviewer and made available to the Design Engineer assigned by the reviewer. The reference standard shall be confirmed that reflection of customer's requirements when reviewing Design Inputs Sheet.

4.2.3 The design engineer must confirm with the customer and the agreement as necessary to ensure the adequacy of the design input requirements for the product to be designed.

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4.2.4 If the customer's requirements are similar or identical to those already in production, design inputs can be cited by citing similar models in the design input.

4.2.5 Adequacy of design input shall be determined by the Engineering Dept General manager.

4.2.6 Any unstable or inconsistent design input is solved in consultation with the customer, and the requirements of the design input shall be reflected in the design output.

4.2.7 Records of design inputs shall be maintained.


4.3 Design output

4.3.1 General requirements of Design Output ;

- 1) be expressed and documented in such a way that it can be verified or validated to meet design and development input requirements;
- 2) include or reference measurable criteria such as tolerance, maximum and minimum values.
- 3) specify the characteristics of the product that are essential for its safe and proper use
- 4) Provide appropriate information for procurement, production and service provision.
- 5) Include the results of the relevant equations.

4.3.2 The design output shall be documented in the following for verification and validation of the input requirements. Figures and pages in the design report shall be numbered consecutively and the documents which are a part of the Design Report shall be identified.

- 1) Design report
- 2) Drawings (Design and production drawings include acceptance criteria such as dimensions and shapes)

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3) Bill of Material (BOM)

4) Statement

5) Specification

4.3.3 Design outputs shall be legible in a form suitable for reproduction, filing and retrievable, and understandable without help of the preparer.

4.3.4 Design output shall be reviewed by the Design Engineer and approved by the Engineering Dept General manager

4.3.5 Design Calculation(* not applied Electric Div')

4.3.5.1 Preparation of Manual Calculations

4.3.5.2 Manual Calculation shall be documented on the calculation sheets, graph paper or special purpose forms, as required.

4.3.5.3 The cover sheet of Design Calculations (Exhibit5 QAP-3.2-05) shall have the following information.

(1) Calculation title, No., and Revision status

(2) Type(or Part) name, associated Program name, if applicable

(3) Document number uniquely assigned to each calculation, if necessary

(4) Problem statement or objective of the calculation, if necessary

(5) Name and signature of the calculation preparer, reviewer

(6) The Engineering Dept General manager approval for completeness and applicability to present design work.

4.3.5.4 Each page of manual calculations, including, the first page, tables, figures and attachments(except for attached final design documents) shall include the following information;

(1) Page number and total number of pages

(2) Calculation number or title

(3) Revision number

(4) Type or Part name

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- 4.3.5.5 The design input data shall be identified in the manual calculation and shall include document title, document number and date or revision number.
- 4.3.5.6 The methods, assumptions and references used in the manual calculations shall be clearly identified. The basis for the assumptions shall be clearly stated with referencing supporting documents when appropriate.
- 4.3.5.7 Source of input data, factors, equations and codes shall be identified throughout the calculation to provide traceability to each reference. Supplier's data, such as equipment performance curves from which information has been derived and used as input, and other unique data (including letters and internal memos) shall be included with the calculation or otherwise be traceable and retrievable.
- 4.3.5.8 After completion of the calculation and prior to reviewing, the preparer shall sign and date on the calculation.
- 4.3.5.9 In the case of the valve applied API 6D specification, A value of Allowable Strength (Bearing Stress) of stem compare with ASME Code; $0.5 \text{ SMYS} \sim 0.675 \text{ SMYS(AD-132.1)}$ and record a results.
- 4.3.6 Revision to calculations(*not applied Electric Div')
- 4.3.6.1 Revision to manual and computer run calculation shall be prepared, reviewed and approved by the same method as the original. Only those items revised or affected by the revision shall require reviewing.
- 4.3.6.2 Revised sections of manual calculations shall be indication by vertical lines in the left margin. The revision indicators are removed for subsequent revisions to the Page. Each revised Page and the cover page shall be signed and dated by the preparer and reviewer. The new revision number shall be indicated on the cover page and each revised page.

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4.3.7 Design Drawings


4.3.7.1 Preparation of design drawings (Exhibit 8 QAP-3.2-08)

1) The Engineering Dept General manager (Design Team Manager) shall assign the Design Engineer to prepare the Design Drawing and shall provide the necessary direction and Design input data and include the following;

- (a) A description of rough sketch drawing of the structure to be shown on the drawing.
- (b) Any special requirements associated with preparation of the drawing.


2) Each sheet of a design drawing shall include the following information as applicable.

- (a) A drawing title
- (b) Customer and project name
- (c) A drawing number
- (d) Sheet number
- (e) Preparer, checker and approver signatures and dates
- (f) A drawing purpose
- (g) Reference document or Number
- (h) Revision status
- (i) Identification of the scale, if any
- (j) Unit if not specified, SI Unit
- (k) Projection, if not specified, 3rd projection
- (l) Notes, including Code classification, operation condition, design condition, material specification and others.
- (m) References to interfacing or design documents, as necessary, to provide design completeness and continuity.
- (n) The all tolerance requirements required by API 6D specification shall be written on the drawing

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4.3.7.2 Review of design drawings

- 1) The Design Drawing shall reviewed by the Design Engineer. If preparer is the Engineering Dept General manager (Design Team Manager) shall designate a reviewer.
- 2) The check shall include the following items, as a minimum;
 - (a) Verifying dimensional accuracy
 - (b) Confirming the functional adequacy of the design
 - (c) Confirming design consistency with the calculations and other input data as indicated on the current and approved design input data.
 - (d) Confirming that applicable project technical criteria have been correctly applied
- 3) The design reviewer shall review the print of design drawing prepared by drafting personnel, and shall document any comment by following methods.
 - (a) Marking up the print drawing
 - (b) Signing and dating the check print upon completion of the check
 - (c) Identifying comments of marking "No comment"
- 4) When the check is completed, the checker shall return the check drawing and any documents generated during the checking process to the responsible design personnel. The Design Engineer shall resolve all comments and shall provide input to drafting personnel to make the necessary changes on the design drawing.
- 5) The Engineering Dept General manager shall resolve any comments that cannot be resolved between the responsible personnel and the checker.
- 6) When all checking activities have been completed of if no comments

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were made, the original design drawing shall be signed by the reviewer and approved by the Engineering Dept General manager.

7) When all checking activities have been completed or if no comments were made, the original design drawing shall be signed by the reviewer and approved by the Engineering Dept General manager.

4.3.8 Design Reports(*not applied Electric Div')

4.3.8.1 Preparation of Design Report

- 1) Design Reports are the design documents which include stress analysis or calculations or both to show that loadings specified in Design Specification are not exceeded to the allowable limits.
- 2) Design report shall be prepared by the competent Design Engineer who is assigned by the Engineering Dept General manager and may be provided by subcontractors who are qualified.
- 3) Design report shall include the following information, as appropriate
 - (a) Identification of the design input utilized in the final design
 - (b) Identification of the assumptions that were made in the performance of the Design Work.
 - (c) A list of the computer type and the revision status that was utilized.
 - (d) Demonstration of compliance with the requirements of the Design specification
 - (e) Reference to any calculation, analysis, test results and other information that was the basis for the Design Report.
 - (f) Identification of any drawing resulting from the design addressed in the Design Report
 - (g) Identification of preparer, reviewer and approver.
- 4) Cover sheet of the Design Report (Exhibit6 QAP-3.2-06) shall be identified by the following;

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- (a) Document title of calculation number
- (b) Revision status
- (c) Document No. and issued data.
- (d) Type or Part Name, associated program name if applicable
- (e) Name and signature of preparer, reviewer
- (f) The Engineering Dept General manager approval for assuring and Completeness

5) Each page of the design reports shall show the document number, document page and revision status.

4.4 Design Review

4.4.1 The Engineering Dept General manager (Design Team Manager) shall designate reviewer / checker for the accuracy and criteria of Design Report, using copy of Design Report

4.4.2 The check shall include the following items, as a minimum;

- 1) Verifying that all data and figures included in the design report are accurate with respect to the source documentation and that references are complete
- 2) Confirming that the requirements of the Design Specification are met
- 3) Satisfaction with legal and regulatory requirements
- 4) Confirming that the design report fulfills the Owner's Design Specification and input data and are reasonable.

4.4.3 The check shall review a copy of the document and shall document any comments by the following methods.


- (1) Marking up the print drawing
- (2) Signing and dating the check print upon completion of the check
- (3) Identifying comments of marking "No comment"

4.4.4 When the checking is completed, the checker shall return the copy of the

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document and any other documents generated during the check to the preparer. The preparer shall resolve any comments.

- 4.4.5 The Engineering Dept General manager(Design Team Manager) shall resolve any comments that cannot be resolved between the checker and the preparer.
- 4.4.6 If the interface review calls for technical change, the change shall be checked as outlined above.
- 4.4.7 When all checking and review activities have been completed and all comment resolved, the document shall be approved by Engineering Dept General manager(Design Team Manager).
- 4.4.8 Records of the design review results and all necessary actions are recorded in the “QAP-17.1 Quality Record Control Procedures.
- 4.4.9 Acceptance of Design Output of Engineering Service Vendor(*not applied Electric Div’)
- 4.4.9.1 The Engineering Dept General manager shall assign the competent Design Engineer for the review of design documents which have been submitted by vendor of BMT of customer in accordance with BMT Purchase Order of Contract Agreement.
- 4.4.9.2 Using the Design Report Review Sheet, and the Design engineer shall review the design documents to verify the submitted design documents meet the requirement of the Code and BMT Purchase Order of Contract Agreement.
- 4.4.9.3 The Design engineer shall document any comments on the Design Report Review Sheet and / or Design Drawing Review Sheet.
- 4.4.9.4 The Engineering Dept General manager shall be responsible for the coordination with vendor or customer in order to resolve any comments

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and / or clarify and question.

4.4.9.5 When all comments have been resolved and / or any questions are clarified, the Engineering Dept General manager shall accept the vendor or customer design documents.

4.5 Final design review and verification

4.5.1 General

4.5.1.1 Design verification shall be performed by technically competent engineer other than those who performed the original design, and are assigned by the Engineering Dept General manager (Design Team Manager).


4.5.1.2 Personnel involved in design verification shall have sufficient experience to allow a comprehensive verification of criteria, design details and analyses. The Verification of unique elements of the design shall be performed by Design Engineer. Personnel performing verification shall be from the same discipline as the document preparer.

4.5.1.3 Design verification activities shall be scheduled as a part of the design schedule and timed to coincide with major decision points or milestones during the course of the project. Design verification shall be performed on design documents prior to their issuance externally as final documents for fabrication or other technical activity.

4.5.2 Methods

4.5.2.1 Acceptable design verification methods include, but not limited to, any one or a combination of the following;

- 1) Design reviews
- 2) Alternate calculations
- 3) Qualification tests
- 4) Comparison with a new design and a similar proven design.

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4.5.2.2 Responsibilities

- 1) The Engineering Dept General manager shall identify the verification methods to be used and select personnel to perform the design verification.
- 2) When changes are made to previously verified design output data, the Engineering Dept General manager shall be responsible for determining whether additional verification is required.
- 3) The Engineering Dept General manager shall have final authority to resolve comments in cases where agreement cannot be reached between personnel performing the design and those performing the design verification

4.5.2.3 Documentation

- 1) The design verification shall be documented on the Design Verification Sheet (Exhibit7 QAP-3.2-07) by the assigned verifier.
- 2) The design verification sheet shall include;
 - (a) The identification of all documents form bases for the verification;
 - (b) All comments, observation and resolutions
 - (c) Identification of the checklists utilized
 - (d) Identification of the verifier
- 3) When all comments have been resolved, the verifier shall sign and date the verified design documents.
- 4) The design verification sheet shall be included in the original design or analysis package, or file separately in a manner traceable to the original package.

4.5.3 Design Verification by Design Final Review

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4.5.3.1 Scope

- 1) Design is reviewed by one or more technically qualified and experienced personnel to verify the adequacy of design and analysis.
- 2) The reviewer shall select the depth of the review, depending on what is necessary to acquire confidence in the adequacy of the design. If is anticipated that the reviewer will not review engineering calculations for mathematical accuracy.
- 3) The design review shall be according to the following;
 - (a) Was the inputs correctly selected;
 - (b) Are assumptions necessary to perform the design activity adequately describe and reasonable; Where necessary, are the assumptions identified for subsequent re-verifications when the detailed design activities are completed;
 - (c) Was an appropriate design method used;
 - (d) Was design inputs correctly incorporated-into design;
 - (e) Are the outputs reasonable when compared to inputs;
 - (f) Are the design input and verification requisite for the applicable design organization specified on the design documents or applicable procedures.;
 - (g) Are applicable codes requirements including issue and addenda properly identified, and are the requirements for design met;
 - (h) Are the design and operating requirement for Design Specification met; and
 - (i) Was the material correctly selected, and was the mechanical property of material adequate.

4.5.4 Design Verification by Alternate Calculations(*not applied Electric Div')


4.5.4.1 The design verification may be performed through alternate calculations.

4.5.4.2 The form of design verification is suitable for individual design

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documents such as calculation, drawings and specifications, and when performed could take the place of the document criteria check or complete check.

- 4.5.4.3 The checker shall provide a clear comparison between his results and those of the calculation checked.
- 4.5.4.4 The checking shall be documented by a marked up copy of the checked document. The checker shall sign and date the mark up. The checker shall also note, sign and date satisfactory resolution of the comments.
- 4.5.5 Design Verification by Qualification Testing.
- 4.5.5.1 Design verification for some designs or specific design features, can be achieved by suitable qualification testing of a prototype, mock-up or initial production unit. All pertinent design features must be verified for their design condition adequacy, but the tests or verification means used may vary.
- 4.5.5.2 In addition to identifying and documenting the verification method, process and results, the Engineering Dept General manager is responsible for the preparation of a written test procedure.
- 4.5.5.3 The qualification test described by the test procedure shall demonstrate the design adequacy of performance under the most adverse design condition. All pertinent operating modes shall be considered to determine these design condition.
- 4.5.5.4 Qualification testing procedure shall be prepared by the competent engineer assigned by the Engineering Dept General manager and approved by the Engineering Dept General manager.
- 4.5.5.5 If testing indicates that modifications to the tested item are required to obtain the design condition adequacy of performance, the modified item shall be retested or otherwise verified to assure satisfactory performance.

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4.5.5.6 When tests are being performed on models or mock-ups, scaling laws shall be established and verified. The test configuration shall be clearly defined and documented in the test procedure. The results of the model test shall be subject to a verified error analysis prior to use in final design.

4.5.5.7 The test result shall be documented by the assigned Design Engineer.

4.6 Design validation

4.6.1 Design validation shall be implemented after design verification.

4.6.2 When necessary the functional test shall be carried out to validate the design of final product for customer requirements as described in the design plan, Design Engineer shall be make out the functional test procedure and the test results shall be shown on a test record.

4.6.3 Design and development validation is performed in the following manner.


- 1) Review related documents and materials
- 2) Collection and analysis of used records of similar products
- 3) Testing

4.6.4 The functional test shall be carried out to validate the design of final product applied for API 6D specification in accordance with applicable Procedure.

4.6.5 the Engineering Department General Manager shall have not been involved in the preparation of the Calculation Sheet, Design Report, and/or Drawings and he shall be competent individual for the approval of final design.

4.6.6 Validation shall be completed prior to the delivery of the product, when possible.

4.6.7 Records of design validation results and all necessary actions shall be

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maintained in accordance with the quality records management procedures.

4.7 Design change

4.7.1 The design engineer changes the design when a design change is required at each design stage or when the next design change occurs.


- 1) Customer's request
- 2) If there is a nonconformity occurred during the design process
- 3) If there is structural improvement according to design
- 4) If there are changes in laws and regulations

4.7.2 When any changes to design output are required, the adequacy of the changes shall be provided. Those changes shall be subject to the same control measures as required for the original document such as a design verification and evaluation of the effects on the overall design.

4.7.3 Design changes shall be reviewed and approved by the same affected groups or organizations which originally reviewed and approved the design document. Where an organization which originally was responsible for approving a particular design document is no longer responsible, the Engineering Dept. General manager(Design Team Manager) shall designate a new responsible organization or individual. The designated organization or individual shall be competent in the applicable field of design.

4.7.4 Where appropriate, design changes should be reviewed for design, verification of design and verification of design validity, and approval of the Engineering Dept. General manager(Design Team Manager) should be obtained prior to the change.

4.7.5 Where a significant design change is necessary because of an incorrect design, the Engineering Dept. General manager(Design Team Manager) shall review the design process and verification procedure and modify

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them as necessary.

4.7.6 Records of the review of design changes and all necessary actions shall be maintained in accordance with the Quality Records Control Procedure.

5.0 Record and Storage

No	Name	Form number	Retention period	Storage Dept'	Remark
1	Design Plan	QAP-3.2-01	5 years after loss of effect	Eng' Dept/ Design Team	
2	Design Specification Review Sheet	QAP-3.2-02	5 years after loss of effect	Eng' Dept/ Design Team	
3	Control of Design Interface	QAP-3.2-03	5 years after loss of effect	Eng' Dept/ Design Team	
4	Design Input Sheet	QAP-3.2-04	5 years after loss of effect	Eng' Dept/ Design Team	
5	Design Calculation	QAP-3.2-05	5 years after loss of effect	Eng' Dept/ Design Team	
6	Design Report	QAP-3.2-06	5 years after loss of effect	Eng' Dept/ Design Team	
7	Design Verification Sheet	QAP-3.2-07	5 years after loss of effect	Eng' Dept/ Design Team	
8	Design output Sheet	QAP-3.2-08	5 years after loss of effect	Eng' Dept/ Design Team	
9	Design Review	QAP-3.2-09	5 years after loss of effect	Eng' Dept/ Design Team	
10	Design Validity	QAP-3.2-10	5 years after loss of effect	Eng' Dept/ Design Team	
11	Final Review Report	QAP-3.2-11	5 years after loss of effect	Eng' Dept/ Design Team	