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RECORD OF REVISION

Rev	Date	Description	POC	RM
0	9/20/2017	Initial issue. Based in large part on parent company procedures and subject matter expertise.	Tobin Oruch, *ES-DO*	Larry Goen, *ES-DO*

Usage Note

This guidance document is commentary to the SE Requirements document of Chapter 20. Definitions, acronyms, references, and additional information are contained in that document and not repeated herein except where they are brief and deemed important to the reader's understanding.

1.0 SE Planning Guidance (SE-PLG)

1.1 Lifecycle Planning

A. The Department of Energy established a life cycle process for acquiring of capital assets. The process breaks apart the life cycle into phases ranging from need development through engineering, construction, operations and disposal.

B. DOE bounds life cycle phases using specific Milestone reviews to be conducted by the Federal Project Director for the purpose of determining if a project is proceeding in a manner that will provide the needed capital asset in a timely and cost-effective manner. These milestone reviews (and other review types that DOE may employ) are described in DOE G 413.3-9, *Project Review Guide for Capital Asset Projects*. These reviews are summarized in Table SE-PLG-1.

Table SE-PLG-1 DOE Project Milestone Reviews

Review	Purpose	General Criteria
CD-0: Mission Need Review	Confirm there is a need that cannot be met through other than material means	A mission-related need is identified and the functional requirements for filling the need are established. The requirements are based on required inputs and desired outcomes. These requirements should be without bias for a specific solution.
CD-1: Alternative Selection and Cost Range	Confirm that the selected alternative and approach is the optimum solution	The preferred alternative is identified. Conceptual Design is complete and initial cost estimates are developed. Technical risks and Critical Technology Elements (CTE) are identified. CTE have a minimum TRL of 4.
CD-2: Performance baseline Review	Confirm the proposed scope, schedule and cost baseline is achievable	Preliminary Design is complete and a detailed scope, schedule and cost baseline is complete. Technology maturity of TRL 6 is already attained or is likely prior to CD-3.
CD-3: Approve Start of Construction Review	Confirm the project is ready for implementation	All design and engineering is complete and satisfactory for construction. All technology is matured to TRL 6 or greater.
CD-4: Approve Start of Operations	Confirm the project is ready for operations	The Operations organization is train and logistically ready to operate and maintain the facility within the bounds of the authorization basis.
Technical Reviews	There are many kinds of technical reviews.	Refer to the DOE guide for more information.
TRL = Technology Risk Level		

The relationship between milestone reviews and project phases are shown in Figure SE-PLG-1.

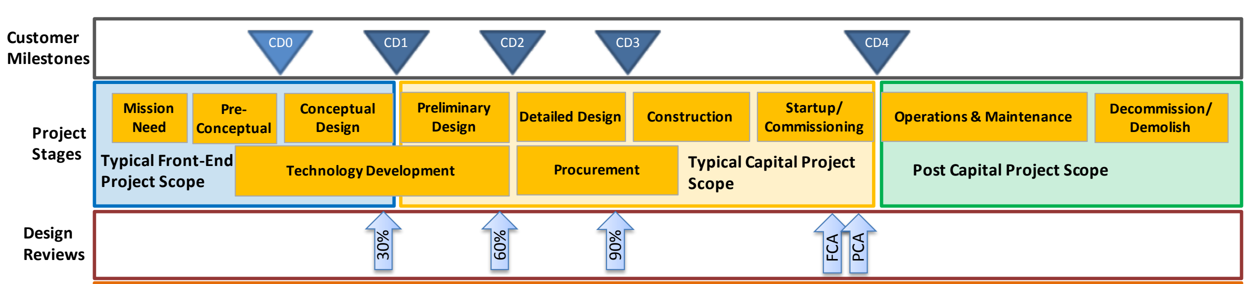

Figure SE-PLG-1 Milestone Reviews and Project Phases

A more detailed example of a project life cycle is provided in Figure SE-PLG-2. This example shows design product maturation versus project phase.

C. Prior to CD-4, DOE will generally subject a nuclear line item project to either an Operational Readiness Review (ORR) or a Readiness Assessment (RA) prior to allowing a constructed facility to enter operations. (Refer to DOE O 425.1C and DOE-STD-3006 for details about these reviews). The work required to successfully pass these reviews should not be under-estimated. Failure of the events can delay facility operations by a year or longer. Consideration of these reviews should be given throughout the project life cycle. The requirements management and V&V processes implemented through this capture helps projects prepare for these reviews. Performing these activities with thoughtful quality will help reduce project risk.

1.2 Acquisition Strategy

A. Once DOE determines that a new or modified system is necessary to support a specific need or mission, then a process for acquiring that system is initiated. DOE has prescribed system life cycles that are used as the framework for acquiring systems. An acquisition strategy is developed to show how the work of providing the new system will be divided among the organizations that engineer, procure, construct and test the new facility and facility modifications. Each strategy will determine contract scope and deliverables, the work that is required by the acquiring agency to ensure they get qualified contractors and ensure quality of the work.

B. The larger nuclear facility projects often employ a strategy known as design-bid-build, meaning the engineering services are procured separately from construction services. The process to acquire the facility or facility modification starts with procuring engineering services from an Architect-Engineering Firm to provide a constructible design. The design can start with conceptual, preliminary or final design activities, depending on the maturity of any previous work. The final design is used as the basis for construction companies to bid for the construction, and perhaps follow-on phases.

C. The AE firm is expected to use systems engineering methods to reduce risk, to ensure clear requirements derived from the mission need, and to provide traceability of those requirements into the design solution. Systems engineering provides a set of processes that cover all system life cycle phases, including processes for conceptualizing, developing, procuring, implementing, testing operating, maintaining and disposing of systems. These processes need to be tailored to address the size, complexity, and risks of the project.

D. In order to acquire the engineering services required for a project, a project should:

1. Establish the acquisition strategy for the facilities and SSCs within project scope, including:

    a. determination of how the scope will be divided between LANL and subcontract organizations, including SSCs by project phases

    b. selecting the solicitation and award method that will provide best value to the Government.

    c. criteria for selecting Design Agencies. Refer to “

    d. ” subsection which follows.

2. Develop the acquisition package according to Federal Acquisition Requirements as implemented at LANL.

3. Provide the budget, tools and other resources required to conduct acquisition planning.

4. Include acquisition activities in the project schedule.

E. A flow chart showing the acquisition planning and project life cycle stages is provided below as Figure SE-PLG-3, Example Capital Project Activity Flow.

F. Design Agency Selection Criteria for Award : Establishing clear and meaningful selection criteria are essential to achieving a successful project. Selecting a contractor with relevant experience, knowledge, and expertise reduces risk of cost and schedule over runs and technical failure. The following selection criteria should be considered when choosing Design Agencies and awarding work:

1. Relevant history of successfully completing projects of similar or greater scope, size and complexity. Corroborate success claims by requesting from the offeror an unaltered report from the US Government's Contractor Performance Assessment Reporting System (CPARS) where in-system. Also request the offeror to provide customer references with contact information for such projects. Interview references for input.
2. Implementation of an engineering quality system that is compliant with ASME NQA-1. This should be corroborated with a LANL audit of their quality system.
3. A demonstrated and clear understanding of the project requirements as demonstrated through their technical proposal and Systems Engineering Management Plan (SEMP).
4. Significant and relevant experience implementing systems engineering processes, including requirements management, technical baseline development, systems analysis, interface management, technical risk management and verification and validation of facilities and SSCs.
5. A competent approach, with acceptable risk, to achieving technical requirements of the contract.

1.3 Systems Engineering Plan (SEP)

The SEP should have the following content. The PE should tailor the specific content information according to project needs and acquisition strategy. A format is provided below and can be adjusted to meet project needs. *This document is initially generated to support the acquisition strategy, but continues to govern project activities after contract award*.

A. PROJECT PLANNING

1. Project scope: Use this section to identify the final products to be delivered (e.g., system, facility, modified facility) in both physical terms and the desired capability. Describe the associated physical and functional boundaries. Describe the customer milestone reviews that will be conducted using project results.

2. Project life cycle stages: Use this section to describe the project life cycle stages that will be implemented in project planning. Identify the design products developed during each stage.

3. Acquisition planning: Use this section to describe the division of responsibility for design development for each design phase. Discuss the selected strategy (e.g.,

design-bid-build, with design-build not suitable for nuclear line item projects), if the scope will be split among one or multiple design agencies, the preparatory work to be performed by LANL Engineering, the contractor selection method (i.e., best value), and the selection criteria. Identify roles and responsibilities for implementing the items listed in the subsection above, titled, “Acquisition Planning”.

4. Technical Oversight: Use this section to identify the activities LANL will perform to oversee the design activities, especially of the Design Agencies. This includes review of design products, technical interchange meetings, engineering process assessments, physical interface control, client and regulatory interactions and review of Design Agency SE Tool contents.

5. Design reviews: Use this section to describe the design reviews to be conducted during each project life cycle stage that will be used to review and approve the various technical baselines (e.g., 30%, 60%, 90%).

B. SE MANAGEMENT

1. Requirements management: Use this section to identify the responsible organization. Describe that the organization will conduct requirements management activities in accordance with this Chapter’s SE Requirements “Requirements Management (SE-RM)” section. Provide any tailoring regarding the extent to which these activities will be performed, such as the depth of information captured, and the types of reports and metrics.

2. Technical risk management: Use this section to identify the technical risk management activities to be performed by the project. Identify roles and responsibilities for implementing the items listed in the subsection above, titled, “Technical Risk Management”. Identify the deliverable reports and who is responsible to generate them. Describe how this risk effort ties into the project management risk register to control project baselines[1].

3. Configuration management: Use this section to identify the CM standards to be applied to the project, including DOE-STD-1073 and ANSI/EIA-649. Identify the implementing procedures, status tracking reports and the audits that will confirm adequacy of implementation. Identify roles and responsibilities for implementing the items listed in the subsection above, titled, “Configuration Management”. Discuss control of the technical baselines and who is responsible to approve changes after a baseline is approved. Address the control authorities and processes for Class I and Class II changes.

C. BASELINE DEVELOPMENT AND INTEGRATION

1. Technical baseline development: Use this section to identify roles and responsibilities for implementing the items listed in the subsection above, titled, “Technical Baseline Development”. Identify the deliverable reports and who is responsible to generate them. Discuss the project phase and activity sequence for generating each product.

2. Systems analysis and development: Use this section to identify roles and responsibilities for implementing the items listed in the subsection above, titled, “Systems Analysis and Development. Identify the deliverable reports and who is

[1] Project will also be concerned with cost and schedule, while SE focuses mostly on technical.

responsible to generate them. Discuss the project phase and activity sequence for generating each product.

3. Interface development: Use this section to identify roles and responsibilities for implementing the items listed in the subsection above, titled, “Interface Management”. Identify the deliverable reports and who is responsible to generate them. Discuss the project phase and activity sequence for generating each product.

D. VERIFICATION AND VALIDATION

1. Design verification: Use this section to describe the roles and responsibilities for conducting design verification and generating required deliverables in accordance with the Section titled, “Verification and Validation (SE-V&V), subsection “Design Verification per ASME NQA-1, Requirement 3, Section 500”.

2. SSC verification: Use this section to describe the progression of SSC verification that will be used for the project including developmental tests used to mature technology and establish design, component-level verifications used to prove component design acceptability, and system-level verifications. Describe the roles and responsibilities for conducting SSC verification and generating required deliverables in accordance with the Section titled, “Verification and Validation (SE-V&V)”, subsection “SSC Verification”.

3. Final product validation: Use this section to describe the roles and responsibilities for conducting SSC verification and generating required deliverables in accordance with the Section titled, “Verification and Validation (SE-V&V)”, subsection “Final Product Validation”. Describe how these activities relate to customer milestone reviews.

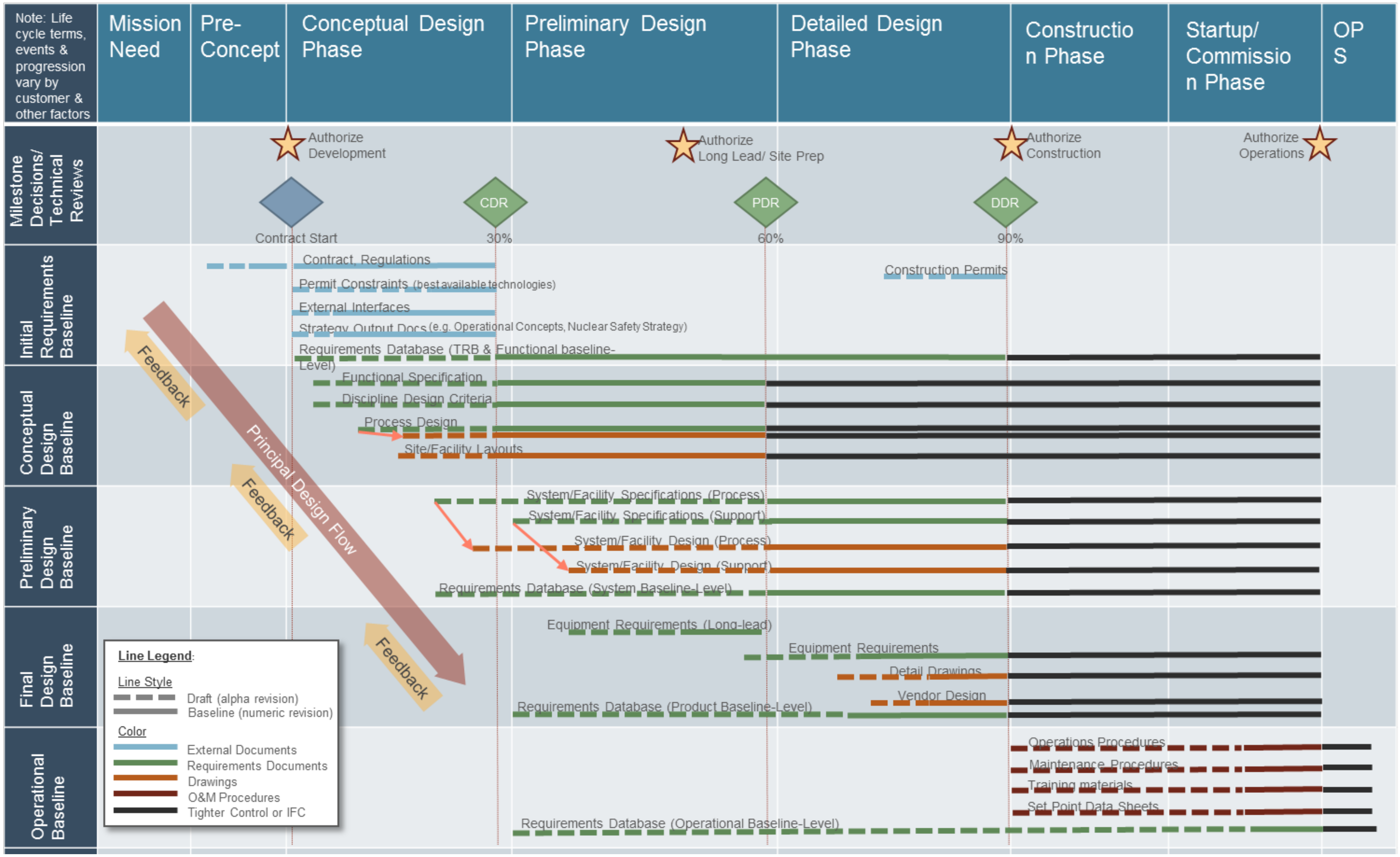

Figure SE-PLG-2, Detailed Example of a Project Life Cycle

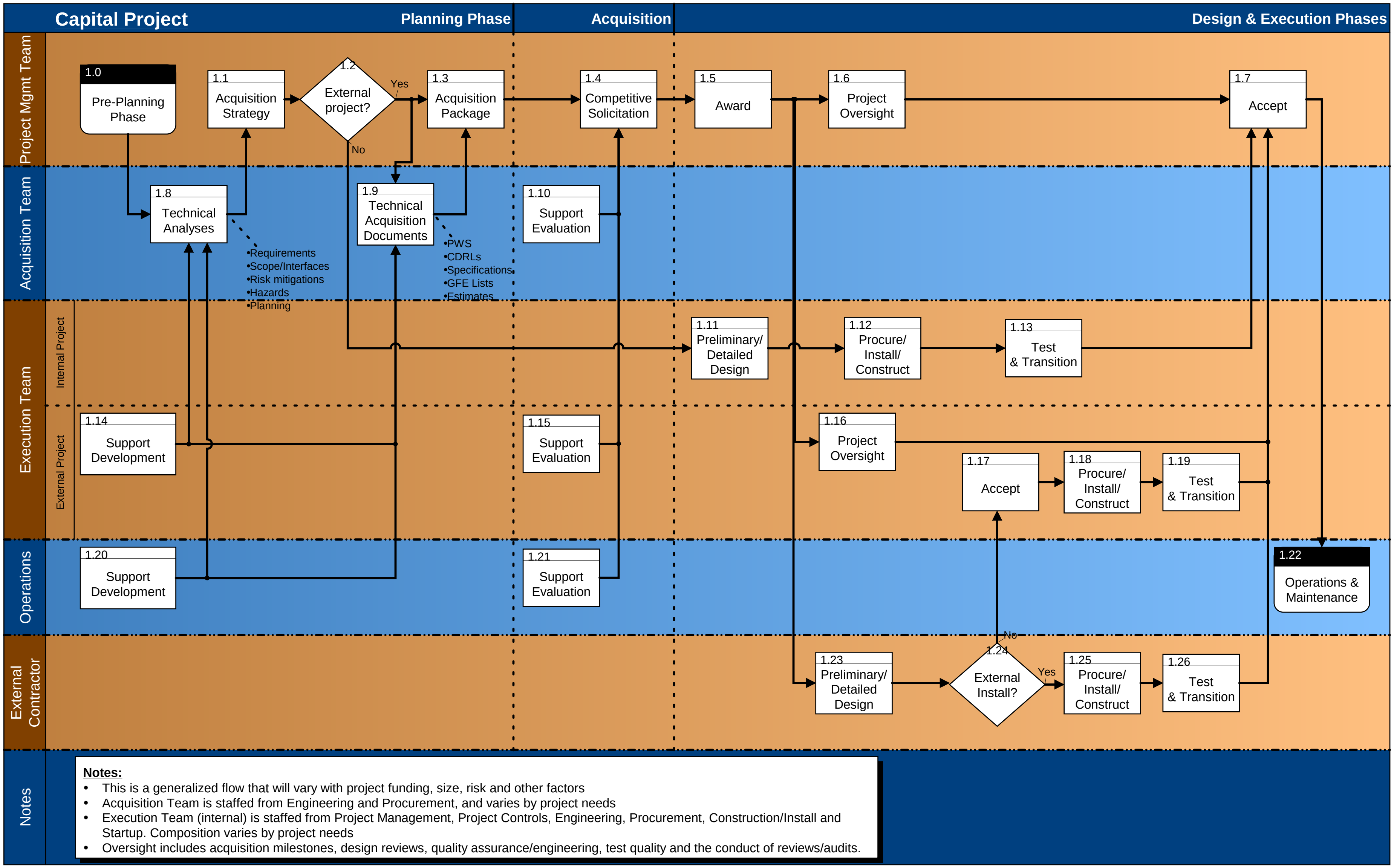

Figure SE-PLG-3, Example Capital Project Activity Flow

2.0 RM Guidance (SE-RMG)

2.1 Client and Regulatory Source Documents

A. The project should identify and list the contractual, stakeholder and regulatory source documents. The following list identifies types of documents to be pursued when generating the list. Each of these documents will likely cite other documents that should be evaluated for requirements:

1. contract statement of work,
2. documents cited by the contract as technical requirements (e.g., orders, specifications, codes, standards),
3. Federal, state, and local statutes and regulations that are specifically cited, or are applicable to project scope,
4. applicable regulatory permits and licenses,
5. LANL-specific documents that impose technical or workmanship standards, environmental conditions, NPH standards or geo-technical conditions,
6. approved authorization basis (safety and related regulatory) documents providing constraints to the project technical solutions (e.g., the safety basis documents for an existing facility might imposed constraints based on interfacing items not within contract scope),
7. physical and operational constraints resulting from an agreed interface with organizations representing the operator, or owning systems external to the project.

B. The project should identify the specific requirements within each document that are applicable to SSC design. The project should use SMEs for each requirement area (e.g., environmental protection, nuclear safety) and legal staff to ensure correct and complete identification of the requirements within these sources. Consensus codes and standards should be listed in the SE Tool so they can be allocated to SSCs; however, these standards should not be imported and parsed into the tool—engineers are expected to be familiar with these documents and to ensure compliance as part of the standard design process.

C. During the requirements identification process, the project should also identify requirements that affect required activities of the project doing the work. These could be requirements for how analyses are to be conducted, how permits will be obtained, or other project activities. Managing requirements of an organizational nature is not within the scope of this Chapter, but should be performed by the project to ensure compliance.

D. These requirements form the Initial Requirements Baseline (IRB) and should be documented at the beginning of a project. Each document that is part of the IRB should be maintained under strict configuration control. Strict control means:

1. No changes may be made to any document without approval from the authority that originally approved the document, or who currently holds the role of document approver.
2. Changes to documents that affect contractual requirements may not be changed without consent of the responsible contracting officer.

3. Changes should be analyzed for technical, cost, schedule and risk impacts prior to approving the change.

4. The document may not absorb information that uses as a basis any documents lower than it in the document hierarchy.

2.2 Design Criteria Documents

A. Design criteria documents are those developed by the design agency and approved by LANL to state LANL-specific requirements, to state discipline-specific design codes and standards, to establish required design methods and margins, or to provide generally applicable project-wide requirements that will be used as a basis for design. Criteria should be valid and clearly stated in accordance with the Requirement Validation Guidance subsection (see heading below).

B. The following sources should be considered in preparing design criteria:

1. LANL design standards and guides,
2. Requirements that standardize practices, methods and solutions across the project or throughout the site,
3. Industry best practice and consensus codes and standards,
4. The results of trade studies and risk mitigation decisions,
5. Material and process selection and standardization criteria,
6. Site conditions,
7. Procurement, construction, and startup considerations,
8. Reliability, human factors, operations, test and maintenance considerations,
9. Agreements with the client as a result of project scope execution (e.g., resolving technical issues or agreeing to a constraint), that are subsequently approved through contractual means,
10. Design input considerations provided in ASME NQA-1, Part III, Subpart 3.1, Nonmandatory Appendix 3A-1, when applicable to the project/task, and
11. Lessons learned from previous projects.

C. These requirements can be published in stand-alone design criteria documents (e.g., site conditions document, basis of design document, Code of Record document, discipline-specific design criteria documents), and referenced by the Initial and/or Conceptual Design Requirements baseline documents (e.g., RCD, FRD). Refer to Table SE-RM-1 for the type of design criteria that form part of the technical baselines.

2.3 Requirement Categories

A. Requirements need to be categorized for easy reference when searching through a database. The categories can be adjusted to meet the needs of the project, but the following categories are recommended as a starting point. A requirement may possess one or more labels. For more exact definitions, refer to the definitions in the procedure. Refer to AP-341-602, Section 4 for additional categories.

Category	A requirement (that)…
Functional	specifies *what* a system must do, without stating *how* it will be done.
Performance	quantifies *how well* a system must execute a function, or capability.

Category	A requirement (that)…
Interface	specifies a specific attribute required for an interface between two physical objects. These attributes can identify what is exchanged across the interface, the physical, data or logical characteristics of what crosses the interface, or the required physical implementation details of the interface (Note: software is considered a physical object).
Security	specifies capabilities or features necessary to protect the project's end products from identified threats.
Environmental Protection	specifies capabilities or features necessary to protect the environment and comply with environmental regulations
Operational Environments	specifies capabilities or features necessary to ensure the SSCs abilities to withstand operating conditions (e.g., temperature, humidity), site conditions (e.g., weather), induced conditions (e.g., vibration, EMI), and natural phenomenon hazards
Nuclear/Chemical Safety	specifies capabilities or features necessary to ensure SSCs prevent or minimize human and environmental exposure to radiation/chemicals, damage to equipment caused by nuclear/chemical material characteristics, or undesirable events (nuclear criticality event)
Human-Machine Interface	specifies capabilities or features necessary to ensure usability of the systems and access to the SSCs
Industrial Safety	specifies capabilities or features necessary to protect humans from industrial hazards
Fire Protection	specifies capabilities or features necessary to protect people and equipment from fire, and to reduce or eliminate the potential for fire
RAMI	specifies SSC performance and characteristics with respect to reliability, availability, maintainability, or inspectability
Codes, Standards	specifies use of specific codes and standards
Pressure Safety	specifies meeting codes and standards related to 10CFR851 and ESM Chapter 17
Software Quality	specifies meeting requirements of ESM Chapter 21
Quality Assurance	specifies meeting requirements of NQA-1 and DOE O 414.1D
Regulatory	imposes a governmental regulation based on law or regulatory authority
Derived	derived by the project from a requirement in another source to meet contractual, stakeholder or regulatory requirements. Derived requirements are supported by justification (e.g., approved analysis) that confirms its validity.
Criteria	is directly imposed by the client, regulator, stakeholder through approved contractual or legal means. They can also be imposed by project design authority as described in the Design Criteria Documents section.
General Constraint	Is a general requirement that impose limits on design solutions. The constraints are often specified by the client, regulator or stakeholder, but can be established by the project design authority. Examples include use of specific technology, SSC color, and specific materials of construction.

B. Review AP-341-601, Attachment A (*Section 6.3*) for other constraints that may be relevant.

2.4 Baseline Development

A. As the design progresses and matures through the design phases, more detailed requirements, derived requirements, and constraints are developed and documented. These may include more detailed functional and performance requirements and constraint for systems, subsystems, structures, components and interfaces; the establishment of new controlling parameters; the solidification of agreed upon design solutions; the results of hazard, fire, and nuclear safety assessments; security requirements; environmental protection requirements, etc. When the results of these analyses impose requirements or constraints upon the design, the PE should capture and incorporate them into the SE Tool in a timely manner. The best approach to developing this information would use the tool to generate the information, rather than to generate it in external software (e.g., Microsoft Office products) and then later importing it.

2.5 Design Document Hierarchy

A. Figure SE-RMG-1, Design Document Hierarchy, shows the general sequence of development and the precedence of requirements. Precedence indicates which documents have higher levels of approval authority and which must be changed first before authorizing change in downstream documents. The objective is to cause requirements to be flowed in the downward direction with increasing detail and to limit circular referencing.

B. The hierarchy shows two types of requirements needed to be managed. These include organizational requirements (i.e., requirements performed by organizations though their programs and procedures), and technical requirements (i.e., requirements to be performed or implemented by facilities and SSCs). Although this chapter focuses on the technical requirements, projects need to manage organizational requirements as well.

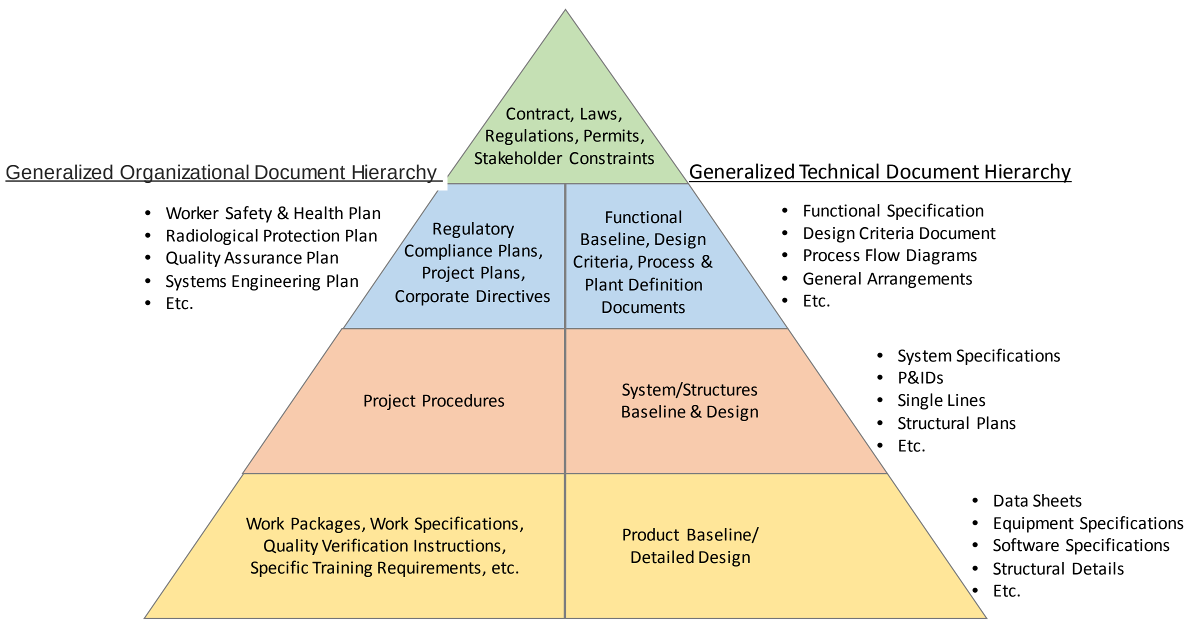

Figure SE-RMG-1, Design Document Hierarchy

2.6 Requirements Database Object Relationships

A. A database structure and linking structure should be defined by the project to ensure consistent and useful entry of information into the SE Tool. Establishing this structure correctly at the beginning of a project is essential to ensure capture of the appropriate information and useful traceability. This enables generation of correct and meaningful reports. The following three figures show the minimum useful linking strategy, which is built around the three key types of hierarchical information generated during the SE process. These include requirements, functions, and architecture (referred to as assets representing the SSCs).

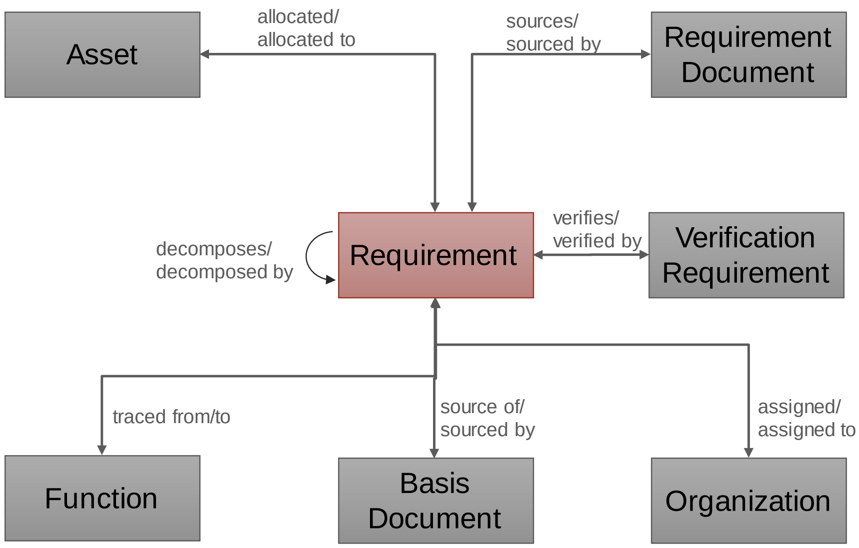

Figure SE-RM-2, Requirement-Centric Perspective

B. Figure SE-RM-2 is requirements-centric. The arrow leaving and pointing to the requirement block indicates that requirements (parents) are hierarchical and are decomposed to sub-requirements (children) while maintaining their traceability link from parent to child requirements. Requirements are linked to the other blocks using a link with a specific title that indicates the nature of the relationship. For example, a Requirement is allocated to an Asset that will achieve the requirement. The inverse is true also since the links are bi-directional. Thus, an Asset is allocated a Requirement. In verbal form, a Requirement:

1. is decomposed by a Requirement (child), which decomposes its parent requirement,
2. is allocated to an Asset. The asset is allocated the requirement,
3. is sourced by (contained in) a Requirements Document. The Requirements Document sources the requirement,
4. is verified by a Verification Requirement. The Verification Requirement verifies the Requirement,
5. is (or can be) traced from a Function (i.e., Functions are used to spawn requirements). The Function is traced to the Requirement,
6. is sourced by (derived and justified by) a Basis Document. The Basis Document is the source of the requirement, and
7. is assigned to an Organization (responsible to perform or to implement in design). The Organization is assigned the Requirement.

C. The following two diagrams are similar, but are centered around Functions and Assets (i.e., facilities and SSCs).

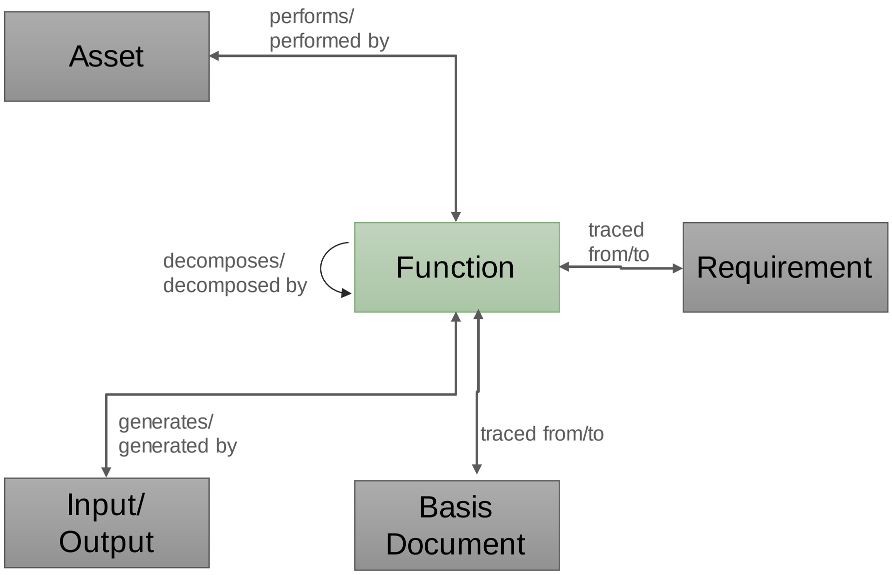

Figure SE-RMG-3, Function-Centered Perspective

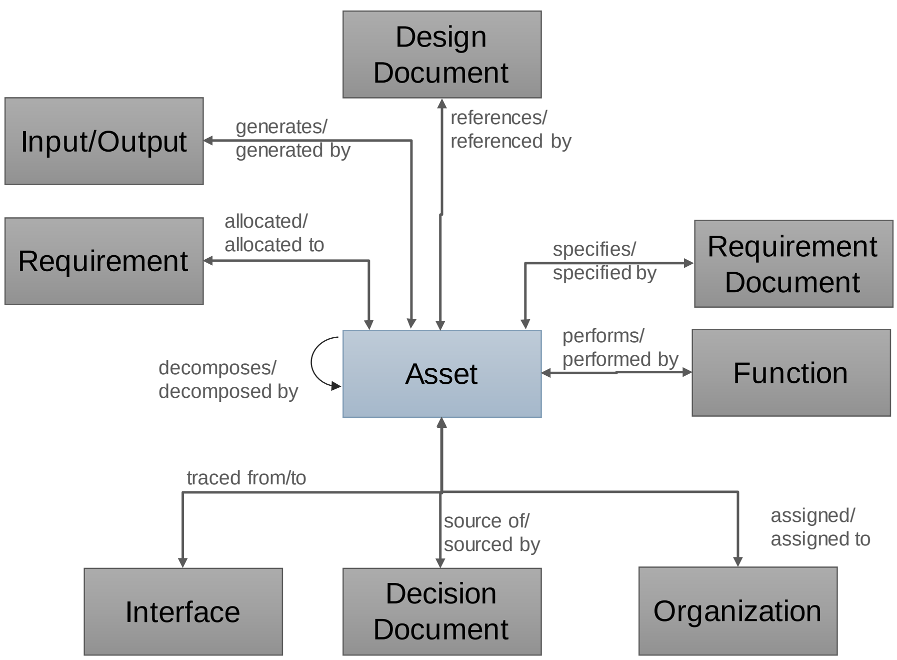

Figure SE-RMG-4, Asset-Centered Perspective

2.7 Requirement Validation Guidance

A. Well-formed stakeholder requirements and system requirements should be developed. This will contribute to requirements validation with stakeholders and ensure that the requirements accurately capture stakeholder needs. Refer to ISO/IEC/IEEE 29148, *Systems and Software Engineering – life cycle processes – requirements engineering* for additional information and good practices with respect to requirements development.

B. A well-formed requirement is a statement that:

1. Can be verified;
2. Has to be met or possessed by a system to solve a stakeholder problem or to achieve a stakeholder objective, such as mission, availability, safety, security, or quality;
3. Is quantified by measurable conditions and bounded by constraints; and
4. Defines the performance or capability of the system.

C. An individual requirement should state the subject of the requirement and what should be done. Each stakeholder and system requirement should possess the following characteristics:

1. Necessary –The requirement defines an essential capability, characteristic, constraint, and/or quality factor. If it is removed or deleted, a deficiency will exist, which cannot be fulfilled by other capabilities of the product or process. The requirement is currently applicable and has not been made obsolete by the passage of time. Requirements with planned expiration dates or applicability dates are clearly identified.
2. Implementation Free – The requirement, while addressing what is necessary and sufficient in the system, avoids placing unnecessary constraints on the design. The objective is to be implementation independent. The requirement states <u>what</u> is required, not <u>how</u> the requirement should be met.
3. Unambiguous – The requirement is stated in a way so that it can be interpreted in only one way. The requirement is stated simply and is easy to understand.
4. Consistent – The requirement is free of conflicts with other requirements.
5. Complete – The stated requirement needs no further amplification because it is measurable and sufficiently describes the capability and characteristics to meet the stakeholder's needs.
6. Singular – The requirement statement includes only one requirement with no use of conjunctions.
7. Feasible – The requirement is technically achievable, does not require major technology advances, and fits within system constraints (e.g., cost, schedule, technical, legal, regulatory) with acceptable risk.
8. Traceable – The requirement is upwards traceable to specific documented stakeholder statements of need, higher tier requirement, or other source (e.g., a trade or design study). The requirement is also downwards traceable to the specific requirements in the lower tier requirements specification or other system definition artifacts. That is, all parent-child relationships for the requirement are identified in tracing such that the requirement traces to its source and implementation.
9. Verifiable – The requirement has the means to prove that the system satisfies the specified requirement. Evidence may be collected that proves that the system can satisfy the specified requirement. Verifiability is enhanced when the requirement is measurable.

D. A set of requirements is:

1. Complete – The set of requirements needs no further amplification because it contains everything pertinent to the definition of the specified system or system element. In addition, the set contains no To Be Defined (TBD), To Be Specified (TBS), or To Be Resolved (TBR) clauses. Resolution of the preceding TBx designations may be iterative and there is an acceptable timeframe for TBx items determined by risks and dependencies.

2. Consistent – The set of requirements does not have individual requirements which are contradictory. Requirements are not duplicated. The same term is used for the same item in all requirements.

3. Affordable – The complete set of requirements can be satisfied by a solution that is obtainable/feasible within life cycle constraints (e.g., cost, schedule, technical, legal, regulatory).

4. Bounded – The set of requirements maintains the identified scope for the intended solution without increasing beyond what is needed to satisfy user needs.

E. Requirements should state 'what' is needed, not 'how.' Requirements should state what is needed for the system-of-interest and not include design decisions for it. However, as requirements are allocated and decomposed through the levels of the system, there will be recognition of design decisions / solution architectures defined at a higher level. This is part of the iterative and recursive application of the requirements analysis and architectural design processes.

F. Vague and general terms should be avoided. They result in requirements that are often difficult or even impossible to verify or may allow for multiple interpretations.

2.8 Verification Methods

The manufactured or constructed SSCs are verified by one or a combination of the following activities:

A. Analysis – The use of mathematical modeling and analytical techniques to predict the compliance of the design with its requirement set based upon calculated data or data derived using lower level component/subsystem testing. This type of analysis is generally used when a physical prototype does not yet exist, when testing is not feasible and affordable, or when the consequences of failure are low.

B. Inspection – The visual examination of the SSC. Inspection is generally used to verify physical attributes.

C. Demonstration – The operation of an SSC to confirm a requirement can be achieved. Demonstrations typically collect simple data that can be used to show the system's adequacy without using analysis. Demonstration is generally used for the basic confirmation of functionality or performance capability.

D. Test – The use of SSC operation to obtain detailed data to verify performance or to provide sufficient data to verify performance through additional analysis.

3.0 V&V Guidance (SE-V&VG)

3.1 General

A. Verification and Validation (V&V) are key processes in Systems Engineering. The verification process examines both design and product for systems, structures and components (SSCs) to confirm that the design process has resulted in a physical configuration that satisfies the SSC requirements. The validation process examines the final product to determine its ability to satisfy the mission.

B. These terms are used very broadly and can result in confusion. The key to keeping them straight is to understand what is being verified or validated, and when it happens in the project life cycle. Verification and validation can be applied to the following:

1. Requirements (contained in specifications)
2. Design (drawings)
3. Physical items and software (Note: the details of performing software V&V are not addressed in this guide; follow ESM Ch. 21).

C. The following table provides a brief comparison.

Table SE-V&VG-1, Verification and Validation Compared

	Verification	Validation
Requirements	N/A	A determination that the requirements are necessary to achieve the mission or other requirements and constraints. Refer to SE-RMG section titled, "Requirement Validation Guidance" for other characteristics confirming validity.
Design	A determination that the design adequately implements nuclear safety requirements, according to the requirements of ASME-NQA-1. This typically takes place prior to procurement of the item based on the design. This verification can be used as item verification that is to be confirmed using analysis.	N/A
Physical Items (Facility, Systems, Structure, Component)	A determination that an SSC meets the requirements of its specification. This determination is based on a combination of analysis, inspection, demonstration and test. Verification by test is typically only conducted on the first item to be completed. Analysis is usually conducted prior to procurement, but could be done afterward to account for as-built conditions.	A determination that the project's final product (e.g., complete facility or system) meets stakeholder and/or mission requirements, integrates correctly with external interfacing systems, and is suitable for its intended use in the actual operational environment.

The content of this table can also be viewed graphically using the annotated V-diagram:

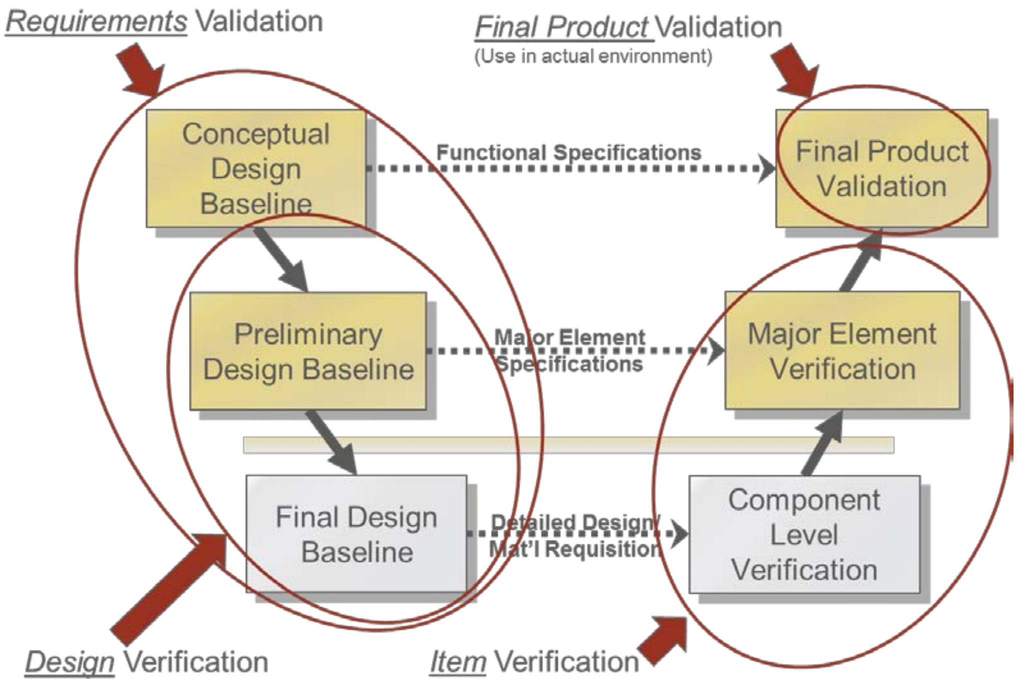

Figure SE-V&VG-1, V-Diagram Annotated to Show V&V Activities

D. Verification of an SSC looks at each requirement specified in component/ system/ facility specifications and determines the appropriate method for confirming the SSC meets that requirement. The methods include a combination of analysis, inspection, demonstration and test. Verification activities apply these methods to provide objective evidence that the SSC satisfies written requirements. Activities performed to prove quality of manufacture or construction are not intended to prove compliance with requirements, and are not addressed by this verification process. It is Engineering's role to specify the verification methods to be used. When testing is specified, it is also Engineering's role to specify test conditions and associated acceptance criteria. Testing is performed by others.

E. NQA-1 requires DV on nuclear-safety-related SSCs.. This chapter requires the use of Design Verification (DV) to confirm that requirements were properly rolled into the design. DV is a subset of verification that is focused on verifying the design of SSCs responsible for ensuring nuclear safety. It is typically performed prior to procuring the item to ensure designs incorporate the features and capabilities needed to meet the requirements. However, in some cases DV will happen afterward such as when it is not possible to complete DV without data from suppliers, or without test data that can only be collected during post-design phases.

F. The final product validation process is completed by the end of the commissioning phase to confirm that the integration of project-supplied SSCs with the existing interfacing SSCs meet stakeholder expectations, and are suitable for their intended use in the actual operational environment. It is Engineering's role to specify the validation processes and tests needed, evaluate those results, and confirm adequacy of the project results. Validation that the final product meets mission objectives by analysis is generally an Engineering task while testing is generally conducted by the Startup/Commissioning organization as specified by Engineering. NQA-1 requires DV on nuclear-safety-related SSCs.

G. The organizations responsible for each aspect of V&V will vary with the project acquisition strategy. For example, work could be performed by project personnel responsible for design, or by an AE firm. Project planning should address the division of responsibility. Refer to Section SE's Systems Engineering Planning (SE-PL) section and this guide document's SE Planning Guidance (SE-PLG) section above for further information about planning.

H. The following graphic shows V&V activities against baseline development activities and subsequent project phases, regardless of who performs the work.

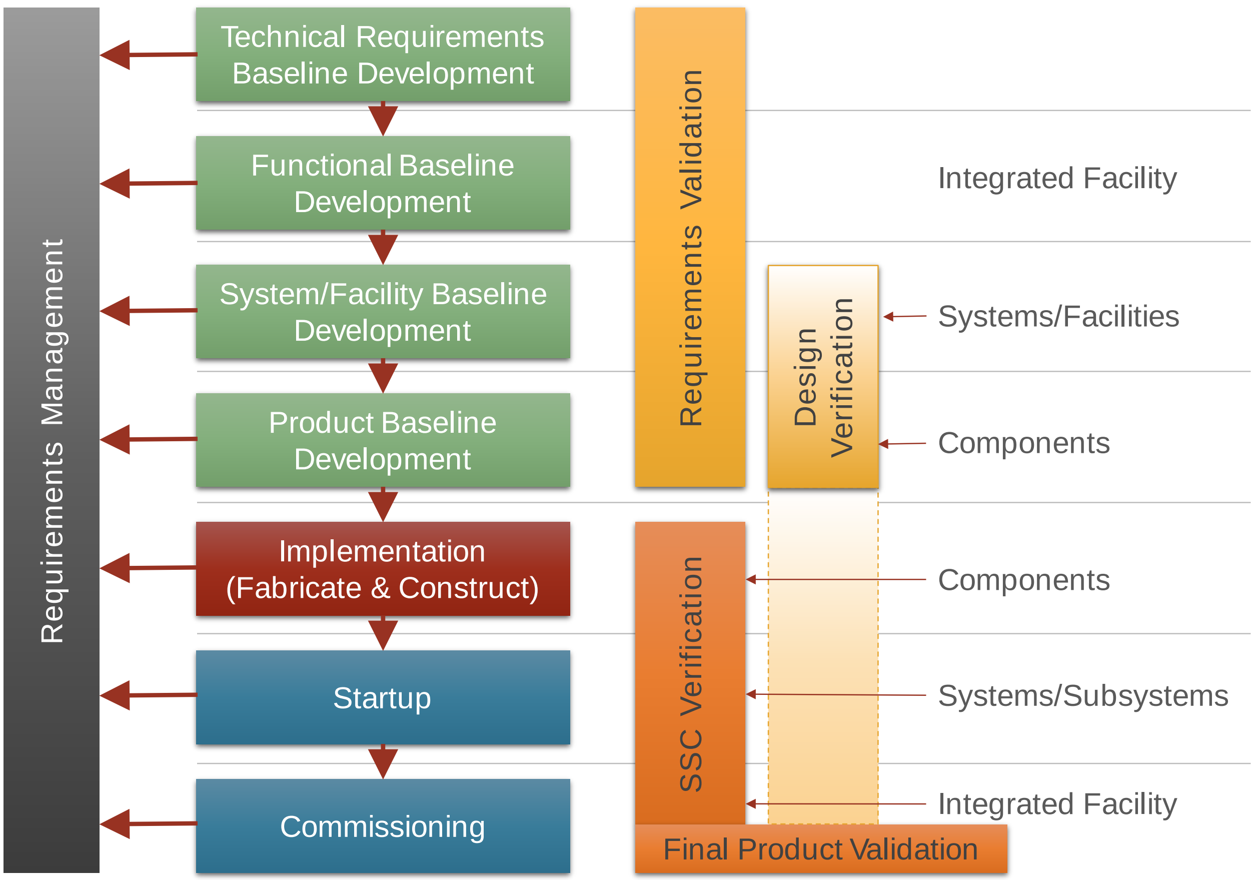

Figure SE-V&V-2, V&V Timing and Targets of Effort

3.2 Design Verification per NQA-1

A. The project should properly manage DV activities to ensure compliance. This includes the need to identify which SSCs require DV, and the appropriate method to be used. A Design Review Matrix (DVM) is the directed method to document these decisions. he type and depth of the verification selected depends upon the nature of the item, the importance of the specific attribute to safety, and its similarity with previous proven designs. The DVM provides the information needed to enable the planned verifications to be addressed in the Systems Engineering Plan. Since SSCs are introduced into design during all design phases (conceptual, preliminary and final), the DVM should start at the beginning of a project and be maintained throughout. In addition, DVM changes need to be integrated with the project performance baseline and Systems Engineering Plan to ensure that adequate time and budget are allocated. Early in the project, planning factors should be used to account for the anticipated number of items that will require DV at the various project stages.

B. DV should be performed by the organization responsible for designing the items. Thus, if the design is subcontracted, then the Design Agency should perform DV, and the requirements to perform DV according to this chapter should be included in their Statement of Work (or equivalent contractual document). Items whose designs are not unique to the project (e.g., common commercial items that can be ordered from a catalog) might also meet the criteria for needing DV, and therefore be subject to the requirements of ASME NQA-1. If DV cannot be performed, then such items might be subject to other requirements in ASME NQA-1 (e.g., commercial grade dedication). These other requirements are not within the scope of this Chapter, and the project should ensure the proper implementation of ASME NQA-1.

3.3 SSC and Final Product Verification

A. SSC verification proves that realized SSCs conform to the requirements they were designed to meet. The objectives of the SSC verification process are to:

1. Conduct activities to show that SSCs fulfill specified design requirements

2. Generate data to confirm SSCs meet requirements

3. Verify technologies used in the design solution

B. SSCs, the physical items, are verified by one or a combination of the following activities:

1. Analysis – Verification using analytical methods (e.g., engineering and scientific calculations, models, simulation, logical reasoning) to provide evidence that a system/facility meets or exceeds a specified system/facility requirement. It is preferable to complete this method of verification prior to procurement or construction. This method is appropriate when:

    a. A calculation, or an alternate calculation, was performed to support specification/design of the SSCs that satisfy the requirement.

    b. Testing is not practical to prove actual performance within limits (e.g., compliance with seismic requirements may be too costly to test on a large vessel).

    c. When required by codes or standards.

2. Inspection – The visual or dimensional examination of the SSC that does not require stimulation of the SSC. Inspection is generally used to verify physical design features meet design characteristics that can be verified by human senses or simple measurements. Verification by inspection is appropriate when satisfaction of a requirement requires specific components, dimensions or physical features to be present in a design. One example might be when a nuclear safety requirement requires a system to possess a redundant component, or use of a standard ALARA design feature. Another example could require the measurement of minimum separation between components. Inspections for items performing nuclear safety or defense in-depth (e.g., OHC) functions should be accomplished per NQA-1 Requirement 10.

3. Demonstration – The operation of an SSC to confirm correct operation against operational and observable requirements. Demonstrations typically do not require physical measurement using special test equipment (may use system instruments), or collect simple data using minimal equipment. Confirmation of acceptable operation can be achieved through observation without using the data to conduct complex analysis. Results are often directly comparable to specification and design information. Demonstration is generally used for the basic confirmation of functionality or performance capability. This method is appropriate when (there is/are):

   a. a need to show that a system/facility, or integrated systems, are capable of performing their intended function;

   b. missing or incomplete portions of a Factory Acceptance Test (FAT), including software testing;

   c. differences in the factory test conditions and the field conditions requiring verification that the equipment is performing as intended;

   d. an integrated equipment or system test is needed;

   e. when required to demonstrate remotability; or

   f. when required by codes or standards.

4. Test – The use of test results to verify that the system/facility design performs as required under specified conditions (real or simulated). Test activities use specialized test equipment or instrumentation to obtain accurate quantitative data to verify a capability or to provide sufficient data to verify a capability through additional analysis. Where verification of the entire requirement using test is not feasible, test results can be used to verify portions of the requirement that can be verified using test. This method is appropriate when:

   a. required performance of an SSC is quantified or needs to be quantified, and should be demonstrated prior to component or system acceptance,

   b. when a component needs to be tested to the extremes of the operational conditions to prove adequacy. (Note: such testing, although necessary, can damage equipment. Items tested to the extremes of operational or most adverse conditions should not be installed in the facility),

   c. needed to confirm key characteristics and assumptions used in analysis or simulation, or

   d. when required by code or standard.

Note: When demonstration or test is used as a means of design verification as defined in the Design Verification subsection above, the activity should be conducted under the most adverse conditions specified to be addressed by the system design. Tests confirming the project's end product adequately performs nuclear safety or important defense in-depth (e.g., OHC) functions should be accomplished per NQA-1 Requirement 11.