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MQP Level 2

Design Development Procedure

The design development is the set of activities to be performed to transform the Technical Requirement Specifications (TRSs) into a complete set of design output documents for a given design phase, as defined in the Design Plan.
The purpose of this procedure is to define the activities to be done starting from given design inputs (and any derived technical constrains identified during the design development process) up to design output generated documents that satisfy the stakeholders requirements.

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Change Log			
Design Development Procedure (U34DDZ)			
Version	***Latest Status***	***Issue Date***	***Description of Change***
v0.0	In Work	26 Oct 2016	
v1.0	Revision Required	28 Jun 2017	First issue. Document created as per MQP doc Request U4DVW5
v1.1	Approved	15 Sep 2017	According to approved MQP doc Request - U4DVW5: This document describes what the Design Developer shall do to control the development of his design: • Check the design plan identifies all the needed inputs for the design, the deliverables for each stage of the design, with the required maturity and agrees/details the objectives of each design stage (CD, PD, FD, Manufacturing Design, ...) • Analyse the logical solution representations (functional et temporal models: diagrams & sequence diagrams) that satisfy the requirements, • Analyse the physical solution representations (physical models: space allocation, geographical situation, routings & interfaces drawings) that satisfy the requirements, • Analyse, optimize consistency between functional, temporal and physical models, • Derive technical requirements (write lower level specifications including interfaces specifications), verify the lower level specifications against design input and prepare design package for the design review of the relevant design stage. The development of the design culminates with a successful manufacturing design review and the authorization to proceed to the Fabrication/Production. However the Design Developer's role extends to the monitoring and acceptance of any change addressed during the assembly & functional integration and product verifications until the system acceptance. The role of the Design developer finishes with the final product acceptance by the user/operator. The final product acceptance is acknowledged against the final design input specification together with the accepted final product description incorporating accepted changes (As-Built models).
v2.0	Revision Required	21 Mar 2024	As per MQP request 9WZKY9 the changes are: - Update to reflect New Project Organization - Alignment with SEMP and requirements from ISO9001 - add reference to Foreign Material Management Procedure 7TDU2L - Improvement of the terminology to match current ITER terminology (some terms were incorrectly used, others are not used/known at ITER), leading to a confusion for readers
v2.1	Approved	25 Apr 2024	All comments from previous version incorporated. In details: 1/ update of chapter 8 to: -separate Digital model for analysis and CAD processes -add section about Commissioning process and add reference to relevant procedure for producing System commissioning plan -update sub-section about O&M process to add reference to System Concept of operation, System Maintenance & In-service inspection Plan 2/ correction of typo in Figure 5 3/ chapter 6.3.3.4: correction of title of 33TTPJ to Instructions for ITER System Load Specifications.

			4/ chapter 6.3.3.4: amended to add links for System Commissioning Plan, System Concept of operations, System Maintenance & In-service inspection Plan

Table of Contents

1. Purpose

The design development is the set of activities to be performed to transform the Technical Requirement Specifications (TRSs) into a complete set of design output documents for a given design phase, as defined in the Design Plan [1].

The purpose of this procedure is to define the activities to be done starting from given design inputs (and any derived technical constrains identified during the design development process) up to design output generated documents that satisfy the stakeholders requirements.

The design development of Protection Important Components (PIC) is a Protection Important Activity (PIA) [2].

2. Scope

This procedure is applicable by the Design Developer primarily to produce the design output data for the ITER Plant or any ITER Structure, System or Component (SSC), at any design phase. The Design Developer (internal or external to IO) may customize the application of this process in their design plan.

The procedure is also applicable when a design change has been approved for implementation [3].

The Design Development procedure is a level 2 document in the MQP hierarchy. It belongs to the overall Design Control process which requirements are defined in Quality Assurance Program (QAP-Level 1) [4].

The design development process is based on the ISO 15288 [32], ISO 26702 [33] and identified in the SEMP [34].

3. Definitions and acronyms

3.1 Definitions

List of Definitions dedicated to this document. For general definitions, refer to ITER_D_X2SH46 - Configuration Management Glossary.

Terminology	Description
Architecture	Fundamental concepts or properties of a system in its environmental embodies in its elements, relationships and in the principles of its design and evolution.
Architecture description	Work product used to express an architecture.
Architecture view	Work product expressing the architecture of a system from the perspective of specific system concern.
Architecture viewpoint	Work product establishing the conventions of the construction, interpretation, and use of architecture views to frame a specific system concern.
Stakeholder concerns	Stakeholder concerns related to architecture are expectations or constraints associated with the system life cycle stages such as: • Utilization (e.g., availability, security, effectiveness, usability). • Support (e.g., reparability, obsolescence management). • Evolutionary development of the system and of the environment (e.g., adaptability, scalability, survivability). • Production (e.g., producibility, testability). • Retirement (e.g., environmental impact, transportability), etc.

3.2 Acronyms

List of Acronyms dedicated to this document. For specific Acronyms, refer to ITER_D_2MU6W5 - ITER Abbreviations.

CDR	Conceptual Design Review
COTS	Commercial Off the Shelf
CON	Conceptual Desing Phase
CRD	Component Requirements Document
DDD	Design Description Document
FDR	Final Desing Review
FIN	Final Design Phase
I&C	Instrumentation and Control
IS	Interface Sheet
PBS	Plant Breakdown Structure
PDR	Preliminary Design Review
PR	Project Requirements
PRE	Preliminary Design Phase
RAMI	Reliability, Availability, Maintainability, Inspectability
SLD	Single Line Diagram
SRD	System Requirements Document
sSRD	Sub-System Requirements Document
SSC	Structures, Systems and Components
TRS	Technical Requirement specification
VCM	Verification Control Matrix

4. Reference Documents

[1]	ITER_D_U34ACR - Design Planning Procedure
[2]	ITER_D_SBYJXD - Guideline for Identification of the Protection Important Activities
[3]	ITER_D_U2QPDS - Design Change Control Procedure
[4]	ITER_D_22K4QX - ITER Quality Assurance Program (QAP)
[5]	ITER_D_3CNWMT - Design Integration Review Procedure
[6]	ITER_D_2832CF - Design Review Procedure
[7]	ITER_D_U34CSG - Design Input Control Procedure
[8]	ITER_D_43S7GL - Expected content of System Design deliverables
[9]	ITER_D_R3KD8C - Design Verification Management Procedure
[10]	ITER_D_44BLNX - Requirements Management Process (RQMP)
[11]	ITER_D_3L6HRT - I&C Software Development procedure
[12]	ITER_D_27LH2V - Plant Control Design Handbook
[13]	ITER_D_2YNEFU - Plant Control Design Handbook for Nuclear control systems

[14] ITER_D_KTU8HH - Software Qualification Policy

[15] ITER_D_22MAL7 - Analyses and Calculations

[16] ITER_D_U348G8 - CAD Execution Procedure

[17] ITER_D_2M24AM - Procedure for the preparation, review and approval of the DDDs

[18] ITER_D_4CK4MT - ITER System Design Process (SDP) Working Instruction

[19] ITER_D_TME48W - Identification of Occupational Health & Safety Requirements related to Design

[20] ITER_D_TZYDUC - Risk Analysis

[21] ITER_D_3T9UK2 - ITER Process for Human Machine Interface (HMI) Development

[22] ITER_D_2NRTWR - Remote Handling Compatibility Procedure

[23] ITER_D_28VNJG - Design Interface Control Procedure

[24] ITER_D_TZV743 - Procedure for Configuration Identification and Configuration Status Accounting

[25] ITER_D_353X9Z - MQP IO Archive and Records Management Procedure

[26] ITER_D_22K5JQ - Document Management Procedure

[27] ITER_D_BG2GYB - Propagation of the Defined Requirements for Protection Important Components Through the Chain of External Interveners

[28] ITER_D_22F4LE - Risk and Opportunity Management Procedure

[29] ITER_D_2M7PJQ - Design Review Checklists

[30] ITER_D_473LQM - Design Compliance Matrix Procedure

[31] EN 14514 Functional analysis

[32] ISO 15288 Systems and software engineering - System life cycle processes

[33] ISO 26702 Std 1220-2005 Systems engineering - Application and management of the systems engineering process

[34] ITER_D_2F68EX - ITER Systems Engineering Management Plan (SEMP)

[35] ITER_D_35CY6V - CAD Manual 14 - Diagram Guidelines

[36] ITER 29FVC2 01 APPROVED CAD MANUAL

[37] ITER_D_GDQF3T - CAD Tools Selection, Customization and Qualification

[38] ITER_D_7TDU2L - Foreign Material Management Procedure

[39] Design Plan - Part 1

[40] ITER_D_7WT3PG - HOW TO - Requirements Validation Matrix

[41] ITER_D_2EXFXU - Sign-Off Authority (SOA) for Project Documents

[42] ITER_D_X8KGJE - Working Instruction for Preparing Commissioning Plans and Test Procedures

[43] ITER_D_5EYHR7 - WI - Management of operational documentation

[44] ITER_D_YH3TFW - Working Instruction for the Preparation of System Maintenance & In-Service Inspection Plans

5. General principles

Design Development consists of three phases: Conceptual Design (CON), Preliminary Design (PRE) and Final Design (FIN). Through each of these phases (moving down the left side of the Vee), technical requirements are continually broken down into lower-level requirements. At the same time, the design is maturing and implementing the requirements from the phase before. Thus, ensuring the project is successfully meeting the stakeholder's needs, maturing, and moving forward.

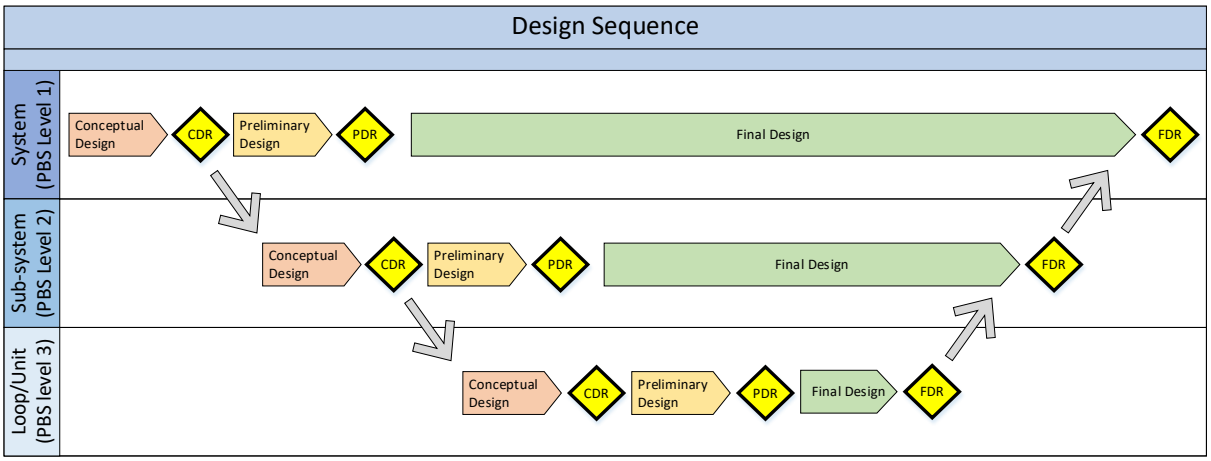


Figure 2: Schematic representation of the design sequence.

Note that to mitigate the risk on the design development, the design work shall be performed in design phases (CON, PRE and FIN) and related review gates (CDR, PDR and FDR) at which the requirement compliance control is performed [1].

The Design Development is articulated through:

- The PBS Design Plan listed in the [34] and [39].
- The implementation of the Transverse Functions through the further refinement of the transverse PRs into detailed SSCs requirements/constraints and/or design input (for a complete list of transverse functions see [34]).
- The Design Integration Review (DIR), implemented according to DIR Procedure [5].
- The verification that specified requirements have been fulfilled through the System Design Review, implemented according to Design Review Procedure [6].
- At the end of each activity phase, a Design Compliance Matrix [30] is needed to provide evidence that the product of the phase is fulfilling the input for the activity phase [7].

The development should be performed based in a Top-Down approach, starting from the top level and moving down up to reach the lowest level (i.e.,: Plant level−>System level−>Sub-system level−>Component level).

The figure below shows the concept of design development throughout the ITER Plant Breakdown Structure (PBS). The tree levels represents the Configuration Management levels at ITER and illustrate the process application.

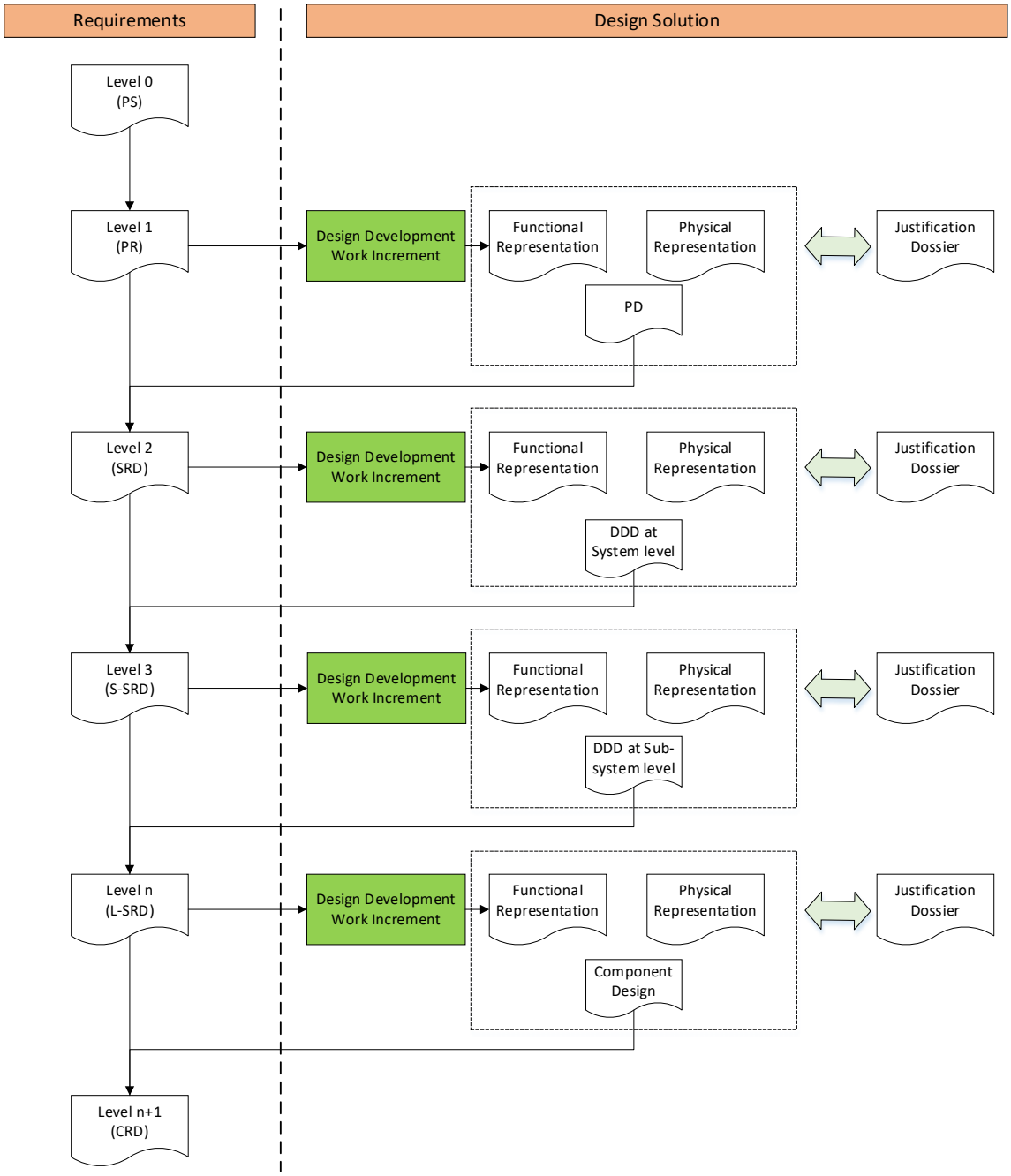


Figure 3: Application of the processes through CM (Configuration Management) levels.

6. Workflow

6.1 Main application of the process

The flow chart below represents a general overview of the design development process workflow within the Design Control process.

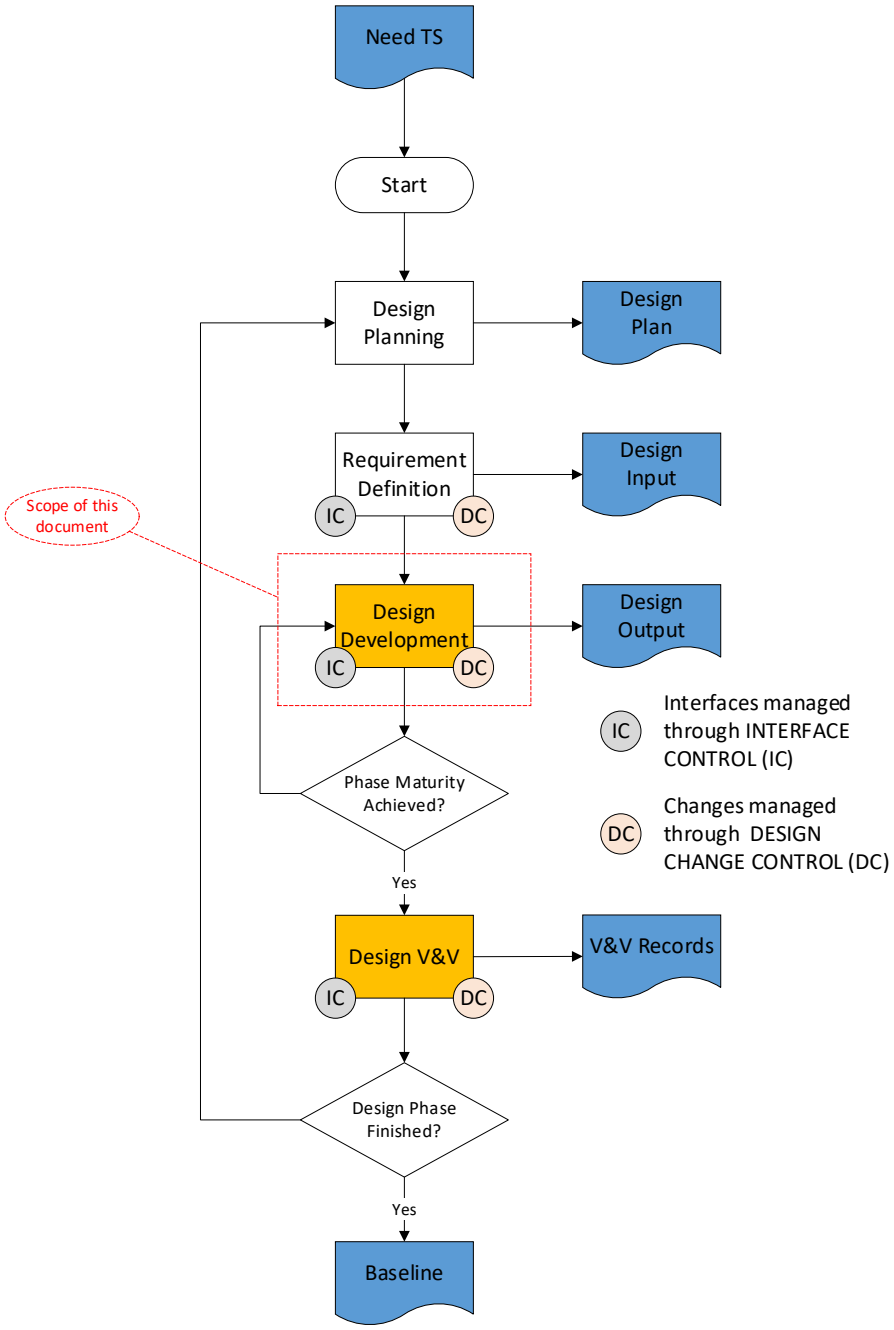


Figure 4: Design development process application during the project lifecycle.

6.2 Flow chart

Due to the development process is recursive, the generic workflow describes how to develop the design between two consecutives PBS levels (e.g., n "system" and n+1 "sub-system"). This workflow shall be applied successively to the level of detail (i.e., from system design development level to subsystem and so on, up to complete the component design level) needed to reach the maturity defined in [8], for the end of each design phase.

The Design Development process is applied in each design activity phase as detailed in the workflow. The process comprises three main sub-activities:

1. Architecture Definition.
2. Design Definition.
3. System Analyses.

The processes of Architecture Definition and Design Definition are highly iterative and interlinked but they are described sequentially for the sake of understanding.

A simpler approach can be applied for simple systems or low risk systems depending on their quality classification. This approach shall be formalized and agreed in the Design Plan.

Design Development Procedure

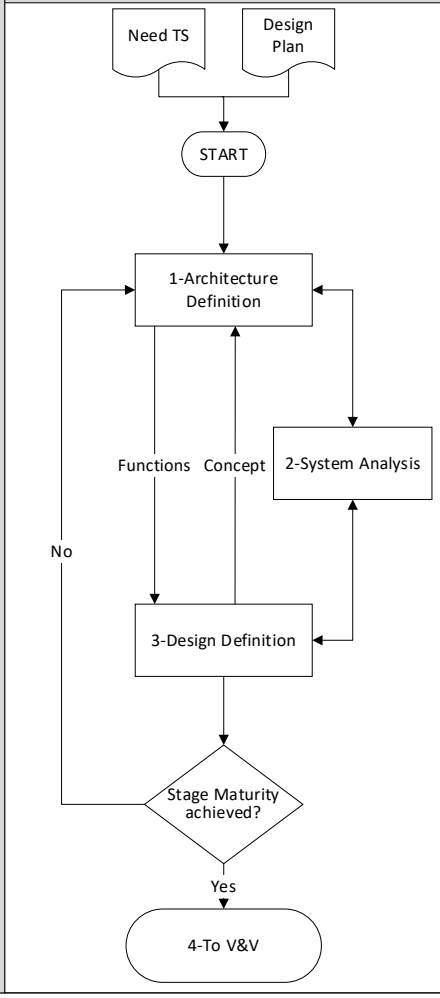
Activity	#	Resp.	Guidance	Deliverable
	0	Design Coordinator	0 - Inputs: Need TS Design Plan	N/A
	1	Design Developer	1 - To generate system architecture that frame stakeholder concerns and meet system requirements, and to express this in a set of consistent views.	FBS or FT, RAM, FFBD, PFD, P&ID, I&CD, IS (Functional Interfaces), SDPD, SLD, Arrangement or Layout Drawing, etc.
	2	Design Developer	2 - To provide a rigorous basis of data and information for technical understanding to aid decision-making across the life cycle.	Engineering Analysis Reports and Calculations, Return of Experience Report, Research and Development Report. Etc.
	3	Design Developer	3 - To provide sufficient detailed data and information about the system and its elements to enable the implementation consistent with system architecture.	System Design Description DD, DM, BOM, Item Type List, other detailed drawings, etc.
	4	Design Approver/ Stakeholders	4 - If stage maturity is: - Not reached, apply the process to a lower CM level. - Reached, proceed to V&V process.	N/A

Figure 5: Design development process generic workflow.

6.3 Description of the generic workflow

As mentioned before, the Design Development process comprises three main sub-activities: architecture definition, system definition and system analyses.

The Design Development of a given system must be performed based on the well-defined inputs. The design development inputs are based on the resulting combination of the Design Planning (Design Plan) and Design Input Control (TRSs such as SRD, sSRD, CRD, etc.) processes that shall be accomplished in advance to properly establish the bases for the design development stage.

6.3.1 Architecture definition

6.3.1.1 Purpose

The purpose of the Architecture Definition is to generate system architecture alternatives and to select the most appropriated one that frame stakeholder concerns and meet system requirements. This activity is used to create and establish alternative architectures, to assess the properties of them (supported by the system analysis activity), and to select the appropriated system elements that compose the systems.

6.3.1.2 Inputs

The inputs are the Design Plan for the documents to be developed, the TRSs (i.e., SRD, sSRD, CRD, etc.) for the product requirements and design output documentation from previous design development phases if applicable.

6.3.1.3 Activities and tasks

1. Prepare for architecture definition:
    - Review pertinent information and identify key drivers of the architecture.
    - Identify and analyze all relevant aspects such as industry, stakeholder concerns, operations, mission, legal, etc. that will help to understand the perspective that will guide the architecture development.
    - Analyze the TRSs and identify functional requirements, nonfunctional requirements (e.g., safety, security, human factors, etc.) as well as life cycle constrains (e.g., maintenance, disposal, deployment, etc.).
    - Identify stakeholder concerns related to architecture.
    - Define the architecture definition roadmap, approach, and strategy.
    - Define architecture evaluation criteria based on stakeholder concerns and key requirements.
    - Ensure that enabling element or services will be available.

2. Develop architecture viewpoints:
    - Establish the specific perspectives or viewpoints from which the architecture will be developed (i.e., functional, physical, information, operational, etc.). Each viewpoint represents a particular set of concerns and focuses on specific aspects of the system.

3. Develop models and views of candidate architectures:
    - Define the system context and boundaries in terms of interfaces and interactions with external entities.
    - Determine which architectural entities (e.g., functions, input/output flow, system element, physical interfaces, architectural characteristics, information & data elements, etc.) address the highest priority requirements.

- Allocate concepts, properties, characteristics, behaviors, functions, or constraints that are significant to architecture decisions of the system to architectural entities. (The items being allocated could be physical, logical, or conceptual.)
- Select, adapt, or develop models of the candidate architectures of the system, usually logical models (e.g., functional, behavioral, etc.) and physical models (e.g., structural block, mass, layouts, etc.).
- Compose architecture views in accordance with identified viewpoints to express how the architecture addresses stakeholder concerns and meets system requirements.
- Decompose to lower-level functions: The decomposition may use various types of analyses known as functional analysis, structured analysis, object-oriented analysis, etc. to identify and define technical functions that can achieve the service functions, their interfaces, states and modes, timelines, data, and control flows of the system, within the operational and design constraints given by the system requirement specification. The decomposition may stop when a COTS component is identified that responds to the technical function.
- Analize and harmonize the architecture views with each other for consistency.

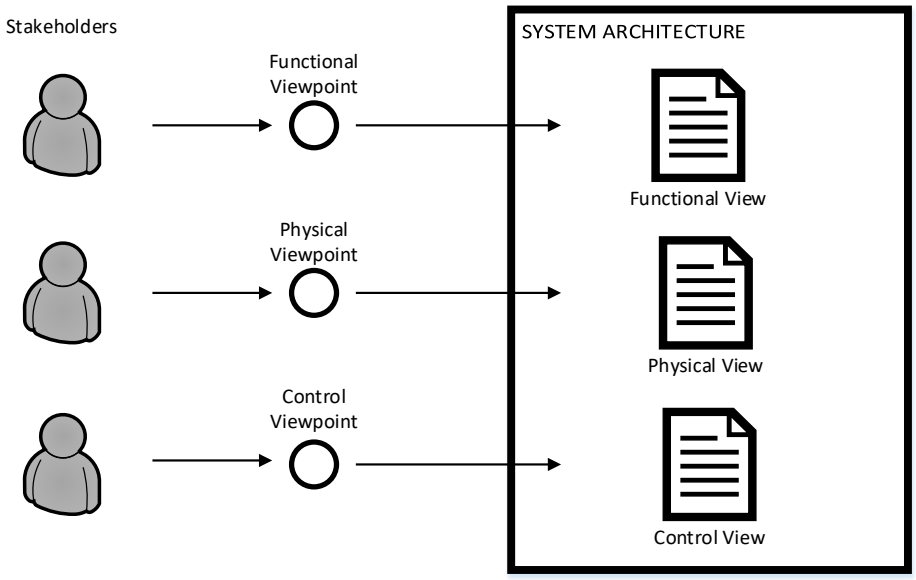


Figure 6: Example of architecture, viewpoints, and views scheme.

4. Relate the architecture to design:
    - Identify system elements that reflect the architectural entities and the nature of these relationships.
    - Perform interface definition for internal and external interfaces that are relevant to the level of detail of the architecture.
    - Allocate system technical requirements and other limiting requirements to all architectural entities and system elements.
    - Determine design characteristics thar are related to system elements and their architecture entities (e.g., constrains, operational conditions, etc.).
    - Identify and define derived technical requirement and resolve conflicts.

5. Assess architecture candidates:
    - Evaluate architecture alternatives based on systems requirement, identified constrains, stakeholder concerns, systems analysis, measurements, and risks assessments.

- Select the most appropriate architecture.

6. Manage the selected architecture:
    - Manage the maintenance and evolution of the architecture throughout the system's lifecycle. Allocation and traceability matrices could be used to analyze the impact of requirement's changes onto the architecture.

Note: The logical architecture verification and validation is done through the V&V process [9] and identified in the Design Plan [1].

6.3.1.4 Outputs

System architecture: Functional Breakdown Structure-FBS or Function Tree, Requirement Allocation Matrix, Functional Flow Block Diagram (FFBD), Process Flow Diagram (PFD), Instrumentation & Control Architecture Diagram, Piping and Instrumentation Diagram (P&ID), Interface Sheet-IS (Preliminary Functional and Physical Interfaces), System Detailed Performance Definition-SDPD, Single Line Diagram (SLD), or One Line Diagram , Arrangement or Layout Drawing.

6.3.1.5 Supporting processes

- Requirement Management Process [10] provides details of these activities and tools for traceability matrices.
- For functional analysis, the [31] provides guidance for determining lower levels functions.
- For guidance for the production of standard diagrams, see [35].
- For guidance for the elaboration and content of I&C documents see [12] and [13].

6.3.2 Design definition

6.3.2.1 Purpose

The purpose of the Design Definition is to provide sufficient detailed data and information about the system and its elements to enable the implementation (manufacturing, assembly, installation, etc.) consistent with architectural entities as defined in models and views of the system architecture. As result, the Design Definition activity provides the description of the design characteristics (e.g., dimensions, shapes, materials, etc.) and design enablers (e.g., equations, algorithms, drawings, diagrams, etc.) for its implementations.

6.3.2.2 Activities and tasks

1. Prepare for design definition:
    - Identify the technologies needed to achieve the design objectives for the system and system elements.
    - Identify the applicable type of design characteristics for each system element (e.g., detailed patterns, structures, size, volume, gauge, template, etc.).
    - Define the design definition strategy, including the need for enabling systems, products, or services.

2. Establish design characteristics and design enablers related to each system element:
    - Perform requirements allocation to system elements for all requirements and system elements not fully addressed in the architecture definition stage.
    - Transform each architectural characteristic related to the architectural entities assigned to the system element into design characteristics (i.e., dimensions, shapes, materials, critical quality characteristics, etc.) using adequate representation such as drawings, diagrams, models, architectures, etc.

- Define and/or select the necessary design enablers such as models, equations, algorithms, calculations, formal expressions, values of parameters, etc. that are associated to design characteristics.
- Assess the feasibility of design characteristics and perform trades in the architecture or requirements when design characteristics cannot be implemented.
- Perform and/or complete interface definition to define the internal and external interfaces that were not defined during the architecture definition or that need to be refined as the design details evolve.
- Capture the design characteristics of each system element on the appropriated documents (e.g., data sheets, lower level TRSs, CRD, etc.).

3. Assess alternatives for obtaining system elements:
   - Identify any existing implemented elements that may be considered for use, including COTS, reused, or other non-developed system elements.
   - Assess options for the system element, including the COTS system elements, the reused system elements, and the new system elements to be developed using a selection criteria derived from the design characteristics.
   - Select the most appropriate alternatives.

4. Manage the design:
   - Manage the maintenance and evolution of the design, including the alignment with the architecture. Assess and control evolution of the design characteristics.
   - Establish and maintain bidirectional traceability between the architecture entities to the stakeholder concerns, system requirements, constraints, system analysis, trades, verification criteria, verification results and design elements.
   - Provide baseline information for configuration management.

Note: The physical architecture verification and validation is done through the V&V process [9] and identified in the Design Plan [1].

6.3.2.3 Outputs

Design definition: Systems Design Description (DD), lower level TRSs (sSRD, CRD, etc.), Detailed Model (DM), Bill Of Material (BOM), Item Type List, Interface Sheet-IS, Part Drawings, Assembly or Component Definition Drawing, other detailed drawings, etc.

6.3.2.4 Supporting processes

- Requirement management process [10] defines requested data at each level of the specification tree and way to demonstrate compliance and support verifications (traceability matrices).
- For software development related to plant systems delivering I&C software see [11].
- For guidance for the elaboration and content of I&C documents see [12] and [13].
- CAD execution procedure [16].
- Procedure for the preparation of the DDDs [17].
- For guidance for the formatting and generation of CAD data see [36].

6.3.3 System analyses

6.3.3.1 Purpose

The purpose of the System Analysis process is to provide a rigorous basis of data and information for technical understanding to aid decision-making across the life cycle.

The system analysis activity performs quantitative evaluation that support the development, providing confidence in the utility and integrity of architecture and design. The system analyses are used either on the architecture definition or on the design definition to analyze and estimate architectural and design characteristics of candidate architectures and/or system elements, providing arguments in order to be able to select the most efficient ones in terms of costs, technical risks, effectiveness (e.g., performances, dependability, human factors), and other stakeholder concerns such as critical quality characteristics, affordability, maintenance, etc.)

6.3.3.2 Activities and tasks

1. Prepare for system analysis:
    - Identify the problem or question that requires system analysis.
    - Define the scope, objectives, and level of fidelity of the system analysis.
    - Select the system analysis methods.
    - Define the system analysis strategy.
    - Identify and plan for the necessary enabling systems or services needed to support system analysis.
    - Obtain or acquire access to the enabling systems or services to be used.
    - Collect the data and inputs needed for the analysis.

2. Perform system analysis:
    - Identify and validate assumptions.
    - Apply the selected analysis methods to perform the required system analysis.
    - Review the analysis results for quality and validity.
    - Establish conclusions and recommendations.
    - Record the results of the system analysis,

3. Manage system analysis:
    - Maintain traceability of system analysis results.

6.3.3.3 Outputs

Different types of engineering analysis and calculations, including Return of Experience (ROX) and Research and Development (R&D) reports.

6.3.3.4 Supporting processes

- The computer programs used for design analysis and calculations shall be controlled according to Software Qualification Policy [14].
- Foreign Material Management Procedure [38] provides guidance for understanding the impact that internal or externally generated FM could have on the system/component. Additionally, it provides guidance for identify and manage requirements related to FM design aspects during the system design phases.
- The overall procedure for product Analyses and Calculations is given in [15].
- The procedure to write System Commissioning Plan is given in [42].
- The procedure to write System Concept of Operations is given in [43].
- The procedure to write System Maintenance and In-Service Inspection Plan is given in [44].
- The different types of analyses that can be done and their possible applications are reminded in the table hereafter:

Analyses (1)	Link to relevant MQP process or working instructions
Operation analyses from ITER_D_S7T73E - Concept of Operations	ITER_D_S7WS29 - Design Plan - Part 1 for TF 25 - Operation & Maintenance & Inspection
Nuclear Safety analyses	ITER_D_SD2E6H - Design Plan - Part 1 for TF 01 Safety & Licensing process
	ITER_D_U33S8T - Realization of Safety Analysis
Reliability, Availability, Maintainability and Inspectability (RAMI)	ITER_D_28WBXD - ITER RAMI Analysis Program
Integrated Logistics support (ILS)	
Failure Modes and Effects Analysis / Failure Modes Effects and Criticality Analysis (FMEA/FMECA)	ITER_D_28WBXD - ITER RAMI Analysis Program
Hazard Identification and Risk Assessment (HIRA)	ITER_D_TME48W - Identification of Occupational Health & Safety Requirements related to Design [19]
	ITER_D_TZYDUC - Risk Analysis [20]
Fire Protection analysis	ITER_D_UKNQJQ - Fire Protection Design Plan
Human factor analysis (HMI)	ITER_D_3T9UK2 - ITER Process for Human Machine Interface (HMI) Development [21]
Overall structural loading and behavior	ITER_D_222QGL - Load Specifications (LS)
	ITER_D_2LULDH - Heat and Nuclear Load Specifications
	ITER_D_33TTPJ - Instructions for ITER System Load Specifications
Material integration	ITER_D_RH68PL - Material Integration Design Plan (TF10)
EM compatibility, magnetic perturbation, etc.	ITER_D_RH6LGC - Electromagnetic Compatibility Design Plan
Radiation hardness	RGU4D7_NIU domain 3 (ERC) Management Plan
Nuclear analyses, shielding/activation, contamination, etc.	ITER_D_RHQ4NB - Nuclear Integration and Analysis design Plan
Simulation analyses (behavioral analyses, assembly and tolerances, maintenance, etc.)	ITER_D_RC9LTR - Design Plan for TKM Tolerance Studies
Remote Handling	ITER_D_2NRTWR - Remote Handling Compatibility Procedure [22]
HAZOP	ITER_D_2F5L5M_Procedure for Performing Hazard and Operability

Notes:

(1) Various tools are provided by the IO Design Office to allow creating diagrams/3D models and performing analyses and simulations (see [36] and [37]).

6.4 Responsibilities

Design Developer:

- The Design Developer is the technical person who supports the Design Coordinator to perform the development activities.

Design Coordinator:

- The Design Coordinator is ultimately responsible to produce design output documents according to the requirements.
- He/she shall coordinate the production of the design output documents according to the Design Plan [1].
- He/she shall coordinate the review and approval of the design output documents according to the SOA [41].

Design Approver:

- He/she shall ensure review, approval and authorization to proceed of these documents according to the Design Plan [1].

Stakeholders:

- The Stakeholders have a mandatory reviewer role in the technical acceptance of the design and end-products. They review and accept documents according to the Design Plan [1] and SOA [41].

7. Records

The output of this workflow is the design package ready for verification and validation [9]. The list of documents of the design package is defined in the Design Plan (specifically in the Document Production Plan) [1]. The detailed list of the expected documents to be deliver at the completion of the design development is defined in [18] and [8], as well as the maturity that they shall achieve at each design phase (i.e., CON, PRE and FIN). The Design Review Check List [29] could be used for the assessment of the maturity of the Design before each Design Review.

The results of the design development process (Design Outputs) shall be verified and validated, according to Design Verification and Validation process [9], in order to identify via the Design Compliance Matrix (DCM/VCM) [30] and Requirement Validation Matrix (RVM) [40] that:

- Design development outputs meet the input requirements.
- Requirements have already been considered in the Design (and those which were not for risk assessment).
- Design options are assessed in terms of risks and the selected design solutions/options are justified and supported by necessary analyses.
- Resulting product can meet the stakeholder’s requirements for the specified application or intended use.

8. Link with other processes

8.1 Digital models for analysis

- Procedure for Analyses and Calculations 22MAL7 [15]: Participates to the design development process and provides supporting documents to the design description. Process used within this procedure.

8.2 CAD

- CAD Execution procedure U348G8 [16]: This procedure defines how to implement Design Development processes using CAD (used for the development of the physical solution).

8.3 Configuration management

- Procedure for Configuration Identification and Configuration Status Accounting TZV743 [24]: This procedure defines how to identify configuration items and manage their status. Input management requirement for this procedure.

8.4 Document and records

- MQP IO Archive and Records Management Procedure 353X9Z [25]: This procedure provides requirements on the way to manage records. Input management requirement for this procedure.
- Document Management Procedure 22K5JQ [26]: This procedure provides management requirements on the way to write, review/verify and approve documents. Input management requirement for this procedure.

8.5 Commissioning

- Working Instruction for Preparing Commissioning Plans and Test Procedures (X8KGJE) [42]. This procedure describes how to prepare system commissioning plans and test procedures, documents which shall be produced during the design development phase. Commissioning tests provide validation of safety and functional requirements and the performance of the concerned system. Process used within this procedure.

8.6 Operation and maintenance

- Remote Handling Compatibility Procedure 2NRTWR [22]: This procedure provides guidance for the management of RH-compatibility during the Project. Process used within this procedure.
- ITER Process for Human Machine Interface (HMI) Development 3T9UK2 [21]: This procedure provides guidance for the management of HMI-compatibility during the Project. Process used within this procedure.
- Foreign Material Management Procedure 7TDU2L [38]: This procedure provides guidance for understanding the impact that internal or externally generated FM could have on the system/component. Additionally, it provides guidance for identify and manage requirements related to FM design aspects during the system design phases.
- WI - Management of operational documentation (5EYHR7) [43]. This procedure provides guidance for developing system concept of operations, that shall be produced during design development phase. Process used within this procedure.

- Working Instruction for the Preparation of System Maintenance & In-Service Inspection Plans (YH3TFW) [44]. This working instruction provides guidance to prepare and write system maintenance & in-service inspection plan, required to be produced during design development phase. Process used within this procedure.

8.7 Nuclear safety

- Propagation of the Defined Requirements for Protection Important Components Through the Chain of External Interveners BG2GYB [27]: This procedure provides requirements for the Propagation of the Defined Requirements during the Project. Input management requirement for this procedure.

8.8 Project control

- Risk and Opportunity Management Procedure 22F4LE [28]: This procedure provides requirements on the technical risk's identification, processing and records. Input management requirement for this procedure.

8.9 Security

- Risk analysis TZYDUC [20]: This procedure provides guidance for the OHS risk analysis. Process used within this procedure.
- Identification of OHS Requirements related to Design TME48W [19]: This procedure provides guidance for the OHS requirement definition. Process used within this procedure.

8.10 Internal interactions

- Design Planning Procedure U34ACR [1]: Defines how to generate a Design Plan. Application of this process provides input for this procedure.
- Design Input Control Procedure U34CSG [7]: Defines how to generate the input data (product requirement and information) for the design development. Application of this process provides input for this procedure.
- Design Interface Control Procedure 28VNJG [23]: Defines how to manage Interfaces requirements (part of TRSs) in Interface solutions (part of design solution). Interlinks with the design development process.
- Design Verification and Validation Procedure R3KD8C [9]: Describes how to verify or validate the compliance of SSCs (design, built and functionality) with the applicable technical requirements. Interacts with the design development process.
- Design Change Control Procedure U2QPDS [3]: Defines how to maintain the integrity of the design during a "Change Project" for the analysis of the impact and implementation of a design change. Application of this process provides new input for this procedure.